

Ensuring access to and safe use of controlled medicines

Dr Gilles Forte
Coordinator

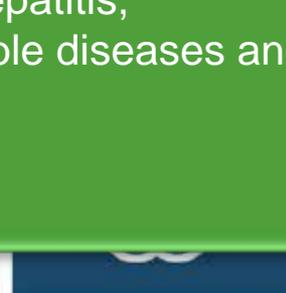
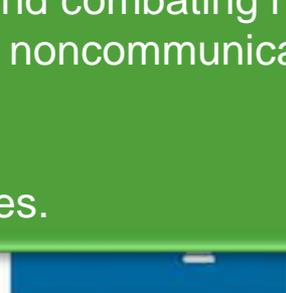
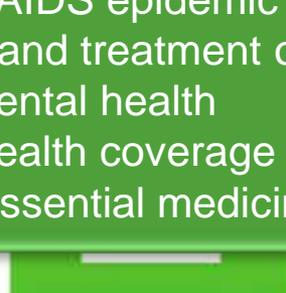
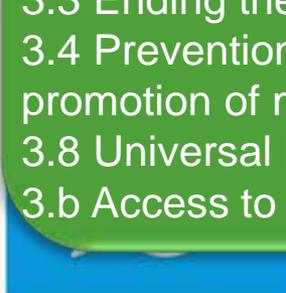
Access to Medicines and other Health Products



**World Health
Organization**



SUSTAINABLE DEVELOPMENT GOALS



Ensure healthy lives and promote well-being for all at all ages

- 3.5 Strengthen the prevention and treatment of substance abuse, including narcotic drugs and harmful use of alcohol
- 3.3 Ending the AIDS epidemic and combating hepatitis,
- 3.4 Prevention and treatment of noncommunicable diseases and promotion of mental health
- 3.8 Universal health coverage
- 3.b Access to essential medicines.

Single Convention on Narcotic Drugs (‘the 1961 Convention’)



- Medicines active on the Central Nervous System & associated with risks of non-medical use, misuse and diversion: they are subject to international control
 - opium and its derivatives e.g. morphine, codeine, heroin as well as other opioids such as fentanyl

Used for pre- and post-operative care, for sedation, for the management of both acute and chronic pain, for palliative care

Used for the management of substance use disorders e.g. opioid agonist therapies.

- cannabis based medicines

Used for the treatment of epilepsy in children and muscle spasticity in Multiple Sclerosis

Convention on Psychotropic Substances ('the 1971 Convention')



Medicines active on the Central Nervous System and associated with risks of non-medical use, misuse and diversion: they are subject to international control

- sedatives e.g. benzodiazepines for anxiety disorders

International drug control conventions: a balanced approach to access



The preambles to both the 1961 and 1971 Conventions recognise that psychoactive substances with medical use are necessary for the provision of healthcare.

The parties,

Concerned with the health and welfare of mankind (1961)

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)

Being concerned with the health and welfare of mankind (1971)

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)

United Nations & WHA Resolutions: Promoting access to controlled medicines



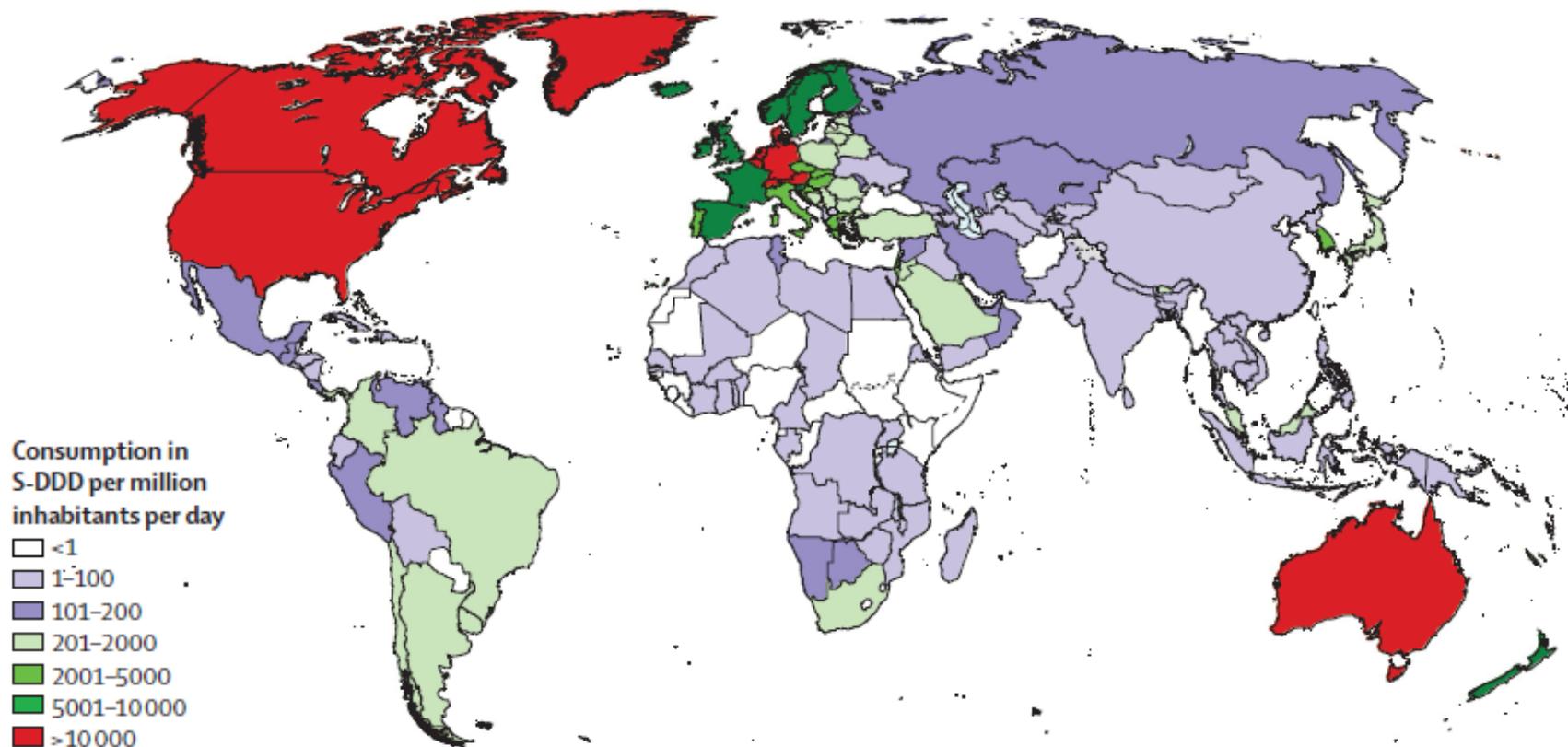
The need for a balanced approach was noted in the United Nations General Assembly Special Session Resolution adopted in April 2016.

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 anesthesia 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

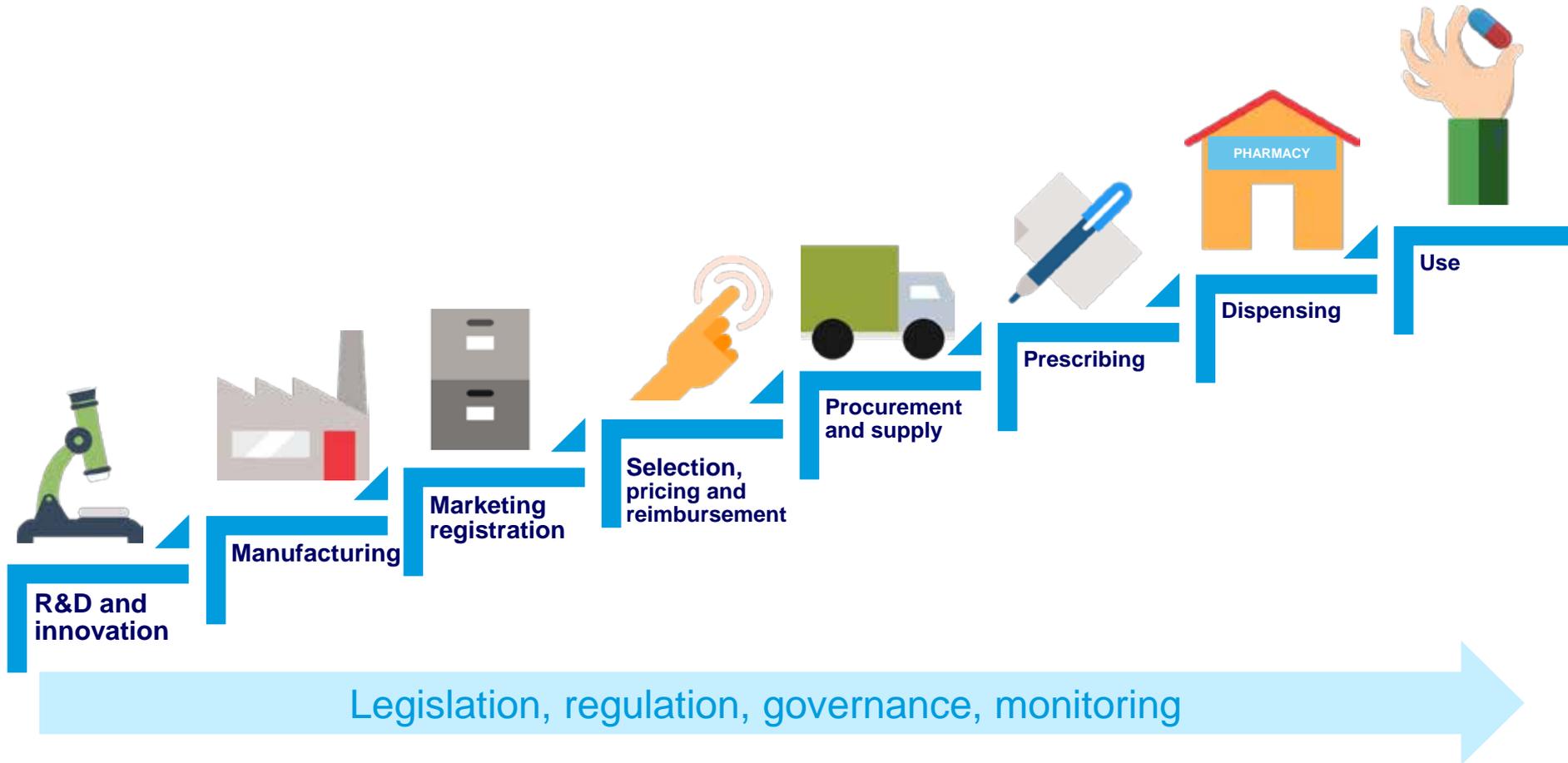
Mean availability of opioids for pain management (2011-13)



The boundaries shown and the designations used on this map do not imply official endorsement or acceptance by the UN. Final boundary between Sudan and South Sudan has not yet been established. The dotted line represents roughly the Line of Control in Jammu and Kashmir agreed on by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed on by the parties. A dispute exists between the Governments of Argentina and the UK concerning sovereignty over the Falkland Islands (Malvinas). S-DDD=defined daily doses for statistical purposes.

Source: INCB and Berterame et al. 2016

Achieving access to medicines



Specific barriers to access to controlled medicines



- q **Insufficient knowledge & training** on efficacy and safety profiles: inappropriate use or no use;
- q **Behaviours**
 - Fear for abuse and dependence
 - Fear for diversion and sanctions
- q **Inaccurate quantification of needs:** shortages, diversion & waste
- q **Regulations**
 - Limited prescription duration; special prescription forms
 - Limitation of dispensing outlets; limitation of prescribing
 - Restrictions on exports and imports- special licences needed

Controlled medicines in the WHO Model Essential Medicines List



- Opioid analgesics:
morphine; codeine; fentanyl
moderate and severe pain
- Long-acting opioid agonists:
methadone,
buprenorphine
treatment of opioid dependence
- Ergometrine and ephedrine:
emergency obstetrics
- Benzodiazepines:
anxiolytics, hypnotics,
antiepileptics
- Phenobarbital:
Antiepileptic

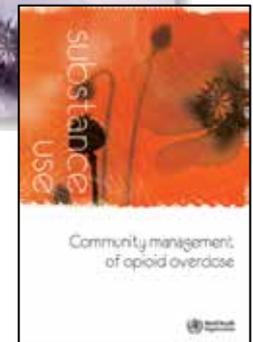
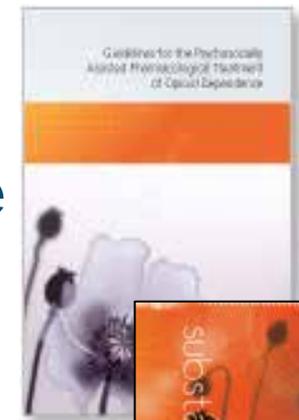
	WHO EML 2017, 2015	2017 BANGLADE SH NEML	2016 BHUT AN NEML	2012 DPRK NEML	2015 INDIA NEML	2013 INDO NESIA NEML	2017 MALD IVES NEML	2016 MYANMAR NEML	2015 NEPAL NEML	2014 SRI LANKA NEML	2017 THAI LAND NEML	2015 TIMOR LESTE NEML
Palliative care (n=15)												
Non-opioid analgesic	ibuprofen	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	paracetamol	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Opioid analgesic	codeine	✓	n	✓	n	n	✓	✓	✓	n	✓	✓
	morphine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	cyclizine	✓	n	n	n	n	n	n	n	n	n	n
	dexamethasone	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	docusate sodium	✓	n	n	n	n	✓	n	n	n	n	n
	haloperidol	✓	✓	✓	✓	✓	✓	✓	✓	n	✓	✓
Medicine for other common symptoms in palliative care	hyoscine hydrobromide	✓	n	n	n	n	n	n	n	n	n	n
	lactulose	✓	✓	✓	n	✓	✓	✓	✓	✓	✓	✓
	loperamide	✓	n	n	n	✓	n	✓	✓	n	✓	n
	metoclopramide	✓	✓	✓	✓	✓	✓	✓	n	✓	✓	✓
	midazolam	✓	n	✓	n	✓	✓	✓	✓	✓	✓	✓
	ondansetron	✓	n	✓	n	✓	✓	✓	✓	✓	✓	n
	senna	✓	✓	✓	n	n	n	n	n	n	✓	n

*also listed in palliative care section; ✓ = API included in list; n = API not included in list; n = API not included but alternative within same pharm class included.

WHO Clinical Guidelines



- WHO guidelines for the management of cancer pain in adults and adolescents (2019)
- WHO guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence
- WHO guidelines for community management of opioid overdose (2014)



WHO Guideline for ensuring balanced national policies for access and safe use of controlled medicines



Objective : to assist policy makers as well as programme managers and experts in countries in the formulation and implementation of balanced policies that ensure access to and safe use of controlled medicines while preventing their diversion, misuse and harm to health.

This guideline is also meant to be used in emergency situations where national regulatory authority and supply chain do not function efficiently or have collapsed.

Guideline revision process

The Guideline will be developed in accordance with WHO guidance on the development of evidence-based guidelines and the World Health Organization handbook for guideline development (2nd ed.). Geneva, 2014.

The guideline would be revised in light of new scientific evidence that has emerged since 2011 and the experts involved in their revision would comply with WHO's new policy for the management of conflicts of interest that had been in place since 2014 . World Health Organization. Web statement on pain management guidance. 20 June 2019.

https://www.who.int/medicines/areas/quality_safety/guide_perspainchild/en/

Progress are made in the development of this guideline and in the consultation process:

https://origin.who.int/medicines/access/controlled-substances/controlled_medicines_access/en/

Conclusion

WHO is concerned that there is very low access to medication for moderate and severe pain, particularly in low and middle-income countries.

WHO also recognizes that the need for access to pain relief must be balanced with concerns about the harm arising from the misuse of medications prescribed for the management of pain, including opioids —such as the development of dependence, overdose and accidental death.

WHO remains committed to working with Member States to support the development of evidence-based policies, regulations and best practices to promote access to safe, effective and affordable medicines for the management of pain, and to prevent their misuse and harm.