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# What can be done to improve safe access to medical morphine?

Reflecting backward and looking forward

12 September 2023



Use Q&A window to post your questions (not “Chat”)



Please keep all comments respectful and constructive



This session is recorded for future viewing on demand



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# WHO report

to describe extent and causes of global variations in access to morphine for medical use and actions to improve safe access



<https://www.who.int/publications/i/item/9789240075269>

# Three short films

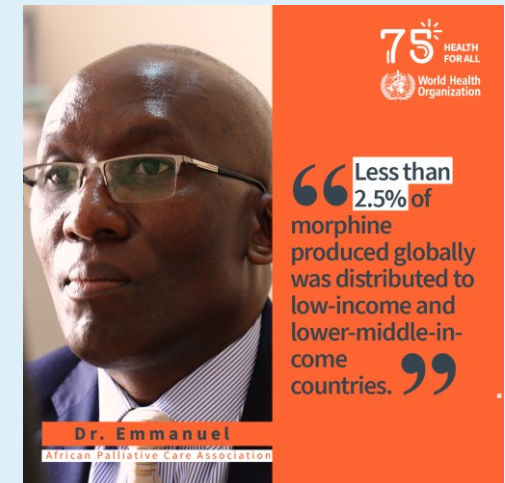
To share three stories from people impacted by access to morphine



<https://www.youtube.com/watch?v=h3klGKSnbQ4>



<https://www.youtube.com/watch?v=T2dVuNGyrAk>



<https://www.youtube.com/watch?v=6NhB7HXrjQc>

# Today's session



## **Stefano Berterame**

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Secretariat of the International Narcotic Control Board (INCB)  
United Nations Office on Drugs and Crime (UNODC)

## **Christa Cepuch**

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United Nations Office on Drugs and Crime (UNODC)

## **Gilles Forte**

Head (Special Projects), Division of Medicines and Health Products, WHO, Geneva  
Secretary, Expert Committee on Drug Dependence, World Health Organization (WHO)

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# Presentations

## Left behind in pain

Extent and causes of global variations in access to morphine for medical use and actions to improve safe access



# Safe access to morphine matters

Dr Gilles Forte

Health Products Policy and Standards  
Medicines and Health Products



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Health professionals and institutions must be prepared to relieve suffering while ensuring respect for the patient's dignity and quality of life.



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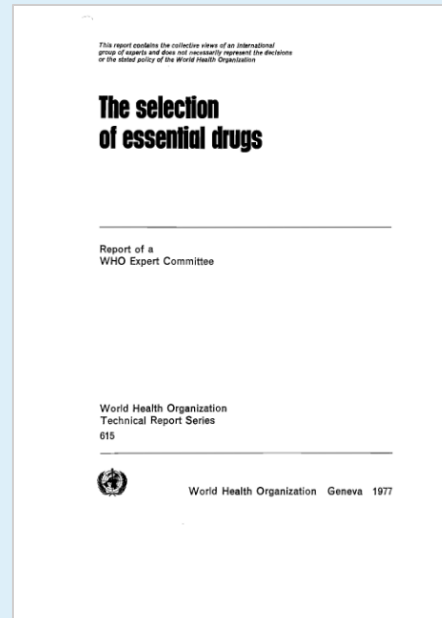


# Morphine is an essential medicine

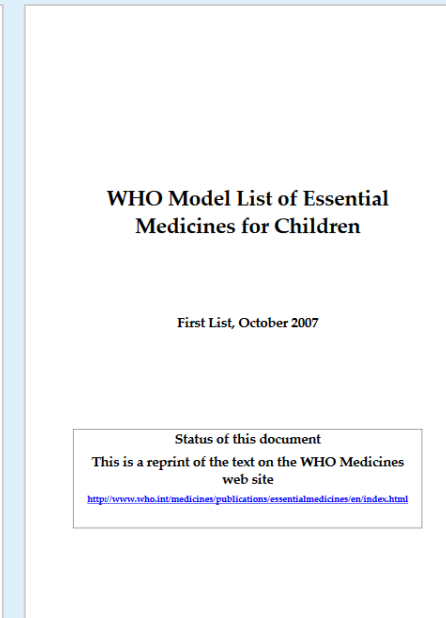
for managing acute or chronic, moderate to severe pain, particularly in palliative care.

## Listed in the WHO Model List of Essential Medicines

First edition 1977



First edition 2007



**Less expensive than other derivative and synthetic opioids** (e.g. oxycodone and fentanyl) which have been associated with the 'opioid overdose epidemic' in a few high-income countries



# Access to morphine is regulated by international and national legal instruments

- **International:** Single Convention on Narcotic Drugs, 1961
- **National:** National laws and regulations



United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs 24 January - 25 March 1961, New York

**Source:**  
<https://www.un.org/en/conferences/drug/newyork1961>



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# Both conventions emphasise the “indispensable” need to maintain access to narcotic and psychoactive substances for medical use

- Limit the possession, consumption, trade, distribution, import, export, manufacture and production of drugs to medical and scientific purposes only
- Fight against drug trafficking through international cooperation
- Protocol amending the Single Convention on Narcotic Drugs in 1972:
  - Treatment and rehabilitation of drug dependence



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 Convention)



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 Convention)

# WHO's work on access to controlled medicines is guided by WHA resolutions

covenants, resolutions, and principles endorsed by the United Nations Human Rights Council and the United Nations General Assembly

Public health

Human Rights

Universal health coverage

Primary health care



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SIXTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA67.19

Agenda item 15.5

24 May 2014

**Strengthening of palliative care as a component of comprehensive care throughout the life course**

SIXTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA67.22

Agenda item 15.4

24 May 2014

**Access to essential medicines**

SIXTY-EIGHTH WORLD HEALTH ASSEMBLY

WHA68.15

Agenda item 17.1

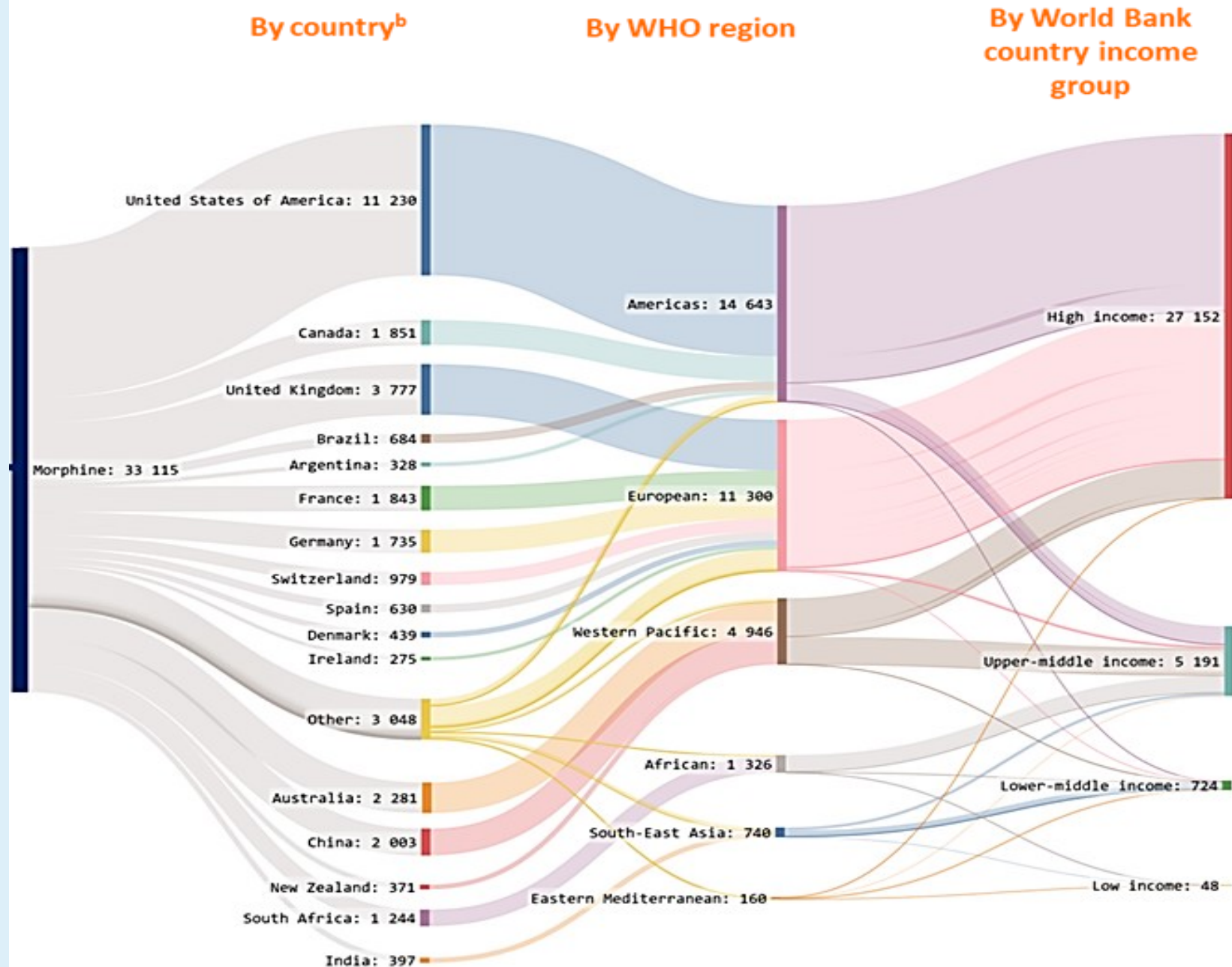
26 May 2015

**Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage**

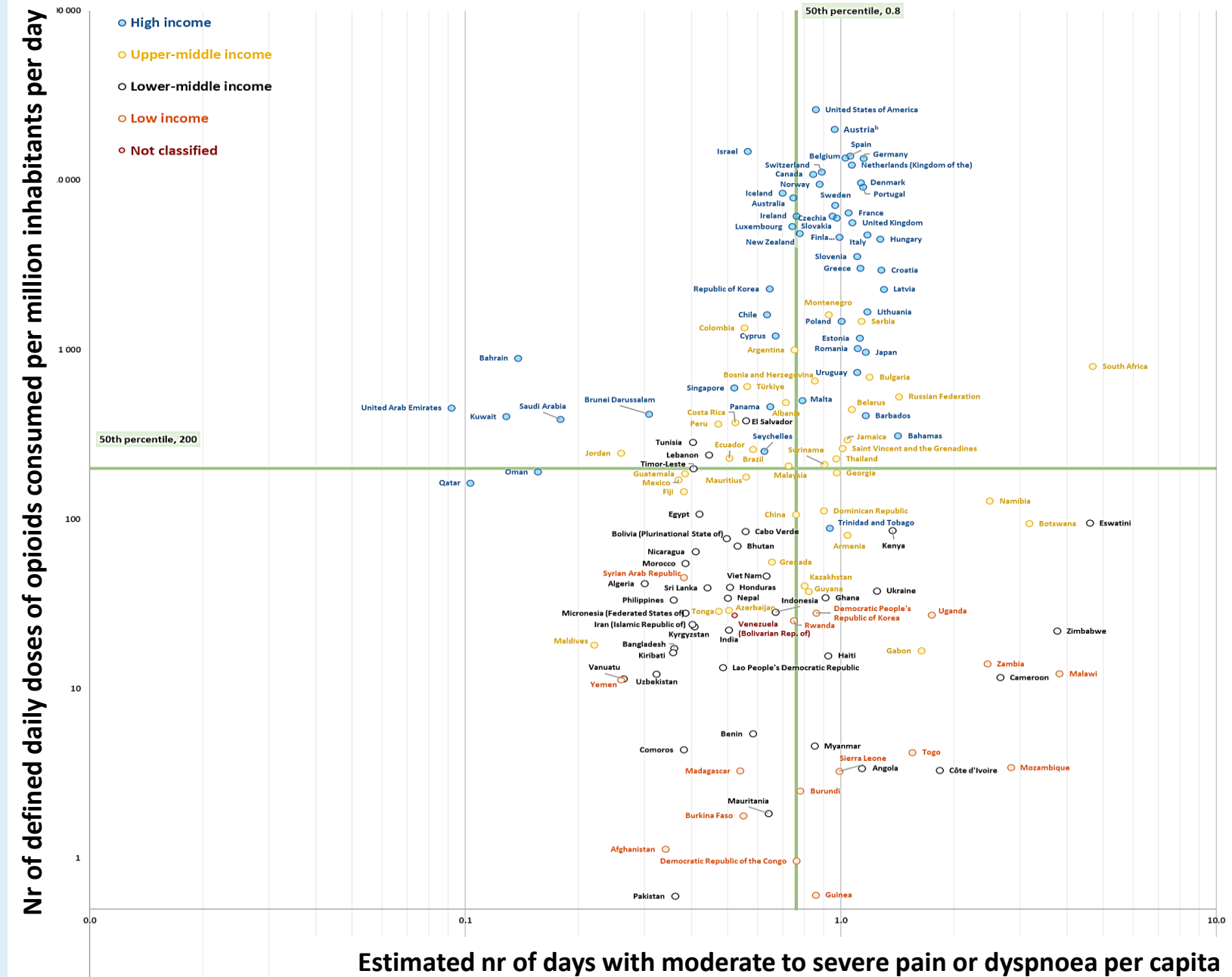
# Persistent lack of access to morphine for medical use is concerning

Less than 2.5% of morphine produced globally was distributed to low-income and lower-middle-income countries

## Distributed for consumption (kg)



Consumption pattern varies significantly across countries of similar wealth and does not correspond to medical need





People in need of pain relief in these countries would be most affected by the unavailability of morphine



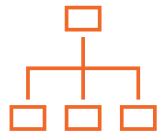
# Enablers and barriers to access are often “two sides of the same coin”

**Enablers**



**Barriers**

## Good governance



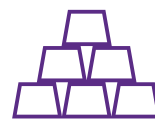
- Regulations or policies
- Medicines/therapeutics committees
- Clinical supervision, formal audit and feedback

## Legislative or policy related factors



- Overly focused on preventing non-medical use
- Prescribing/Dispensing restrictions and administrative reqs

## Adequate resources



- Predictable, stable and adequate funding
- Medicines and equipment to support the safe use

## Service-related barriers



- Irregular availability
- Lack awareness of the availability
- Unaffordable price and costs
- Long distance or poor transportation

## Sufficient capacity



- Skilled workforce
- Training, patient and public education

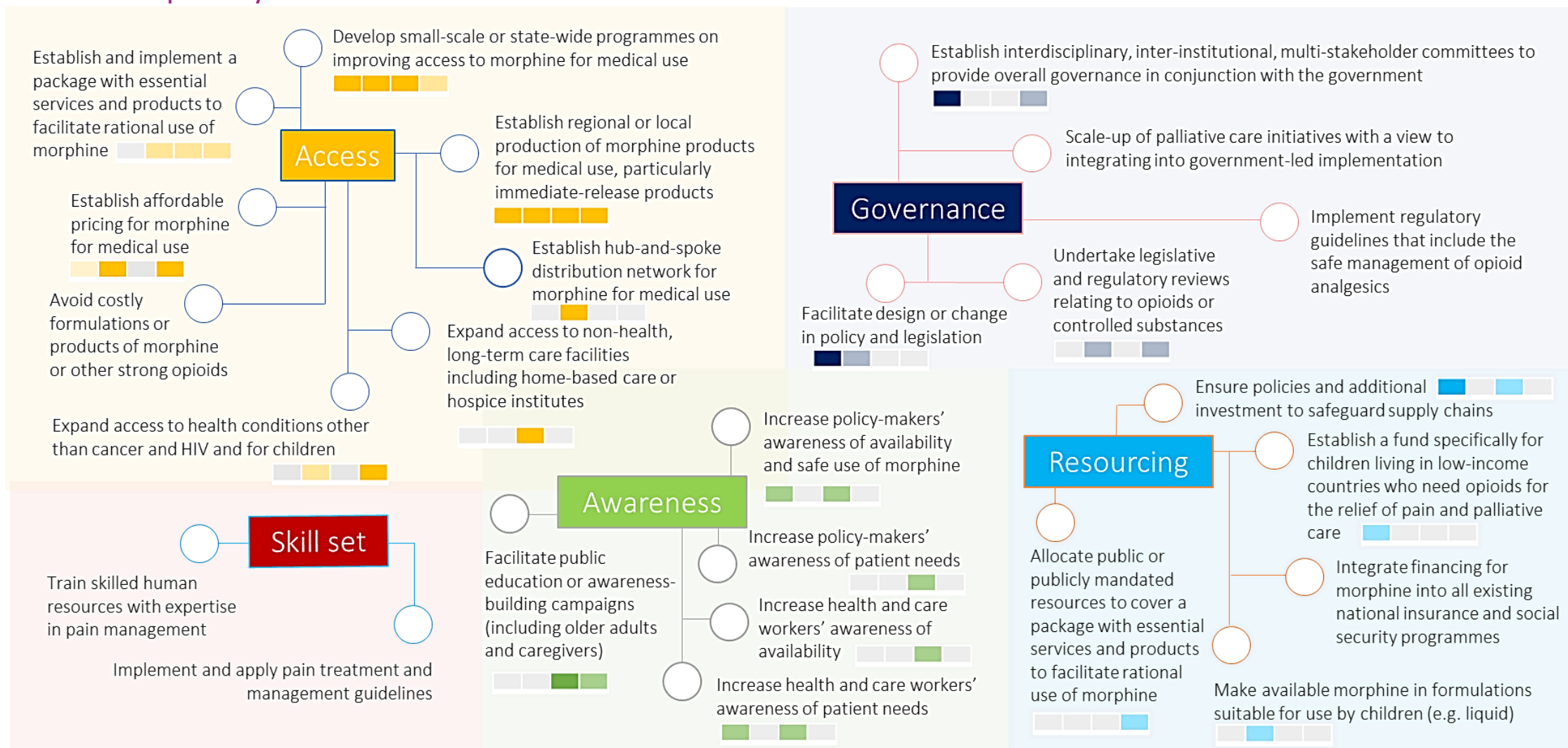
## Attitudes and perceptions



- Fearful of risks
- Associate morphine use only at the end of life, general social stigma
- Low trust

# In taking actions to improve safe access to morphine, **health and human rights** must be at the centre of all policies.

## Five broad **priority areas for action**







Leaving people in pain when effective medicines are available for pain management, especially in the context of end-of-life care, should be a **cause of serious concern** for policy-makers.

We must therefore urgently advocate for **safe and timely access** to morphine for those in medical need through balanced policy, **everywhere**.





Secretariat of the International Narcotics Control Board

## **Informing Policy through data: challenges and opportunities**

Stefano Berterame

Chief, Narcotics Control and Estimates Section

INCB Secretariat

Left behind in pain – Technical briefing on WHO report on extent and causes of global variations in access to morphine for medical use and actions

12 September 2023



# Single Convention 1961

Governments have a dual obligation  
(Preamble, Single Convention on Narcotic  
Drugs, 1961)

Ensure adequate availability of  
narcotic drugs for medical and  
scientific purposes

Prevent diversion and abuse



# Main points

- Global trends
- Estimates
- Impediments and obstacles
- Legislative and regulatory systems
- Health systems
- Affordability
- Training of health care professionals
- Education and awareness raising



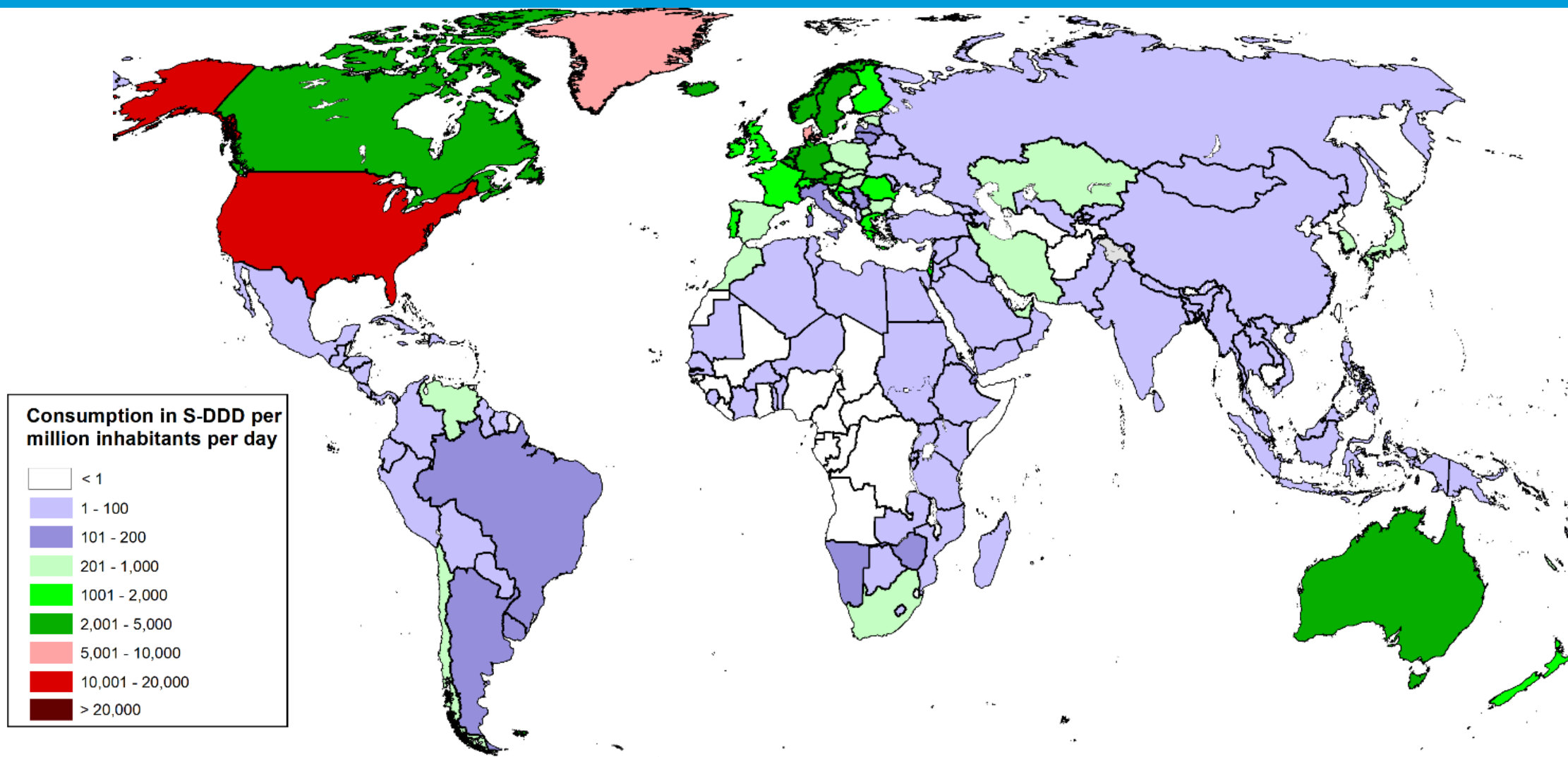
## Global Trends

- Despite a global increase in the availability of opioid analgesics for consumption, mostly in high-income countries, global disparity and imbalance remain evident.
- Increase in the use of expensive synthetic opioids, again mostly in high-income countries, that is not matched by an increase in the wider use of affordable morphine.



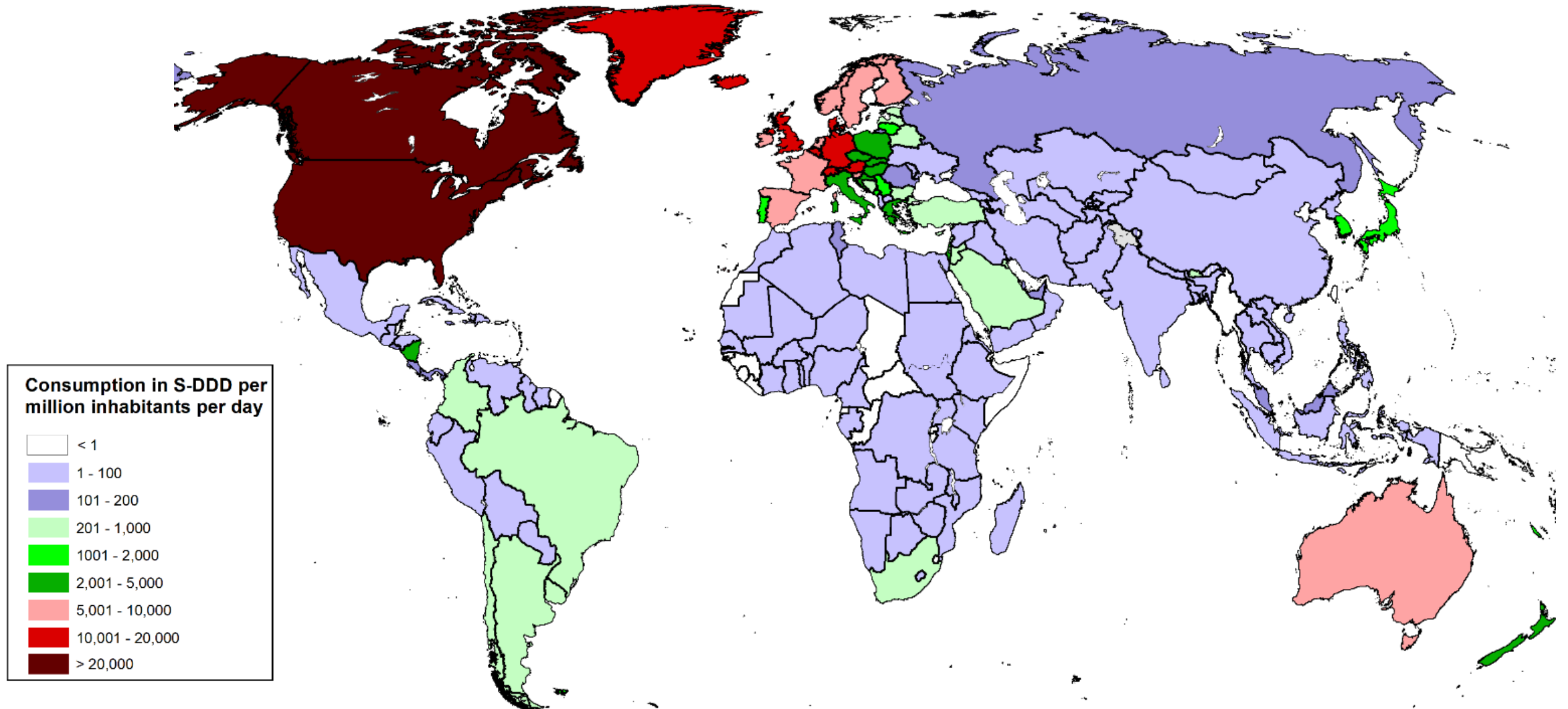


## Global Trends -Availability of opioids for pain management, 1998 - 2000 average



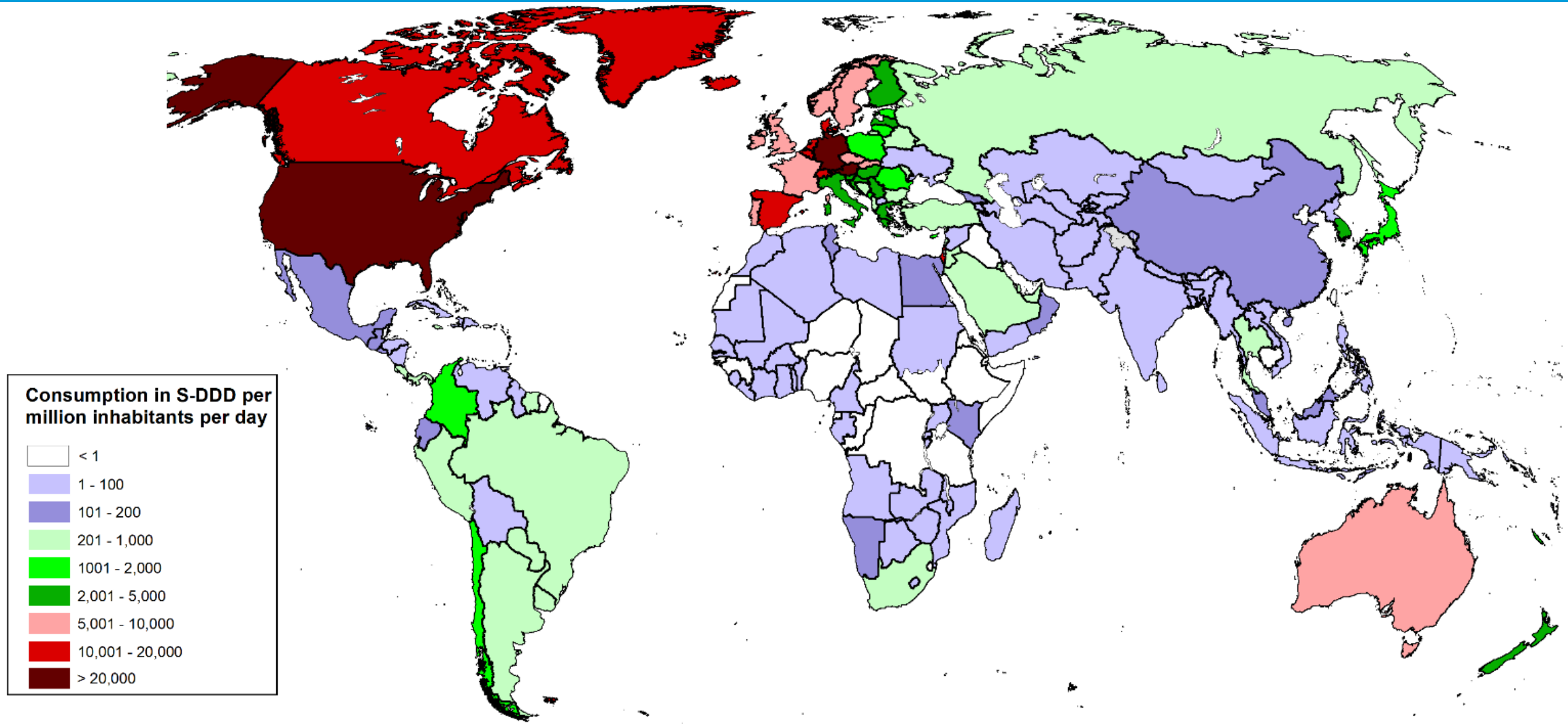


## Global Trends - Availability of opioids for pain management, 2008 - 2010 average



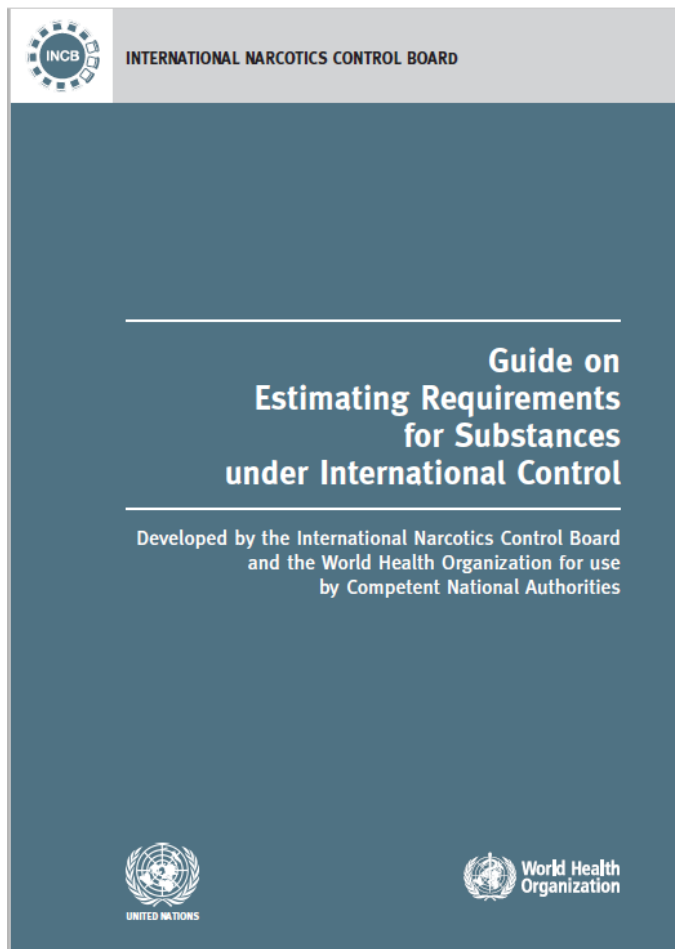


## Global Trends - Availability of opioids for pain management, 2018 - 2020 average





# Estimates

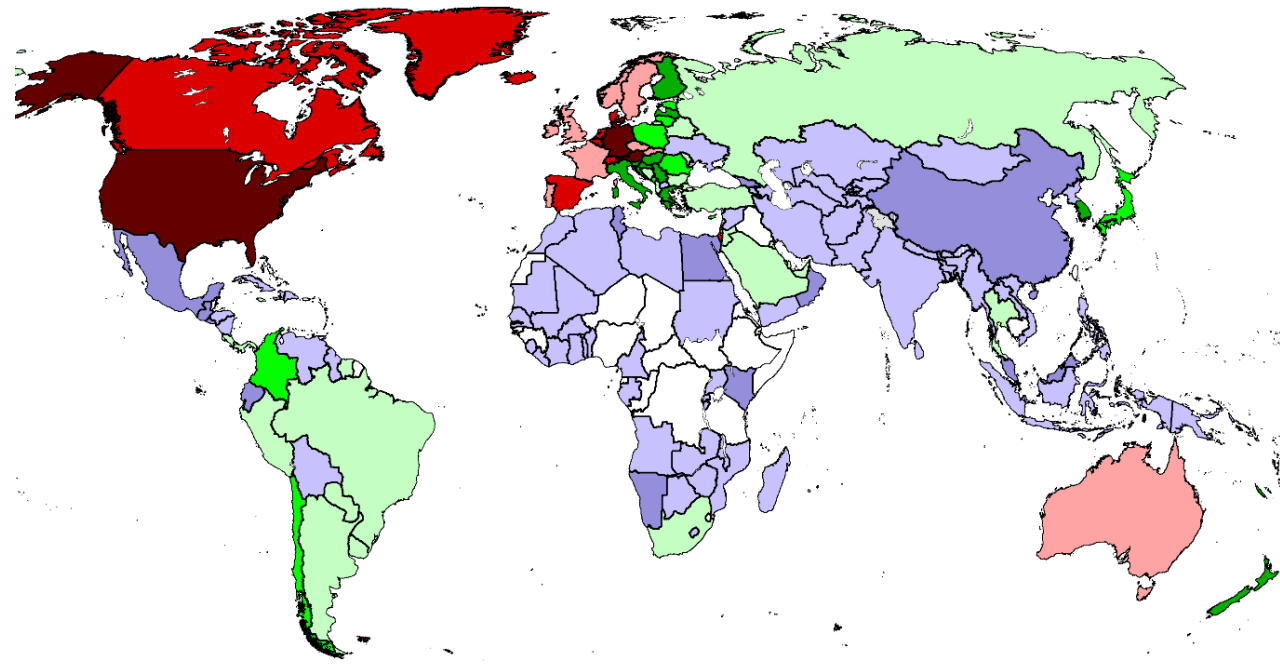
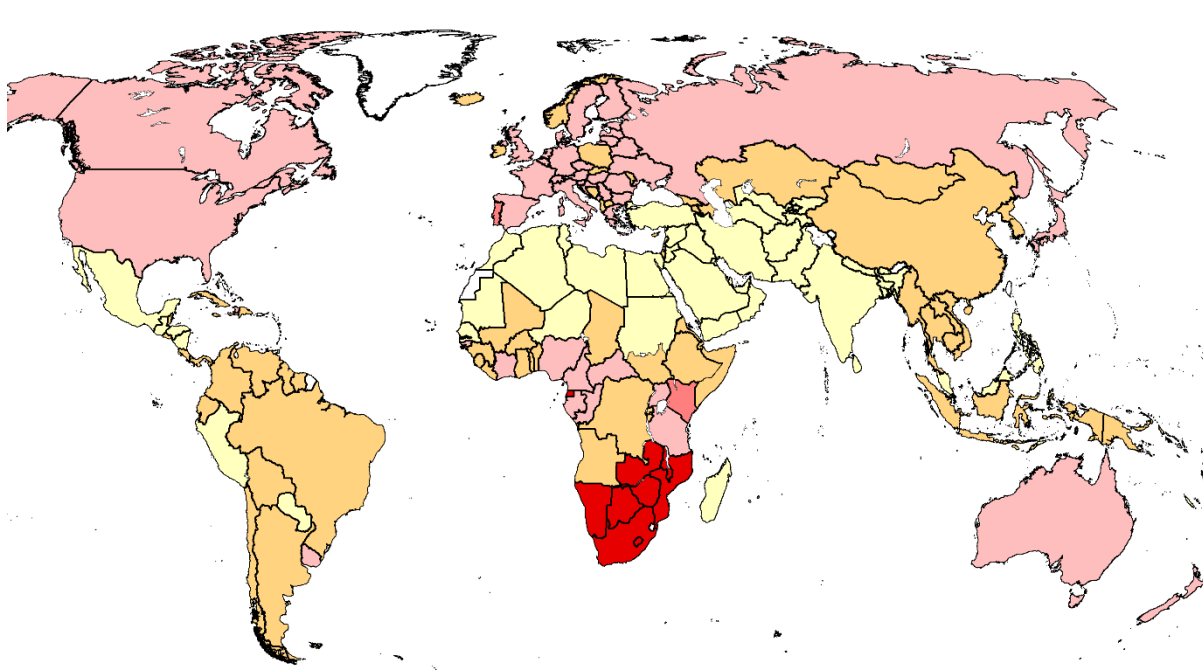


- The **consumption-based method** and its variants are based on use over recent years.
- The **service-based method** calculates requirements for controlled substance based on current levels of use of in a sample of standard facilities.
- The **morbidity-based method** calculates requirements based on an assessment of the frequency of health problems and on accepted treatment norms for the health problems in question.
- Only 25% use service- or morbidity-based methods



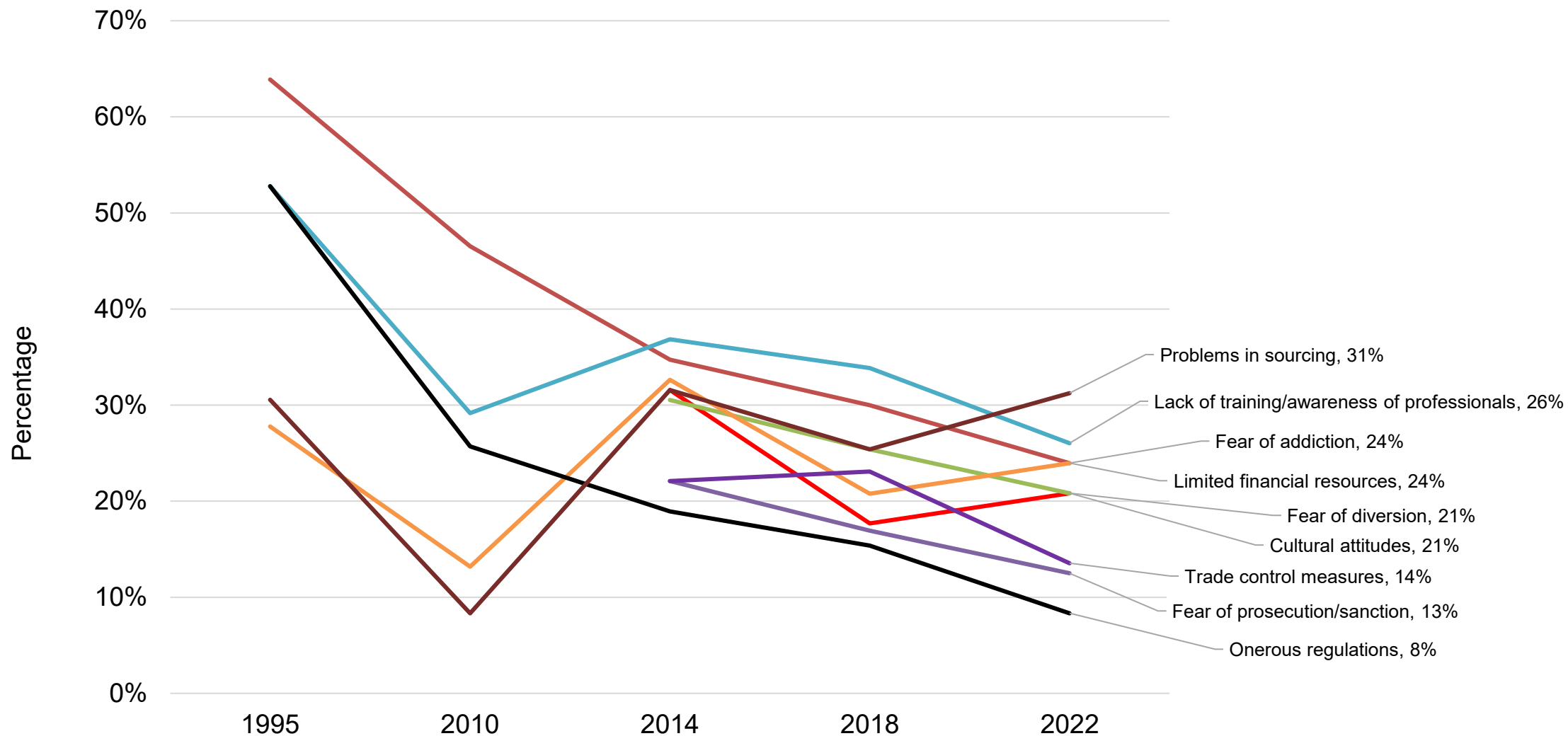


## Estimates - Need for palliative care vs. Availability of opioids for pain





# Impediments and obstacles 1995-2022





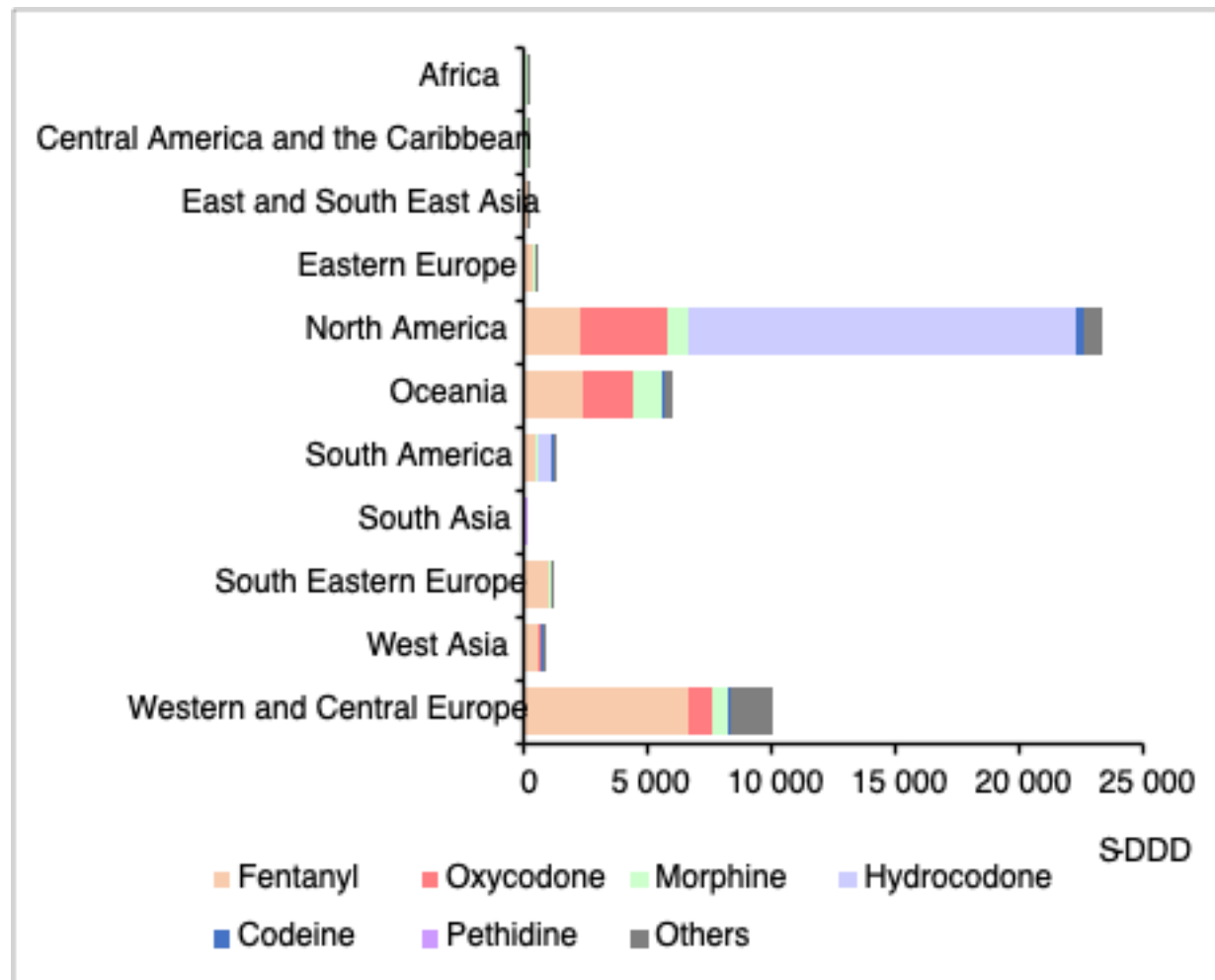
# Affordability

- 24% of competent national authorities mentioned lack of financial resources to procure medicines containing controlled substances.



## Secretariat of the International Narcotics Control Board

### Consumption of codeine, fentanyl, hydrocodone, oxycodone, pethidine and other opioids, by region, expressed in S-DDD, 2020





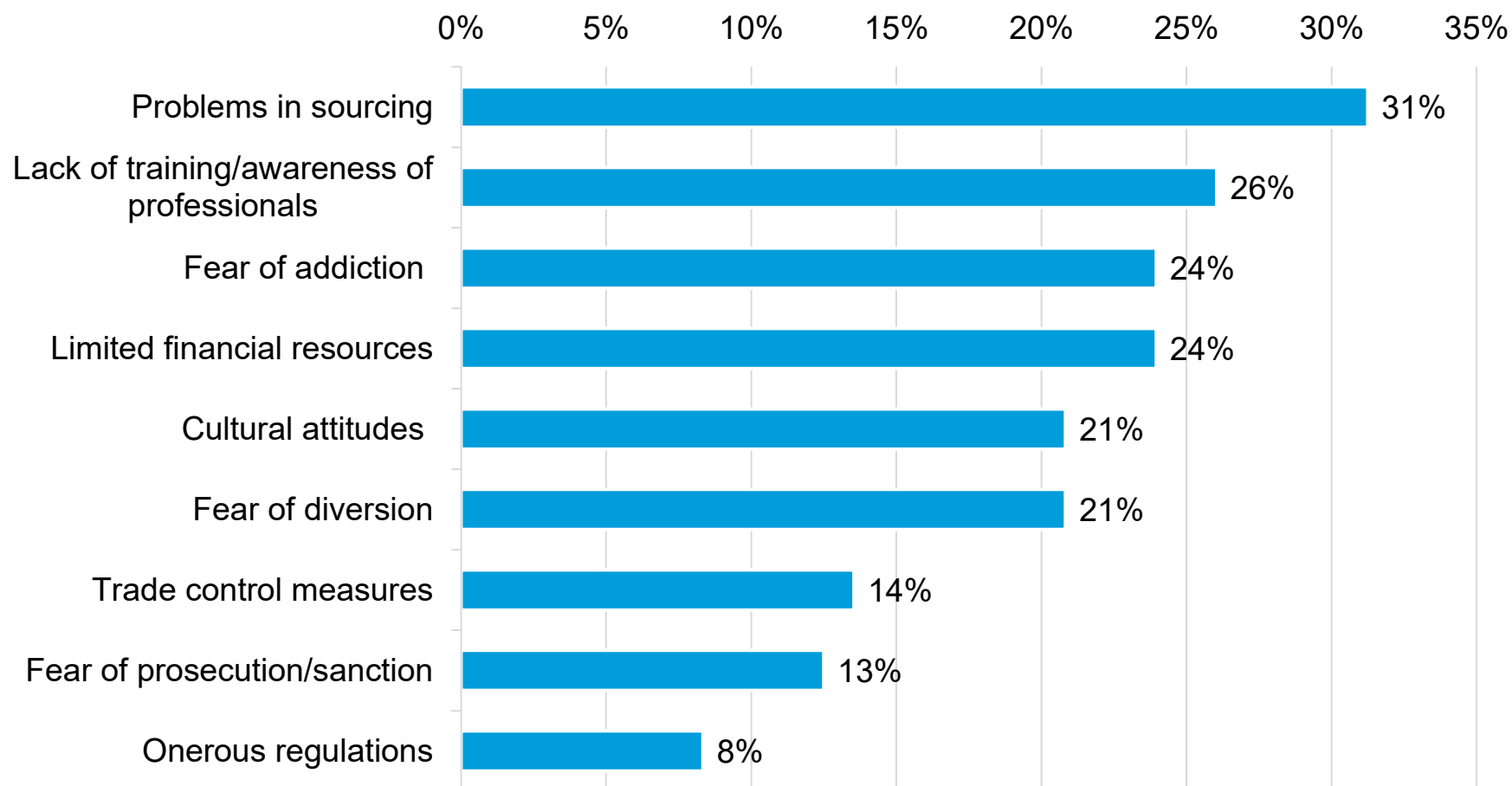
# Legislative and regulatory systems

- Review or change in national legislation and regulatory systems to improve access to controlled substances while maintaining adequate control.
- Only 10% (10 of 96 countries) allow nurses, including nurse practitioners, to prescribe controlled substances.
- Validity of a prescription for controlled substances is in many cases relatively short, making it difficult for patients to procure medicines that are needed on a continuous basis.
- Legal sanctions for health professionals who unintentionally mishandle opioids.





# Impediments and obstacles to availability as mentioned by competent national authorities (2022)



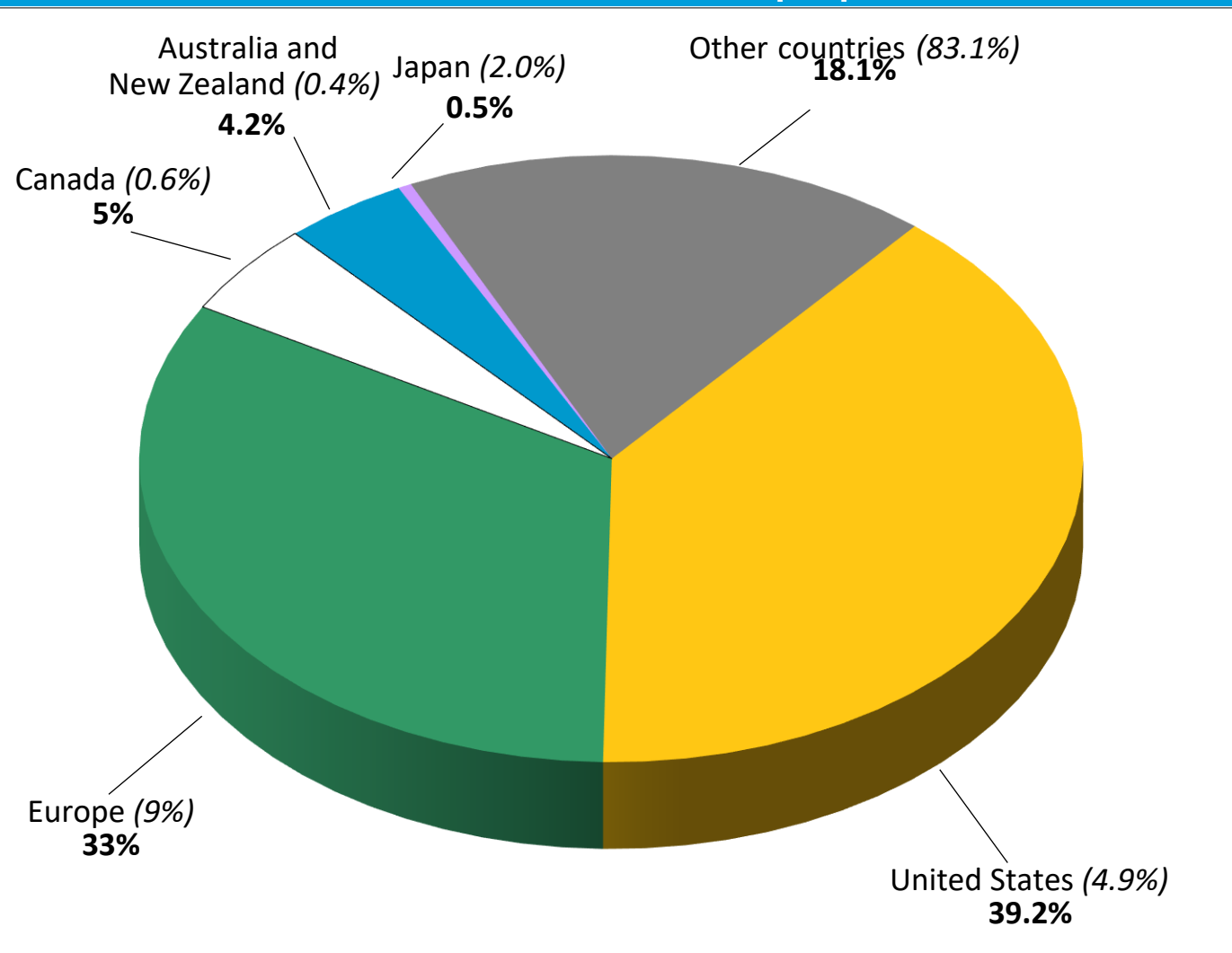


## Health systems

- Palliative care policies and measures had been implemented including low-cost and home-based services.
- 50% of national authorities considered their health infrastructure to be appropriate to the needs of their people.
- Not many authorities reported that in their country there was a problem of accessibility to controlled substances for patients in rural and remote areas.
- However, civil society organizations considered that accessibility in rural areas was a major issue.

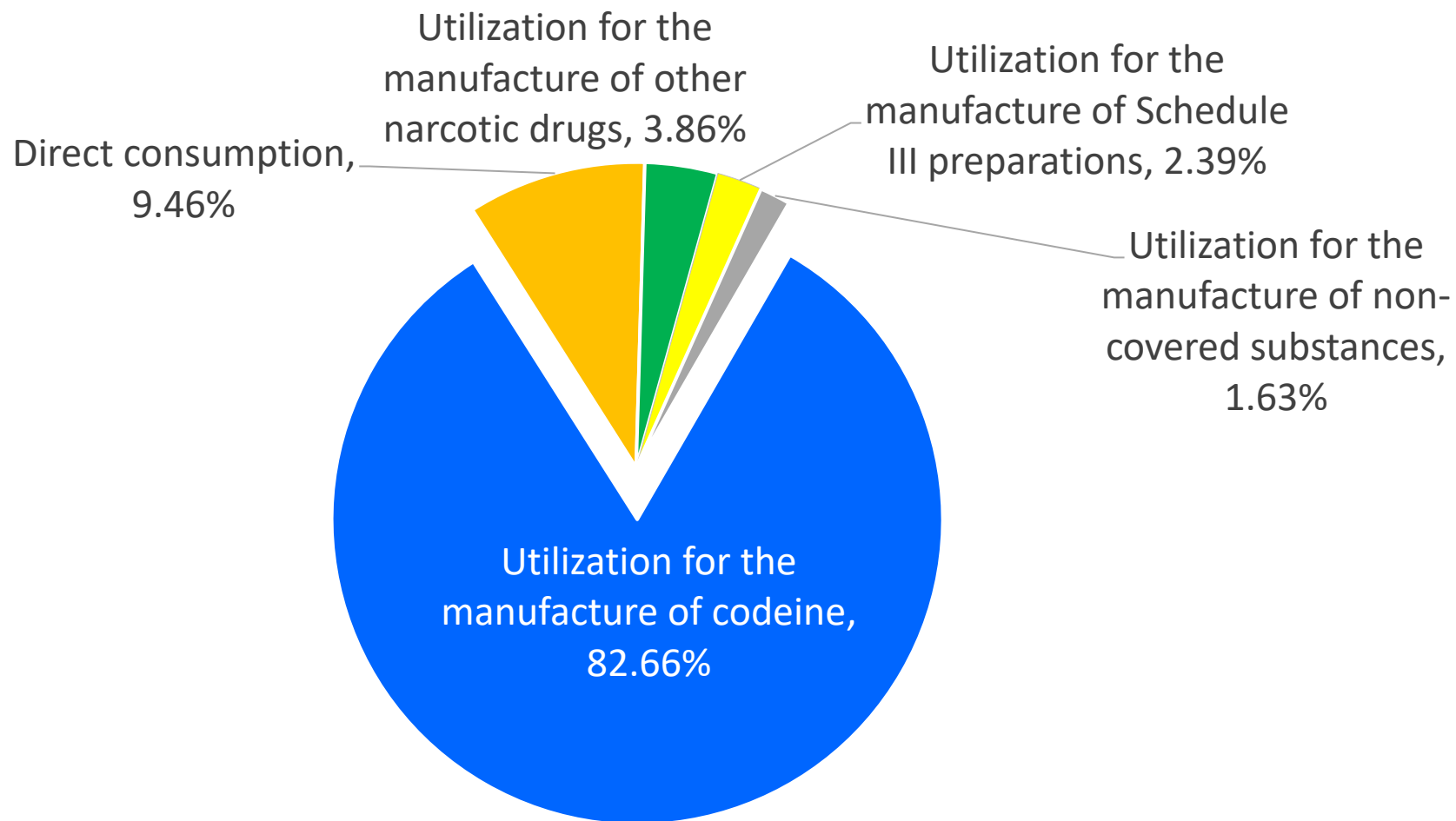


## Morphine: distribution of consumption in relation to share of world population, 2020





# Average Morphine use, 2001-2020





# Education and awareness raising

- Cultural attitudes towards the use of controlled substances for medical purposes have contributed to the limiting access for patients.





# Training of health care professionals

- Many countries reported that training around pain and palliative care is part of the educational curricula of medical and nursing schools but is not always mandatory.



Secretariat of the International Narcotics Control Board

**Thank you**



**UNODC**

United Nations Office on Drugs and Crime

# Ensuring Availability of and Access to Controlled Substances for Medical and Scientific Purposes while Preventing Diversion and Abuse

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CONTROLLED  
**MEDICINES**

INCREASE ACCESS FOR MEDICAL AND SCIENTIFIC PURPOSES  
COUNTER DIVERSION ■ PREVENT NON-MEDICAL USE

Dr. Elizabeth Sáenz  
UNODC Programme Officer

12 September 2023



CONTROLLED  
**MEDICINES**



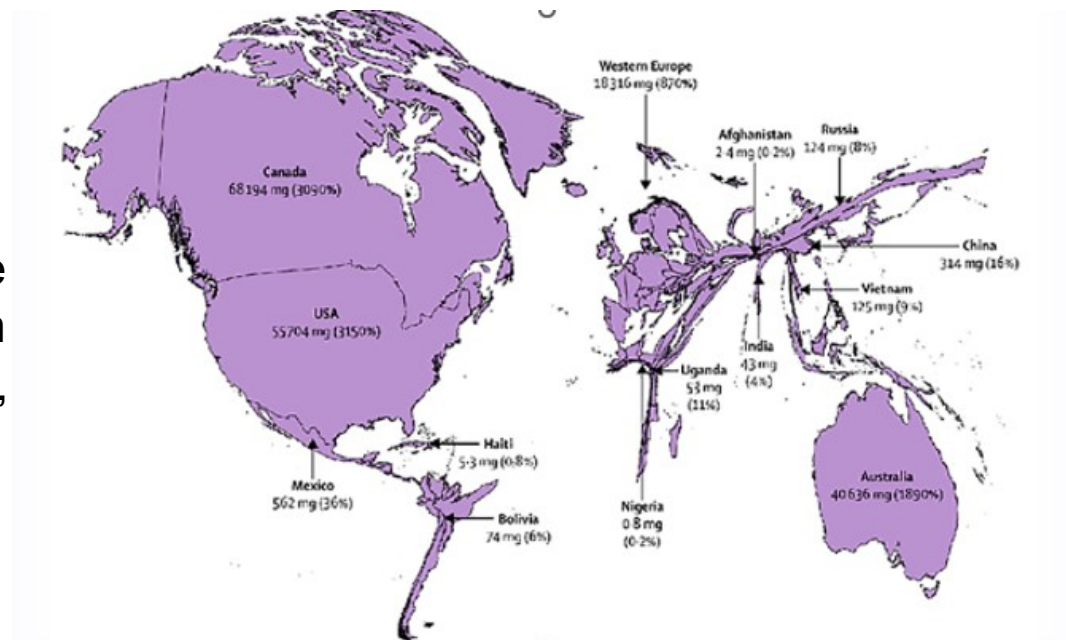
# International Drug Conventions

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- Protect the public health and welfare by indicating that narcotic drugs and psychotropic substances under control should be made available exclusively for medical and scientific purposes
- Make adequate supplies available of drugs for medical purposes while protecting the public from the potentially dangerous effects of controlled drugs used for non-medical purposes
- Governments must avoid over restrictive legislation which adversely affect their availability for medical and scientific purposes


# Two sides – one coin

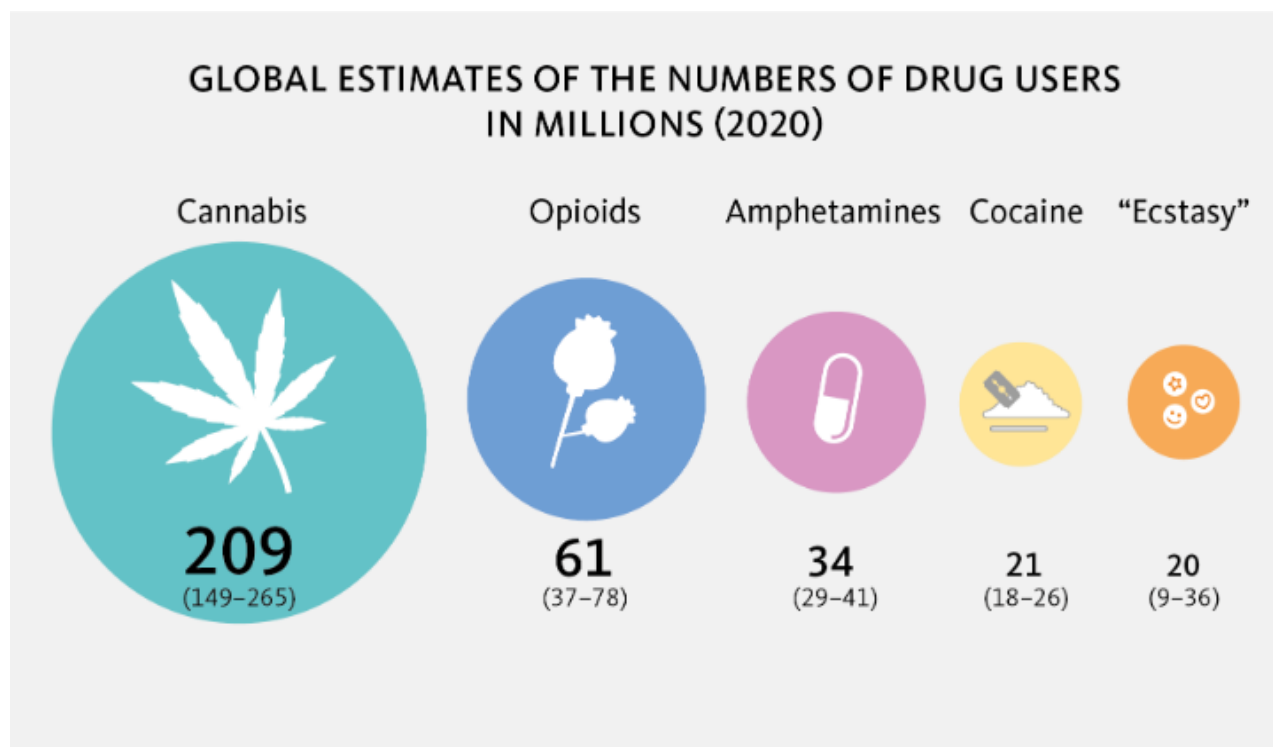
- A variety of internationally controlled substances are vital medications.
- Narcotic drugs like morphine are critical opioid analgesics for pain management and palliative care, while others help to treat mental health disorders and drug dependence.





# Drugs Used

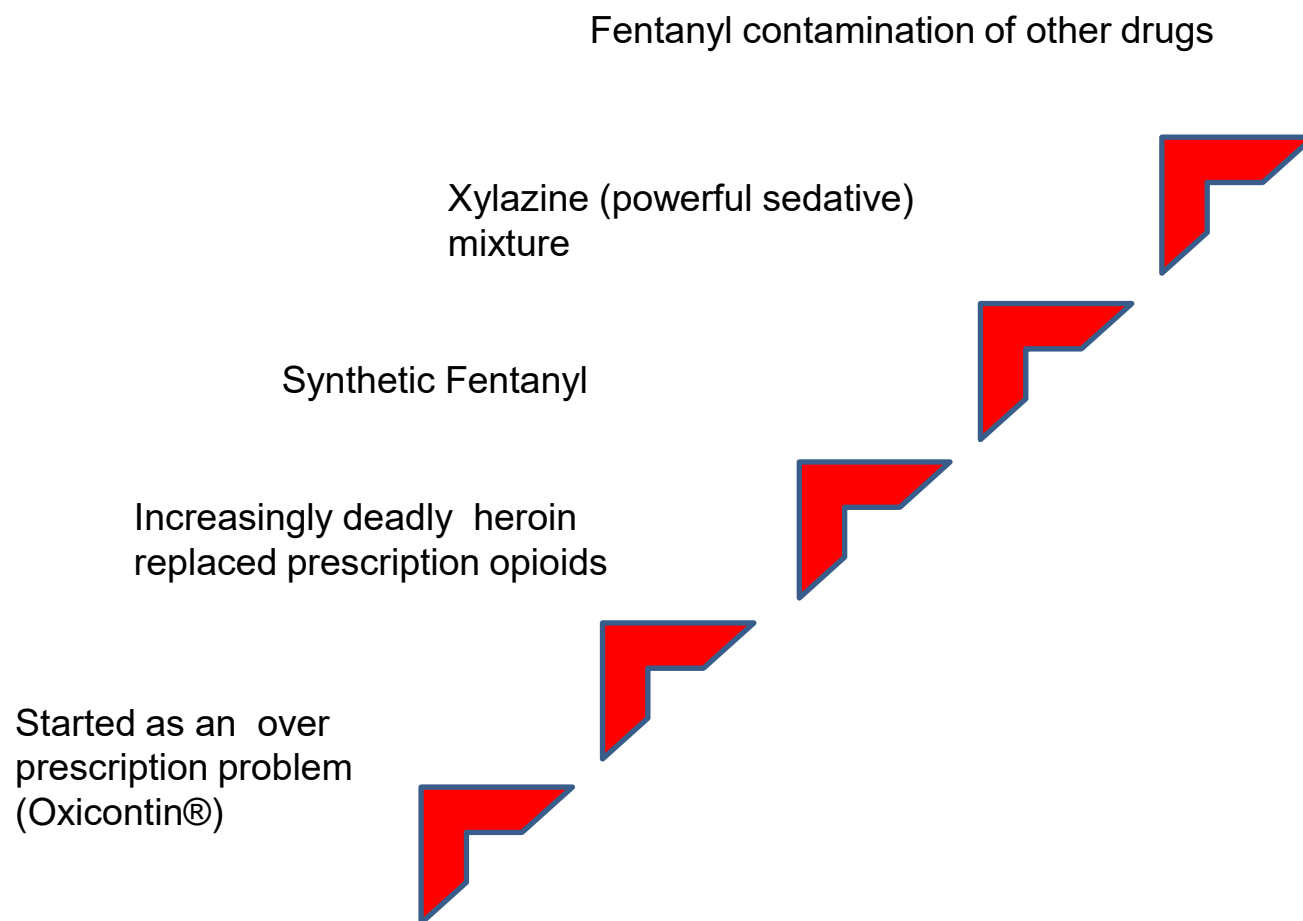
- Opioids  highest contribution to severe drug-related harm, including fatal overdoses.





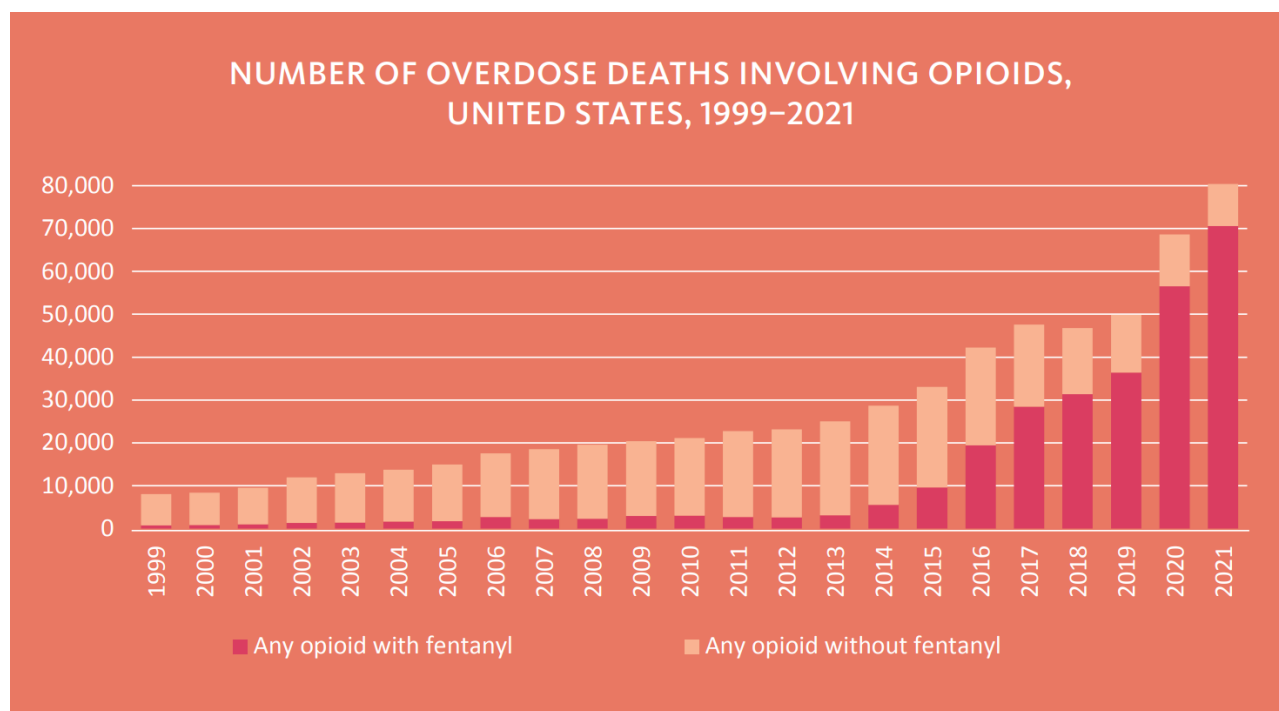
# Opioids epidemic in the USA

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# 107,000 Americans died from drug overdose in 2021



76% of overdose deaths involved opioids, UNODC WDR 2023



## Fentanyl - Facts

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- Fentanyl is a **synthetic opioid** used to treat severe pain usually following a surgery, major trauma, or for chronic pain by cancer
- Fentanyl is the **most potent opioid used for humans** in medical settings for its sedative and analgesic effects being **80 to 100 times more effective than morphine**
- Analogous types of fentanyl such as sulfentanil, alfentanil, and remifentanil have been approved over the years for pharmaceutical usage (UNODC, 2017).
- Alike other opioid drugs such as heroin, oxycodone, morphine, and codeine can result in **tolerance and dependence and cause addiction.**



# Inappropriate use of fentanyl and its role in the opioid crisis

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- Fentanyl under scrutiny since their conception by drug regulatory agencies for their **effectiveness in treating pain** and their **deadly and addictive side effects**.
- The **non-medical use of controlled substances** such as fentanyl has contributed to the **opioid crisis**.
- Recreational use of fentanyl had proven fatal through lethal dosage or change in way of administration.
- Consumers have been found to obtain prescription of fentanyl through **friends, prescribers, theft, multiple doctors and the internet**.
- Consumers also practice **unsafe preparations of fentanyl** by extracting the drug from a medication (e.g., transdermal patch) and convert it into other products (e.g., nasal spray) (UNODC, 2017).
- The lack of precise equipment to inject a safe dosage and quality control instruments lead to a highly potential lethal amount to be consumed.
- Production of **illicit fentanyl** and its distribution enhanced its dominance on the opioid crisis.
- The illegal drug market has been mixing fentanyl with other opioids such as heroin to increase its potency.



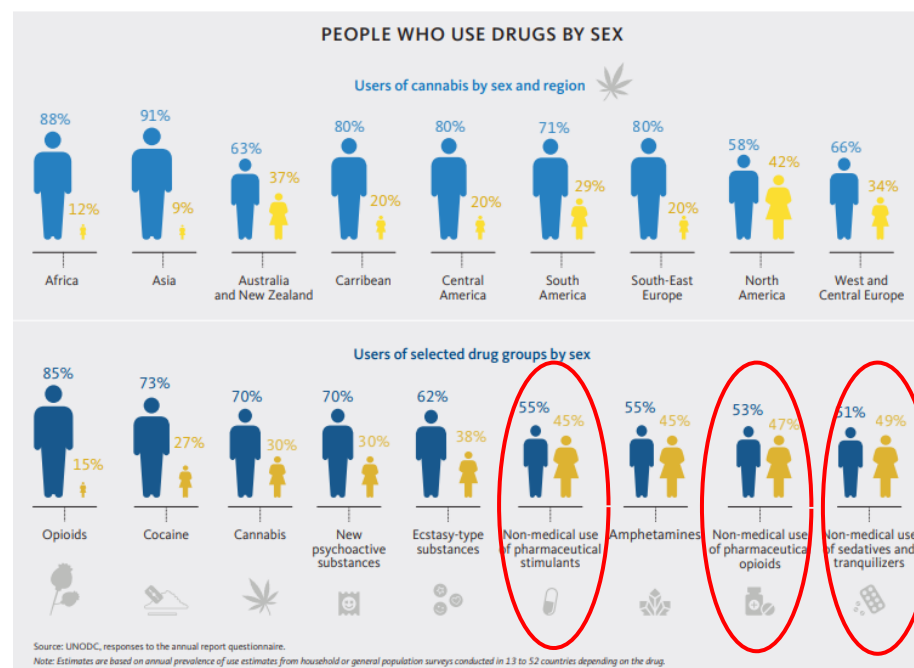


# Opioids crisis USA

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- Over 150 people die every day from overdoses related to synthetic opioids like fentanyl in the US
- DEA Laboratory Testing Reveals that **6 out of 10** Fentanyl-Laced Fake Prescription Pills Now Contain a Potentially Lethal Dose
- This is an increase from DEA's previous announcement in 2021 that four out of ten fentanyl-laced fake prescription pills were found to contain a potentially lethal dose.

Women approx. 30 per cent of all those who died from an overdose of and those attributed to opioids in the United States.



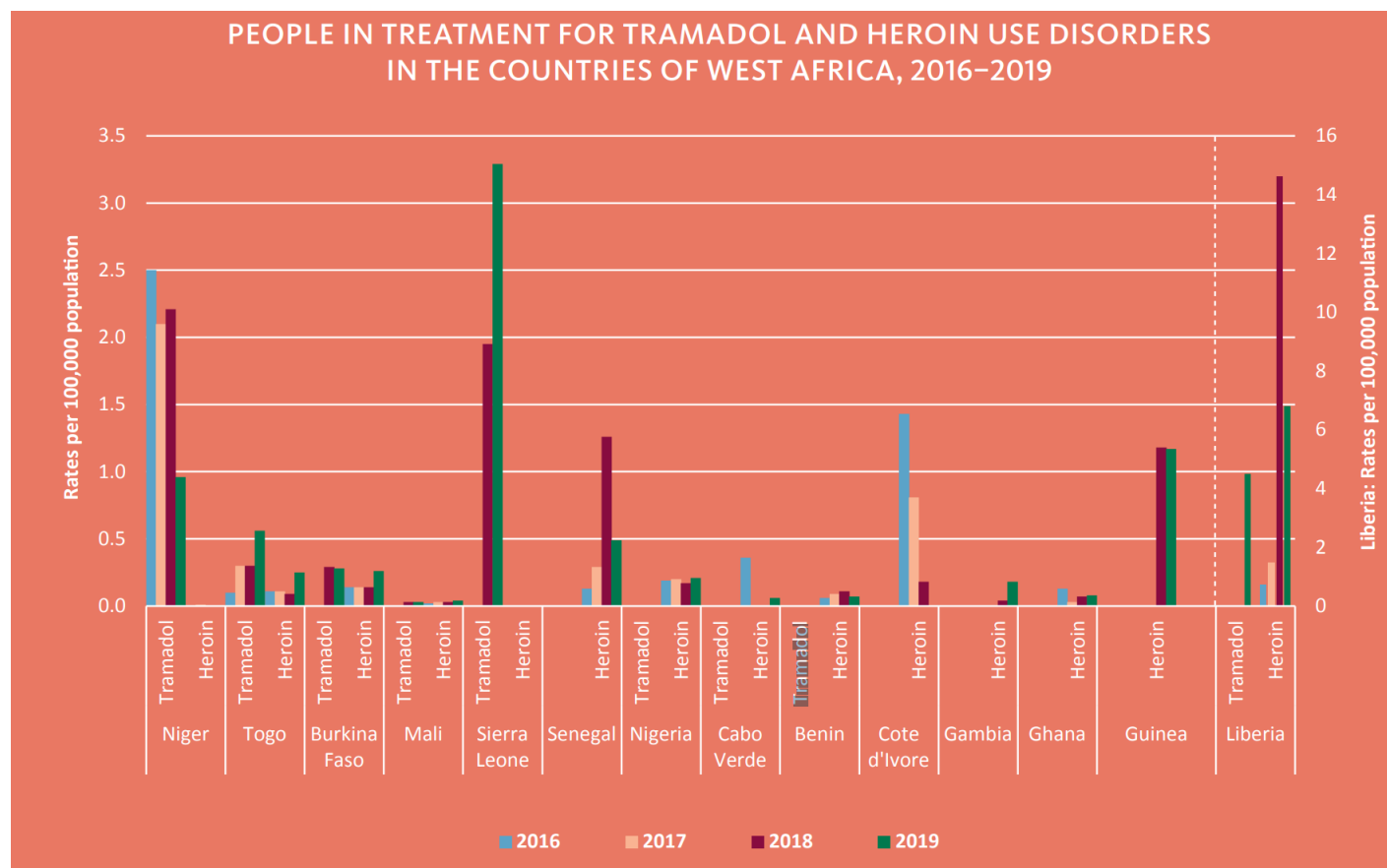
# Impact on Access and Availability

- The non-medical use, misuse and illicit manufacturing of fentanyl is rising, and regulations in place aim at reducing an epidemic that will inevitably result in more deaths due to overdose.
- These regulations have restricted access to the controlled drug to be used preferably in hospitals and for severe pain whereby other drugs are not effective.





## The other opioid crisis – the non-medical use of tramadol – affects countries in parts of Africa and Asia





# Availability of Illicit, Unregulated Opioids

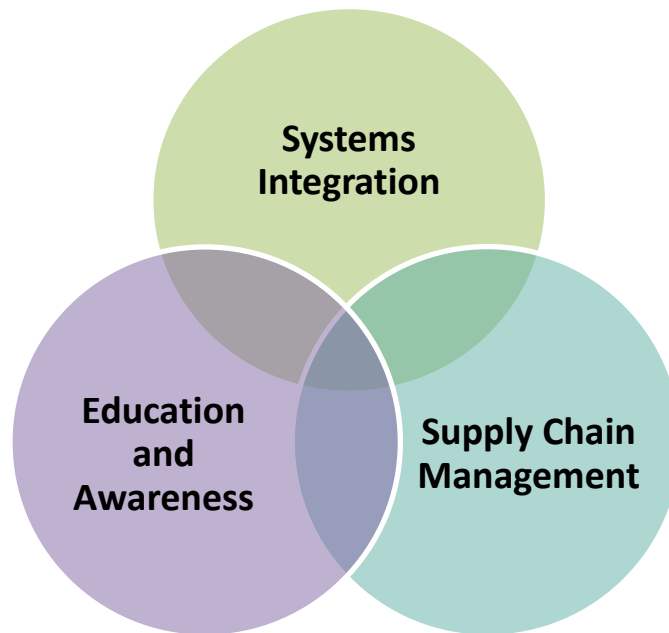
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- 1 and 6 per cent of the population have purchased medicines online ranges between
- Non-medical use of tramadol remains a concern, in West and Central Africa.
- In the first half of 2022, the National Drug Law Enforcement Agency of Nigeria and the Nigerian Customs Service reported several large seizures of tramadol in 2022, including:
  - 1.5 million tablets totaling 886 kg seized in March,
  - 9.1 million tablets totaling 1.3 tons seized in April,
  - 500,000 tablets totaling 407 kg seized in June,
  - 2.7 million tablets totaling 1.6 tons seized in July.
  - Burkina Faso and the Niger also reported seizures of several thousand tramadol tablets





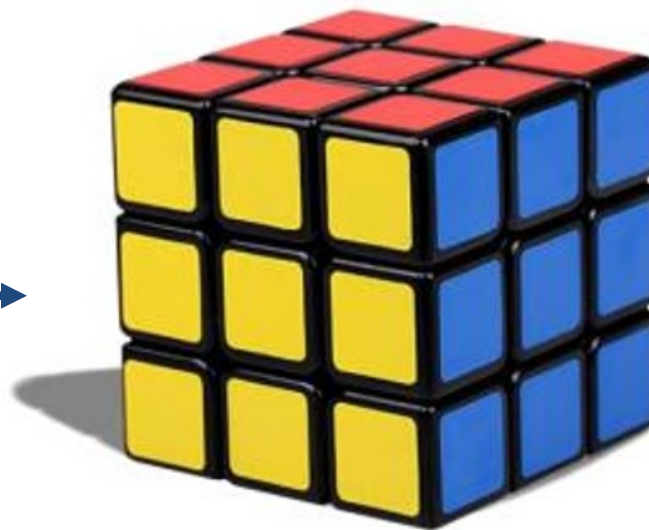
## 3 Core Areas





**UNODC**

United Nations Office on Drugs and Crime



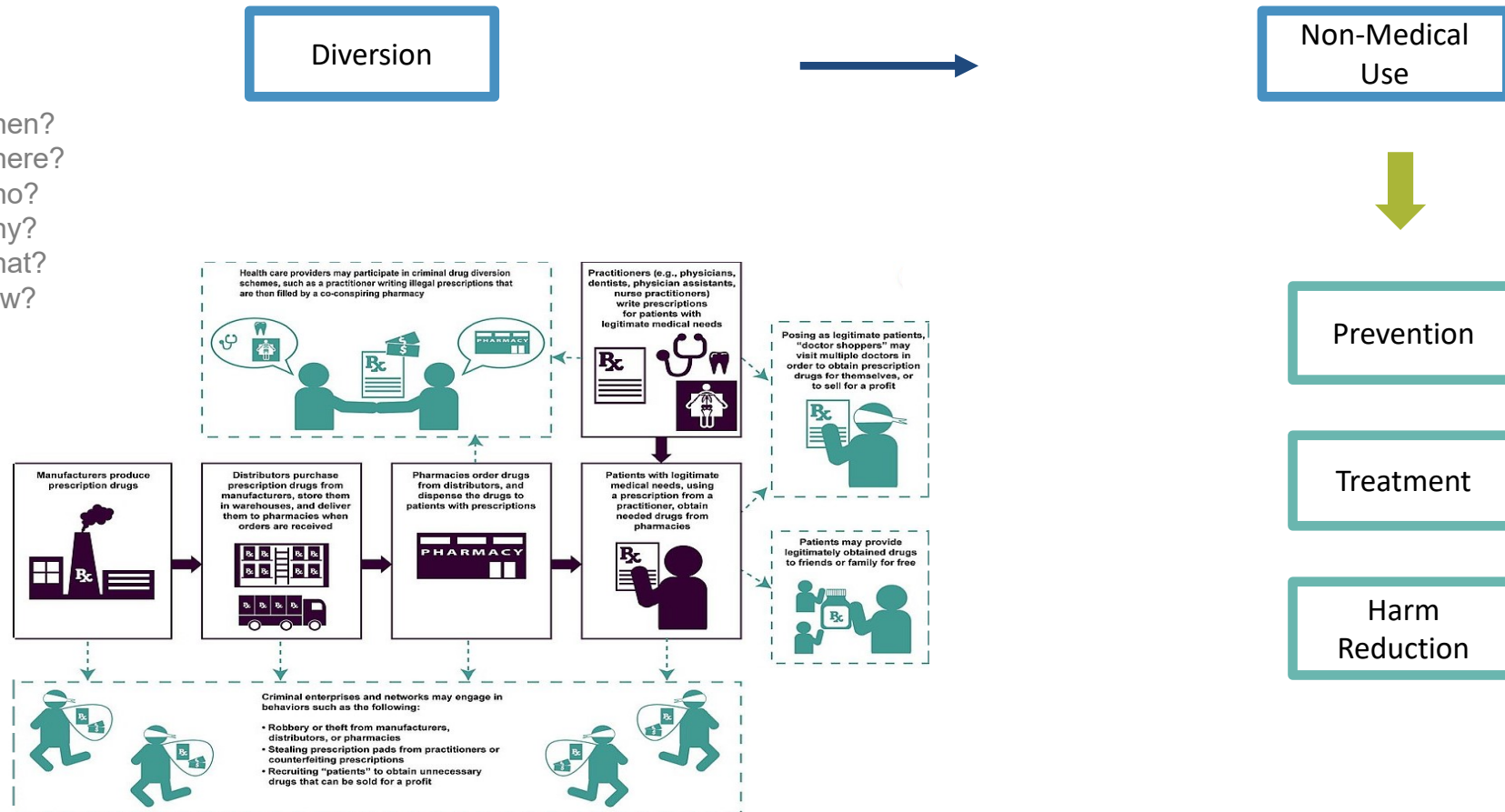


# Availability, Access, Diversion and Non-medical Use





When?  
Where?  
Who?  
Why?  
What?  
How?



Examples of the legitimate flow of prescription drugs  
Examples of where prescription drug diversion can occur

Sources: GAO (data); GAO and Art Explosion (clipart). | GAO-15-471





# Conclusion

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- The lack of access to controlled substances for medical and scientific purposes must be considered a major global crisis.
- Narcotic drugs like morphine are critical opioid analgesics for pain management and palliative care, while others help to treat mental health disorders and drug dependence.
- The Opioid crisis in the USA remains a challenge.
- The regulations aimed at reducing an epidemic have restricted access to the controlled medicines to be used preferably in hospitals
- Non-regulated opioids are an increasing challenge in some regions
- Addressing diversion, non-medical use and misuse is essential to ensure access and availability for people in need of controlled medicines





**UNODC**

United Nations Office on Drugs and Crime

# Thank you!



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@DrElisaenz

#NoPatientLeftBehind

[www.unodc.org](http://www.unodc.org)



# Access to morphine in MSF medical projects and humanitarian settings: a focus on systems barriers

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## «usual» access barriers are not as relevant for morphine

- **Unavailability:** health tools, even if badly needed, are not developed unless they can generate high profit for pharma corporations (tuberculosis, snakebites, Ebola)
- **Unaffordability:** high prices keep people from getting essential medicines, vaccines, and tests (hepatitis C, cancer, TB diagnostics)
- **Unsuitability:** medical tools are often not designed for the people we treat nor for the settings where we work (heat stable vaccines)



# humanitarian crises and essential medicines

- **Adapted formulations**
  - FDC
  - Dispersible tablets, granules, or pellets rather than syrups for paediatric formulations
  - Single dose treatments and long-acting formulations (PrEP and treatment)
  - Thermostable single doses formulations rather than cold-chain
  - Longer shelf-life
  - Breakable formulation
  - Ready to use preparations / self-administration
- **Improved safety profiles** in settings where pharmacovigilance and monitoring is challenging
  - Allowing distribution by lay staff (CHW-peers - counselors)
- **Larger field of approved indications for ATB**
  - broader use per medicine (early stage of emergency response)
- **Affordability and availability**
- **Importation mechanisms that reduce lead time**



# MSF's provision of morphine

- Palliative care projects, and working with Ministries of Health
- morphine, fentanyl, oxycodone, tramadol: MSF Pain Mgt GLs are dependent on what can we get access to / availability
- MSF Procurement Policy:
  - QA sourcing at a central (EU) level or
  - local procurement in countries into which importation is not possible, noting challenges to procure in some local markets
- Importation into countries (when allowed / dealing with import restrictions); export from our EU Supply Centres
- Working within the international rules and regulations of WHO and INCB, including the Model GLs for the International Provision of Controlled Medicines for Emergency Medical Care (WHO Model Guidelines)
- When MSF gets access, it is taken from the total estimated quota, reducing even more what is available for the public sector



# systems challenges experienced by MSF

- Import permits:
  - format and requirements not standardized or harmonized esp during non emergency
  - numerous differences across countries and health authorities
  - validity period varies and may not match the timeline for the issuance of export permit
  - some countries do not allow importation of controlled medicines at all
- Not all countries use the same conversion factors, causing discrepancies with calculations
- WHO Model Guidelines for emergency supply are not universally known or implementable at country level
- Even if countries submit supplementary estimates above the original INCB quantities, export may be blocked



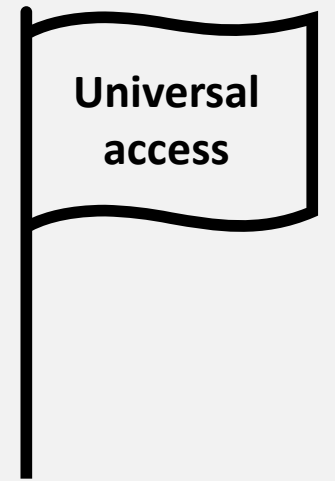
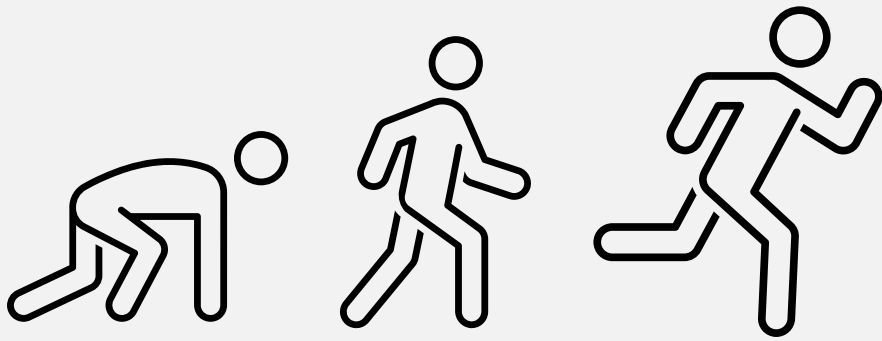




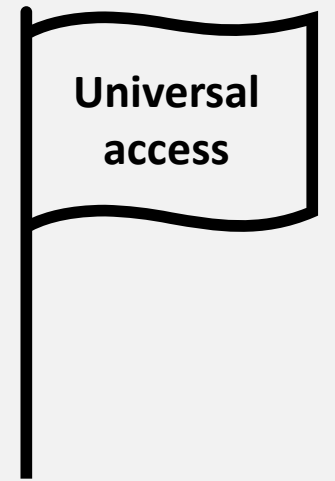
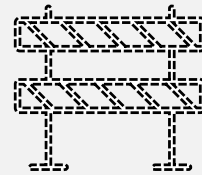
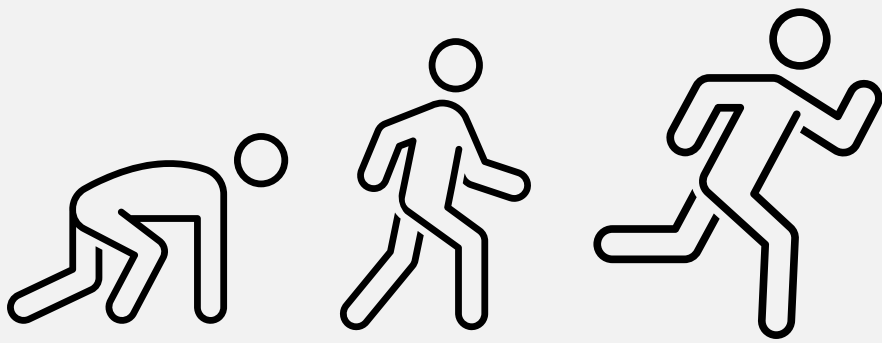
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# Panel discussion

Based on the mandates of your organization, what should be the priorities to **fast-track progress** so that no one with medical need would be left behind in pain?



From your organizational perspective, what are the **challenges and opportunities to operationalize** these priorities to improve safe access?



What are the **projects** being undertaken to improve safe access to morphine and other strong opioids?



2016- 2030



- **3.8** Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all

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# Q&A with the audience



# Thank You

## What can be done to improve safe access to medical morphine?

Lessons from countries

14 September 2023

**1700 to 1830 (Geneva time)**

