Access to controlled drugs for medical purposes: a commitment for the international community

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Drug Prevention and Health Branch
The Single Convention recognizes the medical use of narcotic drugs as indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for this purpose.

1961 Single Convention, as amended by the 1972 Protocol

INCB

UNODC

WHO

International drug control system

National drug control system
Resolution 53/4 and Resolution 54/6 of the Commission on Narcotic Drugs

Promote adequate availability of internationally controlled drugs for medical and scientific purposes, while preventing their diversion and abuse.

Access to controlled medications not existent or almost not existent in many countries.
Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes
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
Help Member States to improve availability of and accessibility to controlled drugs for medical purposes

Help Member States to control diversion misuse and abuse
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.
Medical purpose: indispensable

Non-medical purpose: not permitted

The risk of a double failure
Narcolepsy

ADHD

Cocaine addiction (promising)

Adderall

Methylphenidate

Phentermine

ADHD

Appetite control in obese patients
A review of the history, actions, and legitimate uses of cocaine.
Brain PF  Coward GA

Cocaine

Local anaesthetic

Reducing bleeding

Surgery of ear, nose and throat
Ketamine:
- used for animals in high income countries
- used for humans in low income countries

A dissociative anaesthetic
NMDA antagonist (glutamate antagonist)
Pain relief recognized as part of the human right to the highest attainable standards of mental and physical health

Opioid medications essential for treatment of moderate to severe pain
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
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.
Department of Essential Medicines and Health Products

Drug Prevention and Health Branch

WHO

UNODC

GLO-K67

Union for International Cancer Control
To remove the barriers

Financial (cost of medications/distribution)

Legal (national legislation overruling)

Logistic (distribution/storage modality)

Cultural (mentality attitude)

Professionals qualification (ignorance)
Prepare a new generation of:

Health professionals

Policy makers

Law makers

Family to family programs:

Public opinion mentality
To avoid diversion and abuse

appropriate rules in line with the Conventions

systematic monitoring

case by case management and screening

interpersonal relationship patient/doctor: therapeutic alliance
The iatrogenic epidemic of prescription drug abuse: county-level determinants of opioid availability and abuse.

Wright et al., 2014

The structure of the local healthcare system responsible.

Uncontrolled access to healthcare generally, and to dentists and pharmacists in particular, increases the availability of prescription opioids in communities.

Lack of electronic monitoring

No single code to identify the patient

Lack of training for professionals
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
Stanos, 2012

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
## Screening

1. Focus on opioids/preference/ allergy for other medications
2. Opioid overuse / stolen prescription
3. Other substance abuse/ alcohol abuse
4. Low functional status
5. Unclear aetiology of pain
6. Exaggeration of pain / Old X-ray documentation

- Women
- Young 18-25/26-34
- Childhood - adolescence adverse experiences
- History of mental health
- History of substance abuse
- Multiple prescribers and pharmacies
- History of overdose
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).
PAIN: Less Abusable Analgesics

Abuse-Resistant Opioid Pro-drug (i.e., Signature Therapeutics)

**Signature Bio-MD™**

**opioid prodrug**

**Step 1**
Trypsin removes an amino acid, exposing reactive middle portion

**Step 2**
Middle portion reacts with itself to detach from and release the active opioid drug

**Standard opioid drug**

**Cyclic Metabolite**
providing drugs together with interpersonal relationships, compassion and support
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:

Concurring to addiction:

Compulsive behaviour
Cancer has long been neglected in developing countries, overshadowed
WHO expects the burden of cancer in sub-Saharan Africa to grow rapidly: incidence to exceed 1 million per year by 2030

Little access to diagnostic technology.

80% of cases are in terminal stages at the time of diagnosis

Large proportion of patients with moderate to severe pain

O’Brien et al., 2013
full respect for individuals attitude, culture, religion and concrete needs

complex questions about pain, suffering and mankind condition
The suffering of any human being is my suffering...