

Access to Controlled Medications Programme

Component: *Developing WHO Clinical Guidelines on Pain Treatment*

- Develop guidelines for acute and chronic, paediatric and adult pain
- Raise awareness among policymakers, healthcare professionals and the general public
- Provide guidance to improve management of moderate to severe pain
 - Special focus on children

The development of guidelines for treatment of pain is one part of the Access to Controlled Medications Programme (ACMP). It also comprises other activities to overcome the barriers that make access to controlled medicines difficult. The ACMP also includes development of policy guidelines, country specific analysis, legislation review, training for making estimates and statistics, procurement and monitoring.

Access to treatment for moderate to severe pain is lacking around the world, with the exception of a few industrialized countries. Indeed, even in some highly industrialized countries, access is limited.

Pain Management

The World Health Organization (WHO) estimates that 5.5 billion people (83% of the world's population) live in countries with low to non-existent access to controlled medicines and have inadequate access to treatment for moderate to severe pain.^a

In these countries, each year tens of millions of patients are suffering without adequate treatment:

- 1 million end-stage HIV/AIDS patients
- 5.5 million terminal cancer patients
- 0.8 million patients suffering injuries, caused by accidents and violence
- Patients with chronic illnesses
- Patients recovering from surgery
- Women in labour (110 million births each year)
- Paediatric patients

There are many reasons for this lack of treatment. There is a need for greater awareness among policy makers, healthcare professionals and the general public to dispel the fear that opioid analgesics (i.e. pain

killers derived from opium, such as morphine) will produce harm to patients and society by causing dependence. For non-medical use, the risk of dependence is real. However, fear of the risk of becoming dependent upon medical treatment is unfounded, as almost all patients are able to stop their opioid medication at the end of their treatment with no long-lasting effects.

To protect themselves against the harms of drug dependence, many countries introduced drug control measures, but in doing so impacted the availability and use of controlled medicines for medical use.

In practice, lack of access affects all controlled medicines on the World Health Organization (WHO) Model List of Essential Medicines. Because of their status as essential medicines, their availability for medical treatment is part of the human Right to Health, as defined in the International Covenant on Economic, Social and Cultural Rights.

The need for pain treatment guidelines

It is for this reason that the development of clinical pain guidelines is among the highest priorities to improving the access to controlled essential medicines. Appropriate evidence-based guidelines will contribute to better pain management for patients and the recognition that there is a huge need for improved access to controlled medicines to treat pain.

In the past, WHO published the guidelines *Cancer Pain Relief, with a guide to opioid availability (2nd Ed, 1996)* and *Cancer Pain Relief and Palliative Care in Children (1998)*. These guidelines, created over ten years ago, cover a small part of pain treatment only and need to be updated. However, to promote adequate pain management for *all* patients, it is important

to have WHO clinical guidelines that cover all types of pain. Such guidelines should address when the use of opioids is appropriate and how they should be applied. Such guidelines will address health-care professionals *and* policy makers in governments, hospitals and health insurance companies on how to make this treatment available in a safe and rational way.

The ACMP surveyed pain experts from around the world on which pain guidelines WHO should develop. The results indicated that separate guidelines are needed, to address acute pain, non-malignant pain and malignant pain, with special attention to paediatric pain.

What has been done so far

Based on the survey results and analysis, WHO has built a work plan to develop evidence-based guidelines through a transparent process free of commercial interests that together cover the treatment of all types of pain.

- Chronic pain in adults
- Paediatric chronic pain
- Acute pain

The Persisting Pain in Children Package was published in February 2012 online and a printed edition will follow in Summer 2012. This package consist of the *WHO Guidelines on the pharmacological treatment of persisting pain in children with medical illnesses^b* and a number of additional products to promote the implementation of the methods recommended in the guidelines. They include brochures for specific audiences and pain measurement tools.

Furthermore, scoping documents for similar guidelines for adults - describing the topics to address in such a document - were approved by the WHO Guidelines Review Committee in 2008 and were recently updated, using the experience from the development of paediatric guidelines. For a few "clinical questions" the evidence retrieval has been started, by interns and volunteers.

For the guidelines on acute pain, a draft scoping document has been developed and an panel of experts from around the world will be requested to review that document in the course of 2012.

What needs to be done?

A dedicated staff member will coordinate and organize the evidence retrieval, the drafting and the review of the remaining two guidelines documents.

Printed copies are distributed for free to all governments, to partner organizations and to scientific journals. All documents will be made freely available online and printed copies are for sale at modest prices (reduced rates for developing countries).

In addition, efforts will be made to provide professional training institutions and publishers of text and handbooks with evidence-based information to enable adequate training in pain management and prescribing opioid analgesics.

Who are our partners?

The ACMP team at WHO Headquarters works closely with other WHO departments and units involved in diseases related to pain, including the *Cancer Control Programme, Management of Mental and Brain Disorders, Clinical Procedures, Child and Adolescent Health and Development and the Department of HIV*.

For all guidelines, an international multi-disciplinary Expanded Review Panel comprising 60 to 90 specialists will be invited by WHO to review the evidence, identify missing information, and draft each evidence-based recommendation.

A Guideline Development Group of 10 to 15 experts will be called together by WHO to review the draft guidelines and finalize the recommendations.

For the development of the *WHO Guidelines on the pharmacological treatment of persisting pain in children with medical illnesses* financial and/or in kind support was obtained from The Diana, Princess of Wales Memorial Fund, London, United Kingdom; Foundation Open Society Institute (Zug), Zug, Switzerland; the International Association for the Study of Pain (IASP), Seattle, WA, USA; the International Childrens Palliative Care Network, Durban, South Africa; the Mayday Fund, New York, NY, USA; Ministry of Health, Welfare and Sport, The Hague, the Netherlands; the Rockefeller Foundation, New York, NY, USA;

The True Colours Trust, London, United Kingdom; and the US Cancer Pain Relief Committee, Madison, WI, USA.

The International Narcotics Control Board (INCB), called on governments to contribute to the ACMP and the development of pain guidelines, in its Annual Report 2008.

Proposed budget

The budget to draft, finalize and disseminate a guidelines on chronic pain in adults is estimated to be USD 830 000. The budget needed for acute pain guidelines will be around USD 775 000. Contributions from

governments as well as NGOs are urgently needed.

Further information

More information on the ACMP, including the Framework of the Access to Controlled Medications Programme, the nature of barriers for access to controlled medicines, as well as literature references, is available on the WHO Medicines web site: http://www.who.int/entity/medicines/areas/quality_safety/sub_Int_control/en/index.html

^a Seya MJ, Gelders SFAM, Achara OU, Milani B, Scholten WK.. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *J Pain & Palliative Care Pharmacother*, 2011; 25:6-18.

^b Persisting Pain in Children Package, World Health Organization, Geneva 2012, ISBN 978 92 4 154812 0. Containing:

- WHO Guidelines for the Pharmacological Treatment of Persisting Pain in Children with Medical Illness http://whqlibdoc.who.int/publications/2012/9789241548120_Guidelines.pdf
- Persisting pain in children, Important information for policy makers (Policy-makers and medicines regulatory authorities, Hospital managers and Health insurance managers), Highlights for policy makers extracted from the WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses http://whqlibdoc.who.int/publications/2012/9789241548120_%20Policy%20Brochure.pdf
- Persisting pain in children, Important information for pharmacists, Highlights for pharmacists extracted from the WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses http://whqlibdoc.who.int/publications/2012/9789241548120_Pharmacists_Brochure.pdf
- Persisting pain in children, Important information for physicians and nurses, Highlights for physicians and nurses extracted from the WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses, http://whqlibdoc.who.int/publications/2012/9789241548120_Physicians&Nurses.pdf
- Various other tools (dosing card, wall chart, pain assessment scales)