A balanced approach in the drug control system

Ensuring adequate availability and appropriate use of controlled substances for medical purposes

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Controlled drugs under the Conventions

10 new substances under control in the CND 2015 (Mephedrone…)

… to be used only for medical purposes.

… under the control of health professionals.
Help Member States to improve availability of and accessibility to controlled drugs for medical purposes

Help Member States to control diversion misuse and abuse

From the street to the pharmacy
Methylphenidate

Narcolepsy
ADHD
Obesity

Methylphenidate?

Energy for dancing
Stay awake all the night
Being rewarded/excited

Methylphenidate
Agitation/anxiety
Insomnia
Weight lost
Arrhythmias
Hypertension

Criminals (illicit market)
Pharmaceutical companies (licit market)
Decided by the parliament? By the referendum? By the Court?

Treatment of hypertension

STRATIFY ACCORDING TO ADDRESSED RISK (as in risk chart Table II)
BP LEVEL + MAJOR RISK FACTORS + TOD + ACC

LOW
ADDED RISK

MEDIUM
ADDED RISK

HIGHT / VERY HIGH
ADDED RISK

LIFESTYLE MODIFICATION AS APPROPRIATE

Monitor BP & other risk factors for 6 – 12 months

SBP ≥ 140
or DBP ≥ 90

SBP < 140
and DBP < 90

SBP < 140
and DBP < 90

SBP ≥ 140
or DBP ≥ 90

Continue to monitor

BEGIN DRUG TREATMENT
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 opioid-based medication is 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
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.
The shadow of prohibition for non-medical use influenced medical use
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
Looking to the persons, not to the statistics and to the papers

Fatmata: Tuberculosis infection has fractured her spine
Pain perception is a complex issue
The consequences of pain

Sadness, anxiety, or depression
Irritability, impaired interpersonal relationships
Disruptions in sleeping, eating, and mobility
Lack of concentration and mental clarity
Sexual dysfunction
Impaired immune function related to stress
Incontinence
Poor appetite and bad nutrition

Life quality impairment
Immune function significantly and specifically suppressed in pain

Reduced lymphocytes: lower CD8(+)
Chronic pain

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

emotional-affective component

depression and anxiety

Borges et al. 2015
The person who displayed pain behaviour perceived to be in a more negative mood:
- poorer physical fitness
- less warmth
- less competence

negative social evaluations for social relationships

Ashton-James et al., 2014
Helplessness and hopelessness
Clinical impressions and neurobiological research suggest that physical and psychological aspects of pain are closely related entities.

Nonetheless, remarkably few pain-related themes are currently included in psychiatric residency training.
Untreated pain is morally unacceptable
Untreated pain is not humane
New Users in the Past Year of Specific Illicit Drugs Among Persons Aged 12 or Older, 2009

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Number of New Users (Thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotherapeutics</td>
<td>2,567</td>
</tr>
<tr>
<td>Marijuana</td>
<td>2,361</td>
</tr>
<tr>
<td>Pain Relievers</td>
<td>2,179</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>1,226</td>
</tr>
<tr>
<td>Ecstasy</td>
<td>1,110</td>
</tr>
<tr>
<td>Inhalants</td>
<td>813</td>
</tr>
<tr>
<td>Stimulants</td>
<td>702</td>
</tr>
<tr>
<td>Cocaine</td>
<td>617</td>
</tr>
<tr>
<td>LSD</td>
<td>337</td>
</tr>
<tr>
<td>Sedatives</td>
<td>186</td>
</tr>
<tr>
<td>Heroin</td>
<td>180</td>
</tr>
<tr>
<td>PCP</td>
<td>45</td>
</tr>
</tbody>
</table>

Note: The specific drug refers to the drug that was used for the first time, regardless of whether it was the first drug used.

* Includes pain relievers, tranquilizers, stimulants, and sedatives

Source: SAMHSA, 2009 National Survey on Drug Use and Health (September 2010).
Unintentional drug overdose deaths by major type of drug
United States, 1999-2007

Source: National Vital Statistics System
IMS Health, Vector One: National, Years 1991 to 2011, Data Extracted 2012
IMS Health, National Prescription Audit, Years 2012 & 2013, Data Extracted 2014

CDC National Vital Statistics System, SAMHSA Treatment Episode Data Set, DEA’s Automation of Reports and Consolidated Orders System.)
Access imbalance for the world’s population

5.5 billion (83%): low or non-existent access

250 million (4%): moderate access

460 million (7%): adequate access

430 million (6%): insufficient data

WHO, 2011
Every year:

5.5 million terminal cancer pain

1.0 million HIV/AIDS end-stage

800,000 lethal injuries accidents and violence

110 million women labour

Surgery (80% insufficient anaesthesia)

WHO, 2011
• Global annual consumption of morphine equivalent 61.66 mg per person

• fentanyl,
• hydromorphone,
• methadone,
• morphine
• oxycodone
• pethidine

Source: INCB 2011 and Pain and Policy Studies Group
Disparity in the global consumption or access to pain medication

- Canada and US with 812 and 749 ME/mg/cap
- Nigeria and Myanmar with 0.014 and 0.015 ME/mg/cap
- High income countries 17 per cent of population account 92% of medical morphine
- Half of the countries reporting to INCB in 2011 consumed less than 1 mg of morphine per person
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
Remove the barriers

Financial (cost of medications/distribution)

Legal (national legislation overruling)

Logistic (distribution/storage modality)

Cultural (mentality attitude)

Professionals qualification (ignorance)
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.
The case of ketamine

A dissociative anaesthetic

NMDA antagonist (glutamate antagonist)

China proposed to the Commission on Narcotic Drugs (CND) and WHO to put ketamine under control.

WHO did not accept the proposal of the CND. Being under control would make ketamine less available for Anaesthesia (medical purpose).

This is totally unacceptable: under control = unavailable ???!!!
The fear to create dependence (!)

Dependence / addiction is not related to the drug effects only

Psychobiological vulnerability

Complex series of risk factors not affecting patients with pain
Drug-induced (predictable after chronic exposure)

- mRNA level
- peptides
- proteomics

neurochemistry
behaviors

Genetic (25-70%)
- DNA
- SNPs
- Other polymorphisms

Environmental (very high)
- Prenatal
- Postnatal
- Contemporary Cues

Kreek et al., 2004, NeuroMolecular Medicine
The best way to avoid diversion and abuse

appropriate rules in line with the Conventions

systematic monitoring

case by case assessment

case by case management

interpersonal relationship

therapeutic alliance
Appropriate opioid medications prescription

- Screening risk conditions
- Specific structured interviews
- Assessment and reassessment
- Daily supervision necessity in risky cases
- Electronic monitoring / code in primary care
- Pharmacist responsibility
providing drugs together with interpersonal relationships, compassion and support
Chronic pain and fatigue: Associations with religion and spirituality
Baetz and Bowen, 2008

- better psychological well-being
- positive coping strategies
- an additional component to the overall management of chronic pain
full respect for individuals attitude, culture, religion and concrete needs

complex questions about pain, suffering and mankind condition
Prepare a new generation of:

Health professionals

Policy makers

Law makers

Family to family programs:

Public opinion mentality
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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