

OPEN MEETING

TIRANA

MAY 18TH
2015

Participating in an International Research Network: the experience of “Mother Teresa” University Hospital in the GAPP Project

*Phd. Hoxha (Qosja) Alketa
and*

The GAPP team of University Hospital Centre “Mother Teresa”, Tirana, Albania

3RD OPEN MEETING - DEEP (DEFERIPRONE EVALUATION IN PAEDIATRICS) PROJECT
PROMOTED BY CVBF IN COLLABORATION WITH UHCT

This project has received funding from the European Union's Seventh Framework Programme
for research, technological development and demonstration under grant agreement n° 261483



TAXONOMY

PAIN is → “ an unpleasant sensory and emotional experience associated with actual and potential tissue damage, or described in term of such damage”

(Mersky & Bogduk, 2013)

Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life

(Merskey 1986)

It is a multidimensional phenomenon with sensory, physiological, cognitive, affective, behavioural and spiritual components

WHO(2012)

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CHRONIC PAIN is a

“continuous pain that persists beyond normal tissue healing time, which is assumed to be 3 months”.

- Chronic pain may also arise and persist in the absence of identifiable pathophysiology or medical illness.

IASP 1996

- Lasting more than to 3 months
- Perpetuated by factors not related to the underlying cause
 - Limited autonomic response
 - Important emotional component
- Circadian rhythm disruption and functional alterations



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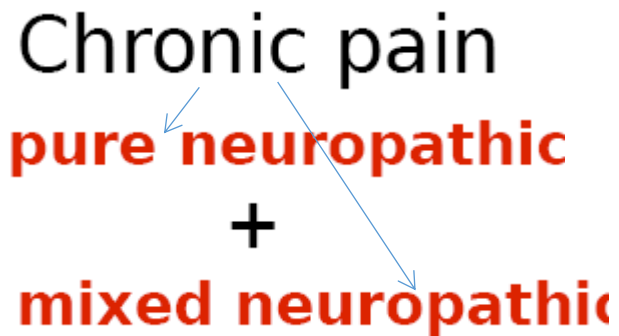


Classification of Pain

Nocioceptive

- **Somatic**
 - Bone, joint, muscle, skin, or connective tissue
 - Well localized
 - Aching & throbbing
- **Visceral**
 - Visceral organs such as GI tract
 - Poorly localized
 - Cramping

Chronic pain
pure neuropathic
+
mixed neuropathic



Neuropathic

- **Central**
 - Injury to peripheral or central nervous system causing phantom pain
 - Dysregulation of the autonomic nervous system (e.g. Complex regional pain syndrome)
- **Peripheral**
 - Peripheral neuropathy due to nerve injury
 - Pain along nerve fibers

<http://www.med.umich.edu/PAIN/pediatric.htm>

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International Association for the Study of Pain

IASP

Working together for pain relief

PAIN
CLINICAL
UPDATES

Vol. XVIII, Issue 7

September 2010

Diagnosis and Classification of Neuropathic Pain

Neuropathic pain—“pain arising as a direct consequence of a lesion or disease affecting the somatosensory system” according to the NeuPSIG (Special Interest Group on Neuropathic Pain) definition¹—is a challenge to health care. This common type of pain is often underdiagnosed and undertreated, and it is associated with suffering, disability, impaired quality of life, and increased cost.

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Neuropathic Pain: Prevalence

- Chronic pain is thought to occur in about 6% of children and adolescents.

(Van Dijk A, McGrath PA, Pickett W, et al. Pain Res Manag 2006)

- The proportion of these children who have NeuP is not known (critical issues). Epidemiological studies in adults suggest a prevalence of chronic pain with neuropathic features of 3.3%–8.2%.

(Haanpaa M, Pain 2011; Smith BH, Curr Pain Headache Rep 2012)

- Current evidence suggests that although NeuP is seen in a significant proportion of referrals to paediatric chronic pain clinics, the prevalence is much lower, and the conditions with it is associated differ from those reported in adults.

(Howard RF. Anaesth Crit Care Pain; Martin JMD: National Center for Health Statistics, 2010; Borsook D. Neurological diseases and pain. Brain 2012)



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Neuropathic Pain: Causes

Classification	Examples
Traumatic	<ul style="list-style-type: none">▶ Surgery▶ Phantom limb pain▶ Brachial plexus injury▶ Peripheral nerve injury▶ Spinal cord injury
Complex regional pain syndrome type II	<ul style="list-style-type: none">▶ Following a nerve lesion/injury
Neurological and neuromuscular disease	<ul style="list-style-type: none">▶ Guillain–Barré disease▶ Trigeminal neuralgia▶ Multiple sclerosis
Metabolic disease	<ul style="list-style-type: none">▶ Fabry’s disease
Chronic infection	<ul style="list-style-type: none">▶ HIV/AIDS▶ Postherpetic neuralgia
Cancer	<ul style="list-style-type: none">▶ Nervous system tumour (neurofibromatosis)▶ Invasion/compression by tumour▶ Effect of treatment (eg, postsurgery, chemotherapy)
Genetic	<ul style="list-style-type: none">▶ Erythromelalgia▶ Paroxysmal extreme pain disorder

Neuropathic pain in children. Richard F Howard, Suzanne Wiener, Suellen M Walker, 2013

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To date.....

- Opioids, non-steroid anti-inflammatory drugs (NSAIDs), antidepressants and anticonvulsants are among the most commonly used medications to treat pain, but very few of these are formulated or authorised for paediatric use.



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Barriers to treatment of pain

- Age-old myth that children **do not feel** pain in the same way as adults
- Lack of **proper assessment and reassessment tools** for pediatrics
- Lack of **understanding** of the means to quantify subjective pain experiences in children
- Lack of **current knowledge** of pain treatment
- The idea that assessing and treating pain in pediatric patients is too **time consuming** and not always necessary
- **Fear** of adverse reactions in children to analgesic medications
(American Academy of Pediatrics & American Pain Society, 2001)

Pediatrics, 18 (3) 2001



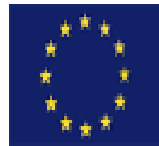
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- The GAPP project aims to improve the therapeutic prospects of children suffering from chronic pain with a neuropathic component, by developing a new paediatric formulation of gabapentin, a drug proven to be efficacious and safe in adults with neuropathic pain and in children with epilepsy.

- The project brings together private and public research institution from:

Albania, Estonia, France, Germany, Greece, Italy, the Netherlands, Spain and the United Kingdom

- Together with the support of the European Commission, they will work to demonstrate that:

GABAPENTIN

administrate in personalized doses

is **safe** and **efficacious** for the treatment of children affected by chronic pain with a neuropathic component

both as monotherapy and, in the most severe cases, as add-on therapy to morphine.

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GABA-1

Randomised, double-blind, double-dummy, active-controlled, multi-centre trial to evaluate the pharmacokinetic, efficacy and safety of gabapentin liquid formulation in children from 3 months to less than 18 years of age experiencing moderate chronic neuropathic or mixed chronic pain.

GABA-2

A randomised, double blind, placebo controlled, multi-centre trial to evaluate the safety, pharmacokinetic and efficacy of gabapentin as add-on to morphine in children from 3 months to less than 18 years of age suffering from severe chronic neuropathic or mixed pain

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Departments involved: pediatric neurology,
 oncology, supportive therapy, emergency

Patient involved:

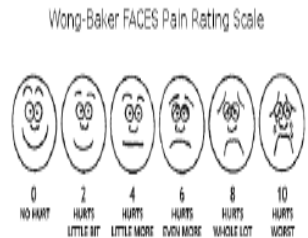
- Hematologic-oncologic illness
- Neurologic diseases (acquired/inherited)
- Metabolic diseases
- Traumatic injuries
- Malformation
- Chronic Infections

Evaluation of pain for each subset:

1. 3 mts-<3 yrs FLACC scale

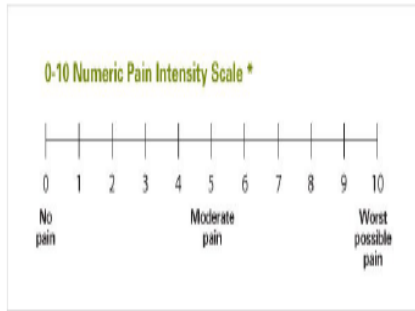
Categories	Scoring		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, distended	Frequent to constant frown, squinting chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying loudly, screams or sobs, frequent complaints
Consolability	Calm, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

2. 3 yrs-7years Faces pain scale



From Wong D.L., Hockenberry-Caton M., Wilson D., Winkelstein M.L., Schwartz P.: Wong's Essentials of Pediatric Nursing, ed. 6, St. Louis, 2001, p. 1301. Copyrighted by Mosby, Inc. Reprinted by permission.

3. 8 yrs-18years Numeric pain scale



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University Hospital Centre "Mother Teresa" in Tirana is:

- Tertiary level Hospital and **the only** academic and Research Hospital Centre in Albania.

Paediatric Intensive Care Unit treats:

- Postoperative patients (abdominal and cardiac surgery and sometimes neurosurgery patients) as well as medical severely ill patients with neurological, rheumatic, malignant pathology, and polytraumatised patients.
- Palliative Care and Chronic Pain management **are part** of UHCT medical activities.
- **Prevention and early diagnosis** of malignant and chronic pathology as well as the improvement of **home palliative care** are the main future goals of this centre.



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University Hospital Centre "Mother Teresa" in Tirana

- Pediatric Surgery
- Heart & Vascular Surgery
- Dermatology
- Infectious Diseases
- Nephrology & Hemodialysis
- Neuropsychiatry
- Ophthalmology
- Orthopedics
- Obstetrics & Gynecology
- Neurosurgery
- Endocrinology, Rheumatology & Metabolism
- Gastroenterology
- Genetics
- Hematology/Oncology
- Lung Diseases
- Cardiology
- Otolaryngology
- Emergency Care
- Pathologic Anatomy
- Intensive Care
- Pharmacy
- Immunohematology & Transfusion Center
- Laboratory of Clinical Chemistry Analysis & Microbiology
- Dentistry & Orthodontics
- Radiology
- Neuroradiology
- Rehabilitation & Physical Therapy

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Why is pediatric pain management so difficult in Albania?



- Pain management by each specialty separately, not organized in a unic Unit.
- Inadequate knowledge of management.
- Poor assessment of pain and lack of use of instruments for pain assessment
- Chronic pain managed mainly by non-steroid anti-inflammatory drugs NSAIDs, tramadol, corticosteroids **NOT** morphine in hospitalized patients, nor outpatient practice in children
- Non pharmaceutical pain management: (conversation, pictures, distraction) used mainly by Haematologists-Oncologists, and in PICU
- Common **patient-related barriers** to pain management



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Staff of University Hospital Centre “Mother Teresa”, Tirana, Albania involved in GAPP

1. Prof. Kola Ermira

Scientific Responsible. She is a specialist in Pediatric Intensive Care. Full Professor of Pediatric Diseases in the Faculty of Medicine, University of Tirana.

2. Phd. Hoxha (Qosja) Alketa

Key Scientific Support Staff. Specialized in pediatrics and neonatology, currently works at UOGH “Koco Gjozheni” NICU. Lecturer at Faculty of Medical Technical Sciences, University of Medicine, Tirana, Albania.

3. Phd. Bali Donjeta

Specialized in pediatrics, onco-hematology. Lecturer of Pediatric Diseases in the Faculty of Medicine, University of Medicine, Tirana, Albania

4. Phd. Deda Leonard

Head of Clinical Pharmacokinetics Unit, Member of National Committee of Bioethics, Lecturer, Farmacology Session, Faculty of Medicine, University of Medicine, Tirana, Albania.

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