Challenges in Access to controlled medicines

Strengthening Pharmaceutical Systems for better access
Vienna, UNODC – 27 September 2017
Agenda

- Global landscape and WHO Mandate
- Barriers for Access to quality medicines
- Selection and procurement of controlled medicines
- Cooperation and Partnership
- Country work supported by WHO
International drug control conventions promoting better health

The preamble of both 1961 and 1971 Conventions refer to their scope and impact on health:

*The parties,*

- **Concerned with the health and welfare of mankind** (1961)
- **Being concerned with the health and welfare of mankind** (1971)

- **Recognizing** that the *medical use* of **narcotic drugs** continues to be *indispensable* for the *relief of pain and suffering* and that adequate provision must be made to *ensure the availability of narcotic drugs for such purposes’* (1961)

- **Recognizing** that the use of **psychotropic substances** for *medical and scientific purposes* is *indispensable* and that their *availability for such purposes should not be unduly restricted* (1971)
WHO Mandate within World Health Assembly Resolutions

2005 WHA58.22: *Cancer Prevention and Control*: treating pain with opioid analgesics

2014 WHA67.19: *Strengthening of palliative care as a component of comprehensive care throughout the life course*: improving access to controlled medicines for pain and palliative care, including for children;

2015 WHA68.15: *Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage*: improving access to essential medicines for anaesthesia and essential surgery;

2015 WHA68.20: *Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications*;
Availability of opioids analgesics
The global context

- 95% of the world morphine is consumed in countries representing 17% of the world’s population: North America, Oceania & Western Europe

- Nearly 90% of the countries in the African region either did not report or reported consumption of opioid analgesics lower than 100 S-DDD per million inhabitants per day, and 65% of the countries in the region have levels below 5 S-DDD – the adequate consumption is of 200 S-DDD

- At the same time, 75% of the world population, predominantly in lower-income countries, is left with low or no access to proper pain relief.
Mean availability of opioids for pain management (2011-13)

Source: INCB and Berterame et al. 2016
Essential palliative care medicines in primary care

Percentage of Member States reporting that oral morphine is available in >50% pharmacies, by WHO Region

Trend in the consumption of opioid analgesics

Figure 7. Trends in consumption for selected subregions, 2001-2013

Source: International Narcotics Control Board.
Barriers to access to controlled medicines

- **Insufficient knowledge & training** on efficacy and safety profiles: inappropriate use or no use;

- **Behaviours**
  - Fear for abuse and dependence
  - Fear for diversion and sanctions

- **Inaccurate quantification of needs**, inefficient supply chain: fragmentation, shortages, diversion & waste

- **Regulations**
  - Limited prescription duration; special prescription forms
  - Limitation of dispensing outlets; limitation of prescribing
  - Prohibition/Restrictions on exports and imports- special licences needed
Monitoring the problem

Figure 32. Impediments to availability of narcotic drugs

Barriers to access to controlled medicines (2)

- **National medicines policies and regulations** are available but often **not effectively implemented** & enforced

- Ministry of Health **lacks resources** & hence insufficient leadership and coordination

- Government **funding is limited**. Out of pocket payment is the major source of financing: need for sustainable coverage of essential medicines including by NHIS

- **Insufficient resources and capacity in National Regulatory Authorities (NRAs):**
  Circulation of substandard/counterfeit products on markets:

- Development of **STGs and NEML** not always based on scientific evidence

- **Irrational use of medicines** which could harm patients, increase resistance and waste resources
Importing a controlled narcotic/psychotropic medicine:

Importer (i.e., hospital pharmacy, wholesaler) applies for authorization from competent national health authority to import controlled medicine.

↓

Competent national authority issues import authorization.

↓

After receiving import authorization, importer provides copy to exporter.

↓

Exporter provides copy of import authorization to national competent authority in its application for export authorization.

↓

Once import and export authorizations are issued, exporter can make shipment.

“It’s extremely complex, takes a lot of time. Six to eight months from the start of the process to when the goods can be air lifted to their final destination.”

- From interviewed organization
But...

- Errors in authorization permits.
- Lack of capacity of authorities in countries affected by political instability and civil war.
- Authorizations may expire before process is complete (in some countries, authorizations are valid for three rather than six months).
- Supplier does not have product in stock, requiring import authorization from national authority and export authorization from manufacturing country.
- Countries may reject import requests if annual quotas or allocations to specific imports have already been used.
Controlled substances (1961, 1971, 1988) - medicines

WHO Model List of Essential Medicines

Medicines for pain and palliative care

Opioid analgesics – codeine; morphine (granules, injection, oral liquid, tablet (slow release and immediate release)); alternatives limited to hydromorphone and oxycodone

Anticonvulsants/antiepileptics - diazepam, lorazepam, phenobarbital, midazolam

Local anaesthetics – ephedrine (for use in spinal anaesthesia during delivery, to prevent hypotension)

Medicines for disorders due to psychoactive substance use - methadone, buprenorphine

Preoperative medication and sedation for short-term procedures – midazolam

Palliative care – diazepam, midazolam

Oxytocics - ergometrine
Controlled medicines in the WHO Model Essential Medicines List

• Opioid analgesics: morphine; codeine; moderate and severe pain

• Long-acting opioid agonists: methadone, buprenorphine

• Ergometrine and ephedrine: emergency obstetrics

• Benzodiazepines: anxiolytics, hypnotics, antiepileptics

• Phenobarbital: Antiepileptic
## 2. MEDICINES FOR PAIN AND PALLIATIVE CARE

### 2.1 Non-opioids and non-steroidal anti-inflammatory medicines (NSAIDs)

<table>
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<th>Medicine</th>
<th>Formulations</th>
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| acetylsalicylic acid | Suppository: 50 mg to 150 mg.  
Tablet: 100 mg to 500 mg. |
| ibuprofen[a]      | Oral liquid: 200 mg/5 mL.  
Tablet: 200 mg; 400 mg; 600 mg.  
[b] Not in children less than 3 months. |
| paracetamol[b]    | Oral liquid: 125 mg/5 mL.  
Suppository: 100 mg.  
Tablet: 100 mg to 500 mg.  
[c] Not recommended for anti-inflammatory use due to lack of proven benefit to that effect. |

### 2.2 Opioid analgesics

<table>
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<th>Medicine</th>
<th>Formulations</th>
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<tr>
<td>codeine</td>
<td>Tablet: 30 mg (phosphate).</td>
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</table>
| morphine[b]  | Granules (slow-release, to mix with water): 20 mg – 200 mg (morphine sulfate).  
Injections: 10 mg (morphine hydrochloride or morphine sulfate) in 1 mL ampoule.  
Oral liquid: 10 mg (morphine hydrochloride or morphine sulfate) 5 mL.  
Tablet (slow release): 10 mg–200 mg (morphine hydrochloride or morphine sulfate).  
Tablet (immediate release): 10 mg (morphine sulfate).  
[d] Alternatives limited to hydromorphone and oxycodone |

### 2.3 Medicines for other common symptoms in palliative care
WHO Therapeutic Guidelines

WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses


WHO Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence

http://www.who.int/hiv/pub/ida/opioid/en/

Other WHO pain guidelines:

WHO is currently developing a new Guideline on Management of Cancer Pain in Adults
Collaboration with partners for improving access to controlled medicines

- The 'Access to Opioid Medication in Europe' (ATOME) programme – improving access to opioids for analgesia and the treatment of opioid dependence in 12 European countries;

- The Joint Global Program to improve access to controlled medicines for pain and palliative care with UNODC and UICC – Ghana; Timor

- WHO-INCB Guide on Estimating Requirements for Substances under International Control

- Development with UNODC of a Model Law related to availability and accessibility to controlled medicines while preventing misuse and diversion;

- Collaboration with AUC for regional workshops on access to medicines for pain and palliative care; and with countries in Africa;
Ensuring balance in national policies on controlled substances

Guidance for availability and accessibility of controlled medicines while preventing misuse and diversion

Activities carried out in countries:

- Analysis of country-specific barriers to opioid accessibility;
- Revision of national drug control legislation and policy;
- Inter sectoral teams develop a national strategic action plan;
- Quantification and data reporting; EMLs; training of staff;
- National consensus workshop on recommendations;
WHO activities within the Joint Global Programme in DRC

1. **Assessment of laws and regulations** on medicines, including controlled medicines

2. Interviews of key players to **explore barriers** to prescribing, procurement and dispensing of controlled medicines;

3. A national workshop on access to controlled medicines
   - **Discussion** of results from the **data collection**; assessment of current legislation; planning policies and best practices to implement and timelines for it;
   - Promotion and **advocacy** of challenges of barriers to access and of **use of WHO guidelines in countries**.
WHO activities within the Joint Global Programme in Timor Leste

Set up of a Coordination Committee lead by the Directorate of Pharmacy

**Capacity building:** training of health professionals targeting mainly medical doctors in primary care health centres

**Technical assistance to the DoP focusing on:**

1) Revision of the controlled medicines listed in the National EML

2) Development of a register of importers, wholesalers and pharmacies dealing with controlled medicines

3) Quality requirements for procurement;

4) Revision of current import/export regulations and quantification of estimates for narcotic / psychotropic substances
WHO Surveys in African countries

1. WHO survey on availability and prices of selected controlled medicines for pain management

Purpose: to map the current availability and price for a selected basket of medicines including controlled medicines for pain and identify shortages.

- Data collection on availability and prices of selected essential controlled medicines (e.g. morphine (injection, tablet (IR, SR), and oral liquid); codeine tablet) using WHO tools and methodologies:
  - in general hospitals and health centers,
  - in wholesalers and pharmacies.

- Carry out data analysis and outline recommendations for improvement of policies and practice
Low availability of CNS medicines in 2016

Proportion of all facilities with medicines available in 2016

* “All CNS” excludes Diazepam, which was only surveyed in hospitals and CMS
Morphine and Ketamine

*Ketamine surveyed in hospitals and CMS only
Ketamine is an essential anesthetic and often the only one available

- It can be administered via a number of routes, including intravenously or intramuscularly for anaesthesia, or orally for sedation.

- It does not depress breathing or blood pressure, which means it is an excellent anaesthetic for trauma victims, patients with hypovolemic and septic shock and patients with pulmonary diseases.

- It is extremely fast-acting.

- It can be used for premedication, sedation, inducing and maintaining general anaesthesia and post-operative analgesia.

- It is the number one anaesthetic in veterinary surgery.

- It is cheap.

- It has a good safety profile and minimal side effects.
WHO Expert Committee on Drug Dependence has recommended against scheduling

“Ketamine is a widely used anaesthetic, especially in developing countries, because it is easy to use and has a wide margin of safety when compared with other anaesthetic agents. While the Committee acknowledged the concerns raised by some countries and UN organizations, ketamine abuse currently does not appear to pose a sufficient public-health risk of global scale to warrant scheduling. Consequently, the Committee recommended that ketamine not be placed under international control at this time. Countries with serious abuse problems may decide to introduce or maintain control measures, but should ensure ready access to ketamine for surgery and anaesthesia for human and veterinary care.”

- Thirty-sixth report of the ECDD, 2014
Consider reviewing domestic legislation and regulatory and administrative mechanisms, as well as procedures including domestic distribution channels, with the aim of simplifying and streamlining those processes and removing unduly restrictive regulations and impediments.

...identify, analyse and remove impediments to the availability and accessibility of controlled substances for medical and scientific purposes.

...provide capacity-building and training...on adequate access to and use of controlled substances.

...expanding the national coverage of distribution networks to rural areas.

...consider the development and wider implementation of relevant clinical guidelines on the rational use of controlled medicines.

...allowing appropriately trained and qualified professionals to prescribe, dispense and administer controlled medicines based on their general professional license.

...adequately estimate and assess the need for controlled substances and paying special attention to essential medicines.

...review national lists of controlled substances and national lists of essential medicines.
Thank you