Indispensable
Adequately provided
and not unduly restricted

Stefano Berterame
Chief, Narcotics Control and Estimates Section
INCB Secretariat
Opioid analgesics: indispensable for the treatment of pain

- Cancer
- HIV/AIDS
- Cardiovascular disease
- Chronic respiratory disease
- Diabetes
- Childbirth
- Surgery
- Injuries
Opioid analgesics

Health Conditions:
• Cancer
• HIV/AIDS
• Cardiovascular disease
• Chronic respiratory disease
• Diabetes
• Childbirth
• Surgery
• Injuries
• Etc.

WHO Model List of Essential Medicines:
• Codeine
• Fentanyl
• Morphine
• Methadone
Psychototropic substances

Health Conditions:
• Anxiety disorders
• Epilepsy

WHO Model List of Essential Medicines:
• Diazepam
• Lorazepam
• Midazolam
• Phenobarbital
Adequately provided
Lack of access to opioid analgesics

- 88% of the morphine is used for cough syrups.
- Only 10% is used for direct consumption.
- Of this 10%: 92% is consumed by 17% of the world population.
- More than 80% of the world population is left with limited or no access to opioids- less than 2% of morphine available.
- Production and stocks are sufficient to cover global demand as expressed by governments.
- Are the estimates correct?
Availability of Opioids for Pain Management
2001-2003 Average in S-DDD

The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations. Final boundary between the Republic of Sudan and the Republic of South Sudan has not yet been determined. Dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties. A dispute exists between the Governments of Argentina and the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas).
Availability of Opiods for Pain Management
2011-2013 Average in S-DDD

*Codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tildine and tramperidone.
The Lancet Commission (2017): Alleviating the access abyss in palliative care and pain relief - an imperative of universal health coverage
S-DDD of various opioids 1997-2016
Morphine and fentanyl distribution of consumption

**Morphine: distribution of consumption, 2016**
- United States: 50.6%
- Europe: 25.4%
- Other countries: 14%
- Japan: 2%
- Australia and New Zealand: 0.6%
- Canada: 6.8%

**Fentanyl: distribution of consumption, 2016**
- United States: 30.1%
- United Kingdom: 5.7%
- Germany: 19.8%
- Spain: 6.4%
- France: 4.8%
- Italy: 2.5%
- Netherlands: 2.9%
- Belgium: 2.2%
- Japan: 2.1%
- Other countries: 18.9%
Not unduly restricted
Impediments to the availability

- Lack of training/awareness
- Fear of addiction
- Limited resources
- Problems in sourcing
- Cultural/social attitudes
- Fear of diversion
- Control measures for international trade
- Fear of prosecution/sanction
- Onerous regulatory framework
- Other
- Action by the Board

Chapter 2:
“Operational recommendations on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion”
(a) Domestic legislation, regulations, administration

- Review domestic legislation, regulatory / administrative mechanisms.
- Simplify and streamline processes.
- Remove unduly restrictive regulations and impediments.
- Maintain appropriate control mechanisms.
- Online platform to facilitate prescribing and dispensing of morphine.
- E-control medicine prescription system.
- Allow nurses to prescribe controlled substances, where needed.
(b) National control systems, assessment mechanisms

- Strengthen national control systems, domestic assessment mechanisms/programmes
- Identify, analyse and remove impediments to availability.
- Maintain appropriate control mechanisms.

The recommendation refers to the WHO publication for guidance.
(c) Import and export authorizations

- Expedite the process of issuing import and export authorizations for controlled substances at national and international level.

Several countries have enrolled in the I2ES (International Import and Export Authorization System). More countries need to join. Resources for maintaining the system are needed.
(d) Affordability

- Address issues related to affordability, e.g. limited resources, problems in sourcing.
- Cooperation with private sector.
- Allow manufacture of generics.
- Expanding coverage and distribution.
(e) Capacity-building and training

- Improve the health systems and the infrastructure to deliver health care;
- Train health care professionals;
- Include palliative care and mental health as part of national health care strategies.
- Provide training for staff at competent national authorities on adequate access.
- Awareness-raising, training of health professionals on medical access and use of opioids.
INCB Learning

• Global capacity-building project (GLOY04)
• Launched in 2016.
• Trained over 180 officials from 79 countries and territories.
• Partnership with UNODC and WHO.
• E-Learning.
• Support from USA, Australia, France and Belgium.
New WHO Guides on palliative care
(f) National supply management system

- Develop national supply management systems.
- Strengthen capacities in adequately estimating needs for controlled substances.

INCB-WHO Guide

- Enhance data-collection and monitoring mechanisms.
Measuring Progress

• INCB questionnaire to Governments on the implementations of recommendations of the UNGASS outcome document and the INCB report.
• 130 countries responded (78% of the world population).
• Results published in a supplement of the INCB Annual Report early in 2019.
Thank you!