Access to controlled drugs for medical purposes while preventing misuse and diversion

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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**

Commission on Narcotic Drugs

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

2010

DISCUSSION PAPER based on a scientific workshop
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

Correct unduly restrictive regulations

Implementing regulatory, financial, educational, administrative measures

Legislation revision

Training competent national authorities, health professionals, including pharmacists

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

UN General Assembly, 2016
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

Balance between control and availability
Ketamine:
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 severe pain (acute pain, cancer 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
Immune function significantly and specifically suppressed in pain.

Reduced lymphocytes: lower CD8(+) cells.

Chronic severe pain.

Koike et al., 2014
Pain

extracellular signal-regulated kinases 1 and 2 (ERK1/2) (spinal cord level)

emotional-affective component

depression and anxiety

Borges et al. 2015
Relationship between Nonmedical Prescription-Opioid Use and Heroin Use

Total U.S. Drug Deaths

More than 64,000 Americans died from drug overdoses in 2016 -- 64,070
The need of interpretation in depth:

Sociological and psychological studies

Qualitative studies

Who dies? Characteristics of the people affected

Subgroups: from pain treatment, from drug use disorders, from recreational use?

Who is more vulnerable?

AVAILABILITY PER SE CANNOT EXPLAIN THE EPIDEMIC
A large rate of overdoses is not “unintentional”: They are suicide cases.
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
Additional restrictive measures:

• 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 reduce the barriers

Professionals qualification (training)

Financial (cost of medications/distribution)

Legal (national legislation overruling)

Logistic (distribution/storage modality)

Cultural (mentality attitude)
Prepare a new generation of:

Health professionals

Policy makers

Law makers

Family to family programs:

Public opinion mentality

Response to Pain
Dismantling prejudices

Pain medications per se create “addiction”

Pain medications undermine identity

Using analgesics is materialistic / as opposed to pain acceptance, that is spiritual

Using analgesics is a sign of fragility and lack of willpower
Concurring to dependence:

- Drug
- Brain adaptation

Concurring to addiction:

- Drug
- Brain adaptation
- Gene/Environmental factors

Compulsive behaviour
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
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 and attitude

Patient expectations for “immediately effective treatment”

More pronounced 'for-profit' orientation of key elements of health care (including pharmaceutical advertising),
1% of doctors responsible for 25% of opioid prescriptions

Persons who are prescribed opioids also are commonly prescribed benzodiazepines

Opioid prescribing rates peaked in either the 45-54 years or the 55-64 years age group.
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).
The aim of screening is not to exclude people in need from appropriate pain treatment

Not to deny medication provision when it is necessary

More accurate monitoring

Daily medical supervision
providing drugs together with interpersonal relationships, compassion and support
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 severe pain.

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

complex questions about pain, suffering and mankind condition
Exploring the Relationships Between Depression, Hopelessness, Cognitive Status, Pain, and Spirituality in Patients With Advanced Cancer

Kyriaki Mystakidou, Eleni Tsilika, Efi Parpa, Maria Pathiaki, Elisabeth Patiraki, Antonis Galanos,
The suffering of any human being is my suffering...
some of the same regions of the brain are activated by personal pain, at left, and by empathy over the pain of a loved one, at right.
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