Operational Recommendations on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion

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CONTROLLED DRUGS USED FOR MEDICAL PURPOSES

Access to controlled drugs for medical purposes

Recognize the dramatic situation of lack of access to pain medication for 80% of the world population

Remove unduly restrictive regulations

Implementing regulatory, financial, educational, administrative measures

Legislation revision

Training competent national authorities, health professionals, including pharmacist

Expedite the process of issuing import export authorizations for controlled substances for medical purposes (guidance INCB)

UN General Assembly, 2016
Ensuring availability of controlled medications for the relief of pain and preventing diversion and abuse

Striking the right balance to achieve the optimal public health outcome

DISCUSSION PAPER based on a scientific workshop 2010
Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes
Protecting the health of people from the dangerous effects of drugs is not in conflict with promoting the medical and scientific use of controlled drugs.
Disparity in the global consumption or access to pain medication

- High income countries:
  - 812 - 749 ME/mg/cap

- Low income countries:
  - 0.014 - 0.015 ME/mg/cap

- High income countries 17% of population account 92% of medical morphine
Take care of people affected by pain: stop indifference
Provisions of the Conventions

• Government import-export authorization
• Provision to the INCB annually of estimates of medical and scientific needs for narcotic drugs
• Record-keeping by governmental authorities and persons engaged in manufacture, trade and distribution, and conduct of inspections by government
• Requirement of medical prescriptions for supply or dispensation to individuals
• Prohibition of advertising to the general public with due regard to constitutional provisions
• Requirement of adequate labelling
• Requirements for commercial documents
• Prohibition of export to post office box
• Establishment of penal provisions for contraventions of the above requirements
Unnecessary barriers

• Limitations on the number of days supply that may be provided in a single prescription;
• Limitations on doses that may be prescribed in a single prescription;
• Excessive limitations on prescription authority, such as only to some categories of medical doctors;
• Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained;
• Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions;
• Excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids;
• Arbitrary restrictions on the number of pharmacies permitted to dispense opioid medications;
• Unreasonable requirements relating to the storage of opioid medications.
To remove the barriers

Financial (cost of medications/distribution)

Legal (national legislation overruling)

Logistic (distribution/storage modality)

Cultural (mentality attitude)

Professionals qualification (ignorance)
A new UNODC model drug law
Revision of national drug laws
Revision of the administrative rules
Training of regulatory authority
Prepare a new generation of:

Health professionals
Pharmacists
Policy makers
Law makers
Family members / community

Response to Pain
Cancer without pain medications: an unacceptable condition
The fear to create dependence (!)

Drug dependence / addiction is not related to the drug effects only

Psychobiological vulnerability

Complex series of risk factors not affecting patients with pain
Concurring to dependence:

- Drug
- Brain adaptation

Concurring to addiction:

- Drug
- Brain adaptation
- Gene/Environmental factors

**Compulsive behaviour**
Dissipating ignorance

Knowledge about pain medications management

Knowledge about pain effects on health and social consequences

Knowledge about vulnerability for addictive behaviour / screening

Knowledge about risk of overdose

Knowledge about rules becoming barriers to access

Knowledge about rules preventing diversion
National Overdose Deaths
Number of Deaths from Prescription Drugs

Source: National Center for Health Statistics, CDC Wonder
Addiction.

Non-medical use of prescription opioids and prescription opioid-related harms: why so markedly higher in North America compared to the rest of the world?

Fischer et al., 2014

Dispensing levels related to harms

Lesser regulatory access restrictions for community-based dispensing mechanisms

Facilitating higher dissemination level and availability (e.g. through diversion)

Medical-professional culture

Patient expectations for “immediately effective treatment”

More pronounced 'for-profit' orientation of key elements of health care (including pharmaceutical advertising)
maintaining therapeutic access for patients with a legitimate medical need for opioids

minimizing the risk of abuse

clinical skill and knowledge of the principles of opioid treatment

assessment of risks associated with opioid abuse and diversion

patient selection and screening

Primary care physicians can become advocates for proper pain management and ensure that all patients with pain are treated appropriately

McCarberg, 2011

Opioid treatment decisions are based not only on the type of pain but also the patient's psychosocial history.

A screening for predicting

- aberrant drug-related behaviours;
- risk factor stratification;
- utilization of opioid screening tools
- urine drug testing

Sehgal et al., 2012
List of Opioid Risk Screening Tools

Screener and Opioid Assessment for Patients in Pain-Revised (SOAPP-R).

Current Opioid Misuse Measure (COMM).

Opioid Risk Tool (ORT).

Diagnosis, Intractability, Risk, and Efficacy (DIRE).

Screening Instrument for Substance Abuse Potential (SISAP).

The Pain Assessment and Documentation Tool (PADT).
GLOK67: Joint Global Programme

• Piloted in Ghana
  – Initial meeting with national stakeholders
  – Training for healthcare providers
  – Changes in prescription practices
  – National approach to cascade training via higher education

• Work in Timor-Leste
  – Initial meeting with national stakeholders
  – Tie to non-communicable diseases and to the National Cancer Plan
  – Change in calculating estimates
  – Ongoing analysis of procurement
  – Cultural issues
GLOK67: Joint Global Programme

- Democratic Republic of the Congo
  - Anticipated Fall 2016
  - Integrated in larger healthcare reform in DRC
  - Strategic planning at the national and local level

- Panama, Antigua/Barbuda
  - Research focus
  - Shift to focus on health and health systems
  - Comprehensive data collection on cancer, non-communicable diseases and palliative care
GLOK67: Joint Global Programme

- Additional areas of focus
- Nigeria
  - Fall 2016 facilitate development of National Plan for Increasing Access to Controlled Medicine
  - Pilot research program related to implementation of legislation and increased access at local hospital level
- Additional areas of focus
  - Model Law
  - Included in HONLEA meeting – Africa
  - UN Task Force on Non-Communicable Diseases
  - World Cancer Congress