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SAFE AND BALANCED ACCESS TO OPIOIDS FOR MEDICAL USES: GUIDANCE FROM DISEASE CONTROL PRIORITIES 3RD ED., THE LANCET COMMISSION ON PALLIATIVE CARE, WHO

Safe and Balanced Access to Opioids for Medical Uses:

Guidance from Disease Control Priorities 3rd Ed., the Lancet Commission on Palliative Care, WHO

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Disclosures

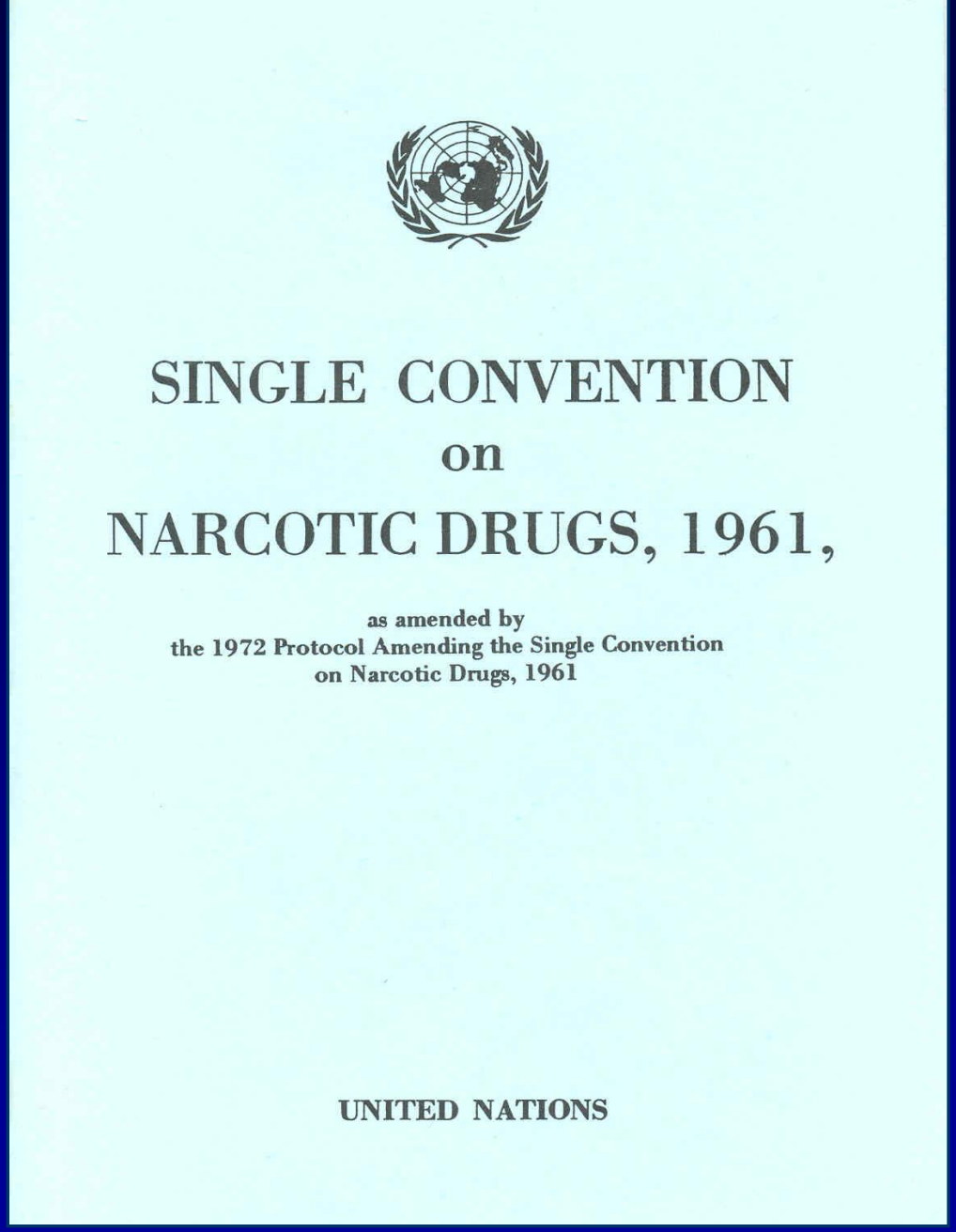
- None

At the end of this presentation, participants will be able:

1. To discuss the global agreement that access to opioids and other controlled medicines for medical uses is imperative.
2. To describe the principle of BALANCE in opioid policy.
3. To discuss guidance on maximizing access to opioids for palliative care while minimizing the risks of addiction and diversion, from:
   - WHO
   - Lancet Commission on Palliative Care
   - Disease Control Priorities, 3rd Edition

1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol:

- Signed by almost all countries (including USSR)
- "The medical use of narcotic drugs continues to be indispensible for the relief of pain and suffering and … adequate provision must be made to ensure the availability of narcotic drugs for such purposes."
- Emphasizes **BALANCE** in national opioid policies:
  - **Maximize availability of opioids for medical uses**
  - **Minimize risk of abuse, diversion, trafficking**



Balance:

1. Prevent abuse and diversion, *and*
2. Ensure the availability of drugs for medical purposes

Ensuring **Balance** in National Policies on Controlled Substances: Guidance for Availability & Accessibility of Controlled Medicines (WHO 2011) …

- "There is broad consensus that opioid analgesics are indispensable for the treatment of moderate to severe pain and some, like methadone and buprenorphine, are increasingly used for the treatment of drug dependence."
- "The central principle of "balance" represents a dual obligation of governments based on legal, political, public health and moral grounds to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking."

http://apps.who.int/iris/bitstream/10665/44519/1/9789241564175_eng.pdf

… Ensuring Balance in National Policies on Controlled Substances (WHO 2011)

- **Guideline 2:** Governments should comply with their international legal obligations to **ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes** through national legislation and drug control policies.
- **Guideline 4:** Governments should ensure that all authorities involved in developing and implementing policies on controlled substances cooperate and meet as necessary for **promotion of their availability and accessibility for medical and scientific purposes** as well as the **prevention of abuse, dependence syndrome and diversion**.
- **Guideline 11:** **Appropriately trained and qualified physicians**, and, if applicable, nurses and other health professionals, at all levels of health care **should be allowed to prescribe and administer controlled medicines**, based on their general professional license, current medical knowledge and good practice **without any further license requirements**.

Other UN Authorities that Assert Imperative of Opioid Accessibility for Medical Purposes

- UN Special Rapporteur on Torture, Cruel, Inhuman, and Degrading Treatment and Punishment: Report to the UN Human Rights Council (2009):

  "Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care."

- International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12, Comment 14 (2000):

  There is a right to "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity."

So, how accessible is morphine or other opioids for treatment of pain in low and middle income countries (LMICs)?

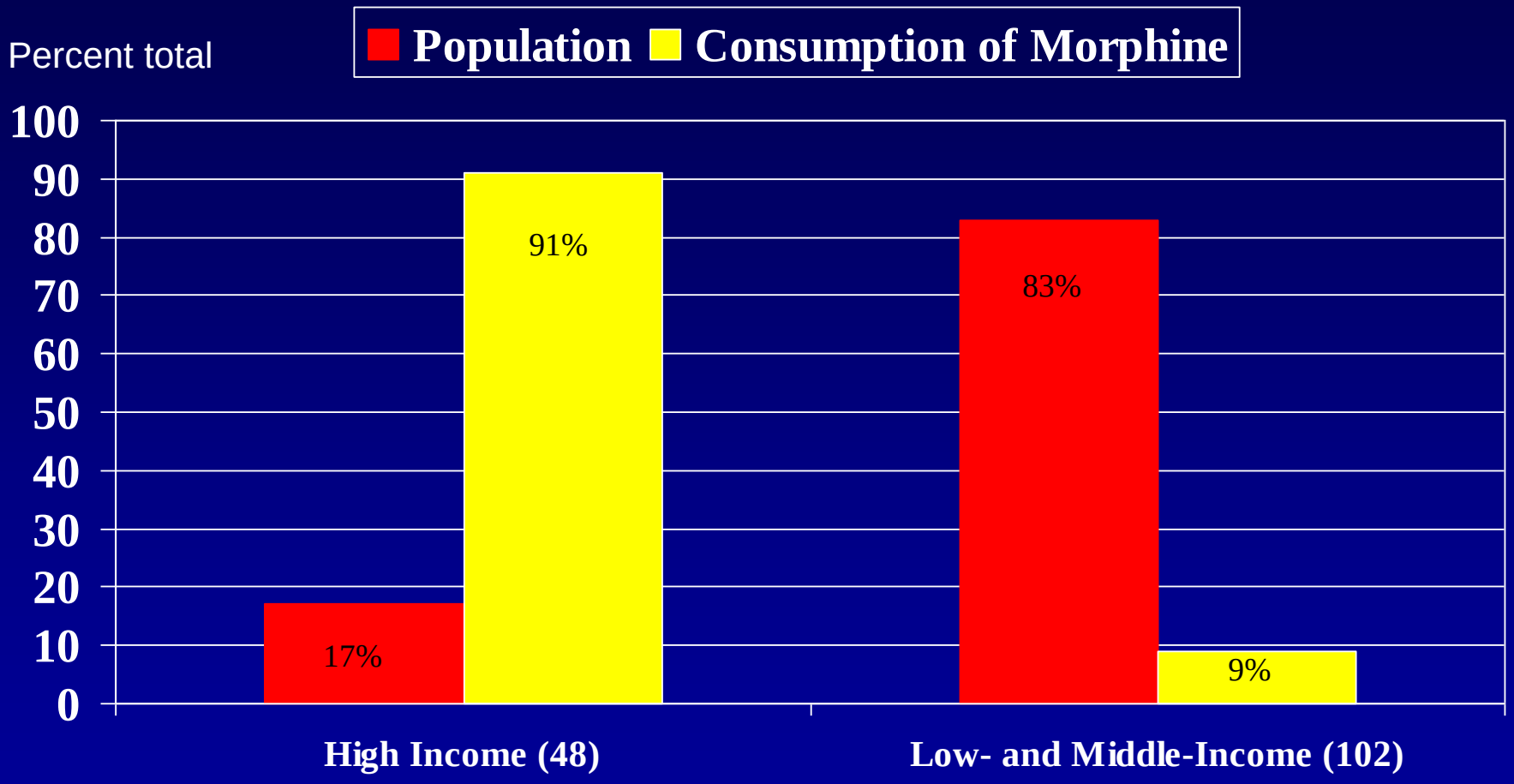
WHO 2011: "The health benefits that can be derived from medicines containing controlled substances remain inaccessible to the large majority of people around the world."

Patients in Low and Middle Income Countries (LMICs) Rarely Have Access to Pain Relief & Palliative Care

- 83% of world's 7 billion people in LMICs (~5.8 billion)
- 5.5 million terminal cancer patients per year in LMICs
- Millions with other serious chronic illnesses (cardiovascular disease, liver or renal failure, lung disease, AIDS, etc.)
- Yet only 9% of world's morphine consumed in LMICs

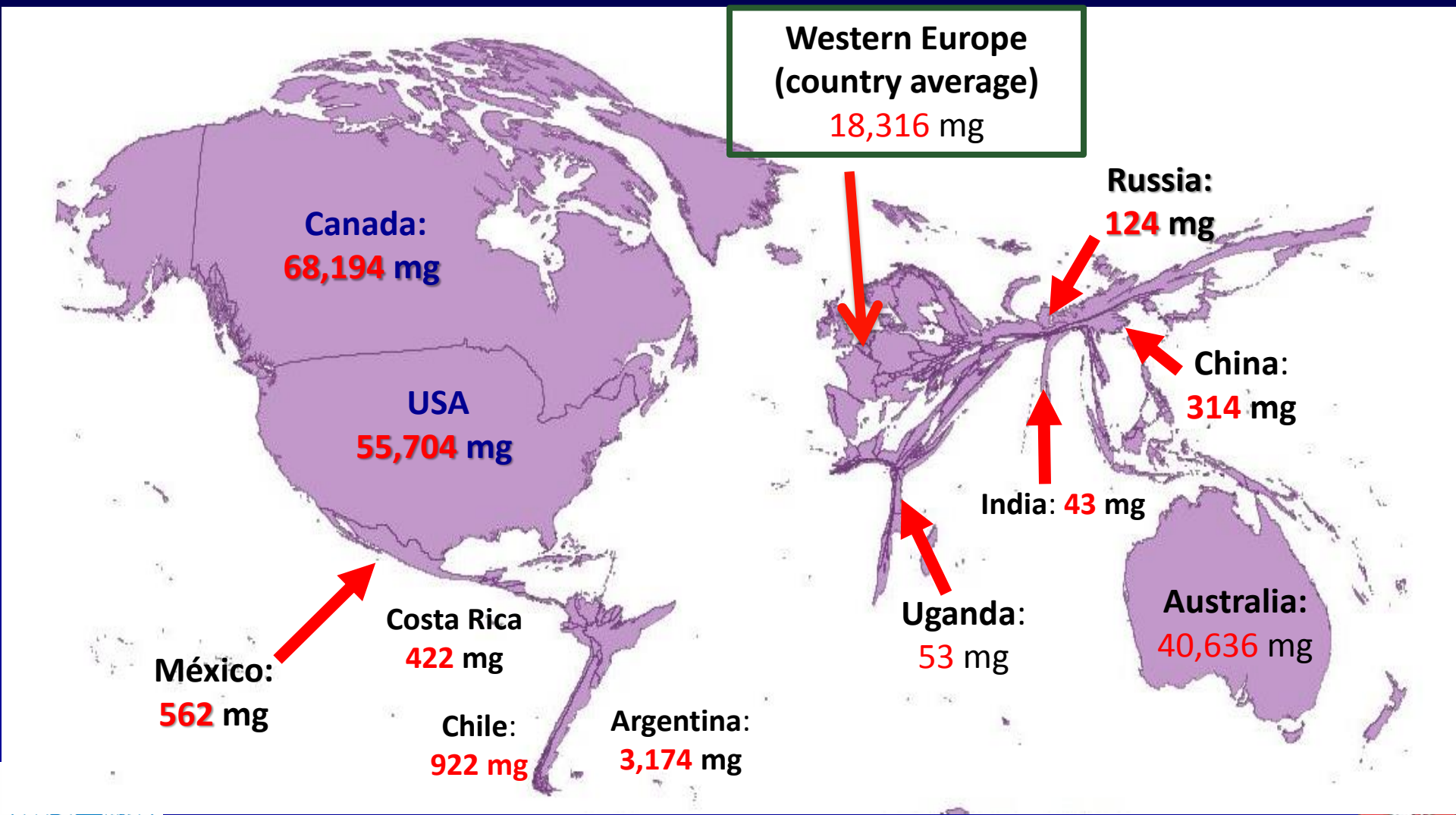
Global Consumption of Morphine

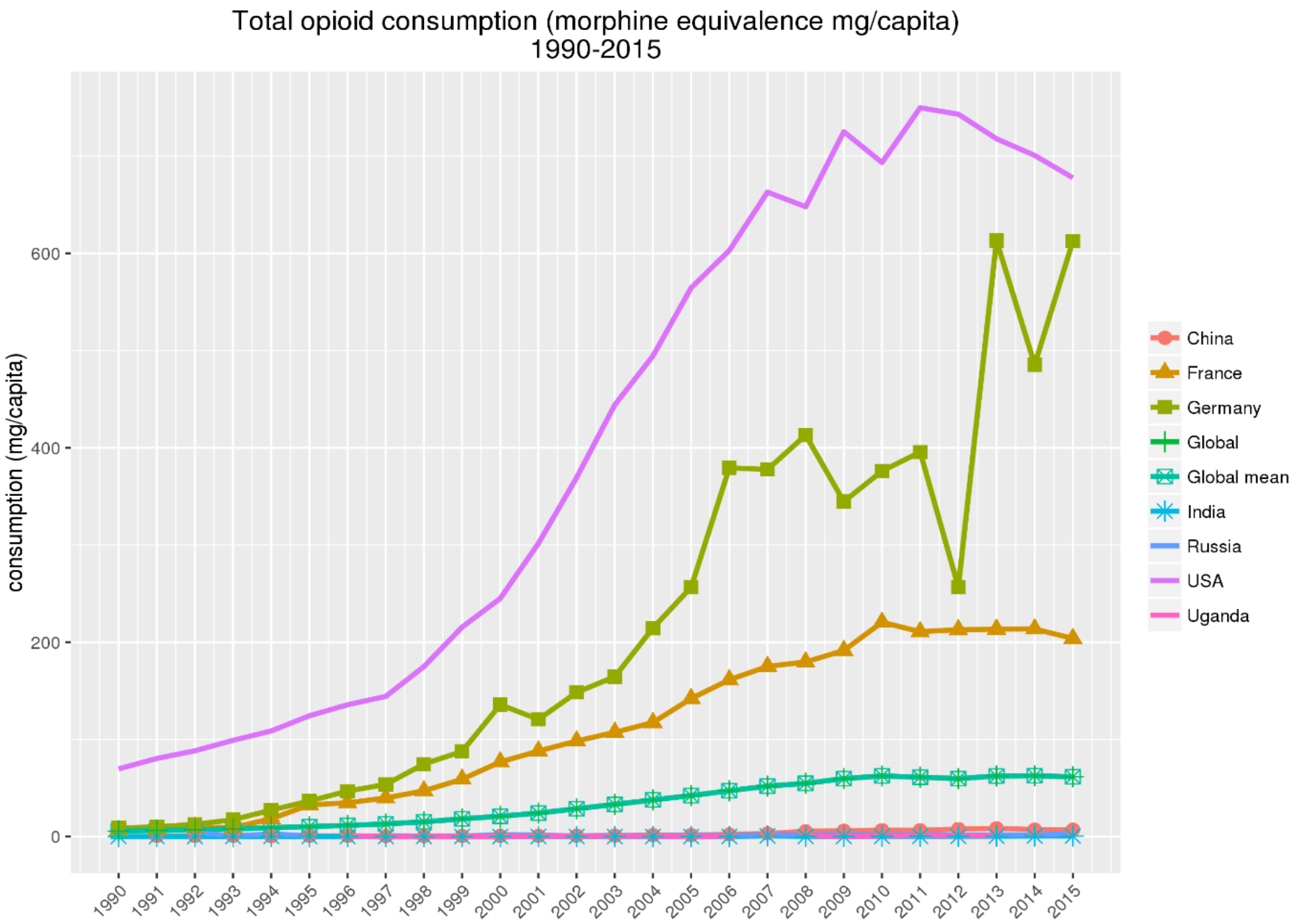
High-Income vs. Low/Middle-Income Countries, 2013



Source: International Narcotics Control Board; United Nations Population Data, 2013; World Bank Income Classification, 2013.
By: Pain & Policy Studies Group, University of Wisconsin /WHO Collaborating Center, 2015.

Morphine in mg per patient with "serious health-related suffering"





Sources: International Narcotics Control Board; World Health Organization population data

By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2017

“Opiophobia”: Needless fear of opioids

- Among political and healthcare leaders:
  - Highly restrictive laws and regulations on opioids
    - Requirements for licensing or permission to prescribe
    - Complicated prescribing forms and authorizations
    - Restrictive rules for pharmacies
  - Explicit or implicit threats of punishment or arrest against clinicians for prescribing opioids.
  - Training in opioid analgesia not provided in medical, nursing, and pharmacy schools
- Among clinicians:
  - Doctors do not prescribe opioids, nurses to not give them, and pharmacists do not stock or dispense them.
- Among patients and their families
  - Pain not reported: no expectation that relief is possible
  - Opioid therapy declined due to fear

Opioid prescribing: theoretically possible, practically impossible!

Consequences of Opiophobia

- Vicious circle:
  - Low opioid consumption in hospitals and in a country
  - Low estimates of opioid need reported to **International Narcotics Control Board** (INCB)
  - Little opioid allocated to that country
  - Little opioid produced or imported
  - Low opioid consumption

Victims of opiophobia: The indigent sick

Admiral Vyacheslav Apanasenko

Admiral Apanasenko was 66 years old and suffered from end-stage pancreatic cancer that caused severe pain. Unable to obtain opioid pain medicine, he shot himself to death in Moscow in February 2014.

The Moscow Times - Feb 12, 2014:

"Suicide of Terminally Ill Admiral Prompts Health Ministry Probe"

The Moscow Times - Sep 8, 2016:

"Russia's Cancer Patients: Dying for Pain Relief"

"Terminally ill patients in Russia struggle for adequate pain treatment, and sometimes resort to extreme action"

World Health Organization (WHO) and palliative care leaders' responses to the global disparity in safe access to opioid analgesics

World Health Assembly Resolution 67.19 from 2014:

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

What does Resolution 67.19 say …

1) Access to PC and to **essential medicines including opioid analgesics** "contributes to the realization of the (human) right to the enjoyment of the highest attainable standard of health and well-being."
2) PC "is **an ethical responsibility of health systems**."
3) " … it is the **ethical duty of health care professionals to alleviate pain and suffering**, whether physical, psychosocial or spiritual, irrespective of whether the disease or condition can be cured …"
4) It is especially important to integrate PC into **primary care**.

… What does Resolution 67.19 say?

7) Efforts to minimize risk of diversion of controlled medicines for illicit purposes **must "not result in inappropriate regulatory barriers to medical access to such medicines**."
8) "… **adequate training** [in PC is needed] for all hospital- and community-based health care providers and other caregivers, including NGO workers and family members."
9) **Adequate funding** for PC is necessary, especially in developing countries.

WHA urges members states: …

1) "to ensure adequate domestic funding and allocation of human resources, as appropriate, for palliative care initiatives, including … supporting the availability and appropriate use of **essential medicines**, including **controlled medicines for symptom management**;"
2) To require:
   - **Basic** training in PC for all medical and nursing students;
   - **Intermediate** training in PC for "all health care workers who routinely work with patients with life-threatening illnesses;"
3) To make available **specialist palliative care training**.

… WHA urges members states:

4) "to **assess** domestic palliative care needs, including **pain management medication requirements**, and … **ensure adequate supply** of essential medicines in palliative care, avoiding shortages;
5) "**to review and, where appropriate, revise national and local legislation and policies for controlled medicines**, with reference to WHO policy guidance, on **improving access to and rational use of pain management medicines**, in line with the United Nations international drug control conventions;"
6) "to update, as appropriate, national essential medicines lists in the light of the recent addition of **sections on pain and palliative care medicines to the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children**;"

WHA requests the Director-General:

1) “to explore ways to increase the availability and accessibility of medicines used in palliative care through consultation with Member States and relevant networks and civil society, as well as other international stakeholders, as appropriate;”
2) “to work with the INCB, the UNODC, health ministries and other relevant authorities in order to promote the availability and balanced control of controlled medicines for pain and symptom management;”
3) “to further cooperate with the INCB Board to support Member States in establishing accurate estimates in order to enable the availability of medicines for pain relief and palliative care … “

How is WHO implementing Resolution 67.19 …

- WHO Cancer Pain Relief Guidelines (revision 2018)
- WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses (2012)
- PC planning and implementation guides:
  1. Planning and implementing palliative care services: a guide for programme managers (2016) http://apps.who.int/iris/bitstream/10665/250584/1/9789241565417-eng.pdf
  2. PC in primary care (2018)
  3. PC for children (2018)
  4. PC in humanitarian emergencies & crises (2018)
- On-line “Community of Practice in PC”
  Contact Isabelle Huguet: hugueti@who.int)
- Mobile PC project

… How is WHO implementing Resolution 67.19

- Palliative Care NGOs in Official Relations with WHO:
  - International Association for Hospice & Palliative Care (IAHPC)
  - Pain & Policy Studies Group, University of Wisconsin

Chapter on “Palliative Care & Pain Control” based on Report of the Lancet Commission on Palliative Care & Pain Relief

http://www.thelancet.com/commissions/palliative-care

Lancet Commission on Palliative Care* / Disease Control Priorities, 3rd Edition (DCP3)

- Estimated global burden of health-related suffering:
  - Identified the serious conditions in the *International Classification of Diseases* (ICD)-10 that most commonly result in physical, psychological, or social, or spiritual suffering.
  - Then estimated the types, prevalence, and duration of suffering resulting from each condition.
- Based on these estimates, designed Essential Package of PC (EP) to alleviate most health-related suffering:
  - Interventions
  - Medicines
  - Equipment
  - Social supports
  - Human resources

*Knaul FM, Farmer PE, Krakauer EL, et al. Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage. Lancet 2017. Available at: http://dx.doi.org/10.1016/S0140-6736(17)32513-8

DCP3

- Morphine, in oral fast-release and injectable preparations, [should] be accessible by prescription by any patient with terminal dyspnea or with moderate or severe pain that is either acute, chronic and associated with malignancy, or chronic in a patient with a terminal prognosis.
- We do not recommend the use of opioids for chronic pain outside of cancer, palliative, and end-of-life care, except in special circumstances.
- All physicians who care for patients with moderate or severe pain of these types, or for patients with terminal dyspnea, should be able to prescribe oral and injectable morphine for inpatients and outpatients in any dose necessary to provide adequate relief.
- Physicians should be able to prescribe an adequate supply of morphine so that obtaining refills is feasible for patients or families without requiring unreasonably frequent, expensive, or arduous travel.
- It is necessary to take reasonable precautions to prevent diversion and nonmedical use [of morphine].

Essential Package of PC: **Medicines**

- Based on WHO's Model Lists of Essential Medicines for Palliative Care for adult and children and adapted for this document. Medicines were selected based on the following criteria:
  - Necessary to prevent or relieve the specific symptoms or types of suffering most commonly associated with serious, complex of life-limiting health problems.
  - Safe prescription or administration requires a level of professional competency achievable by doctors, clinical officers, assistant doctors, or nurse anesthetists with basic training in palliative care.
  - Offer the best balance in their class of accessibility on the world market, clinical effectiveness, safety, ease of use, and low cost.

Essential medicines for palliative care

Amitriptyline, oral
Bisacodyl (Senna), oral
Dexamethasone, oral and injectable
Diazepam, oral and injectable
Diphenhydramine (chlorpheniramine or dimenhydrinate) oral & injectable
Fluconazole, oral
Fluoxetine (sertraline and citalopram), oral
Furosemide, oral and injectable
Hyoscine butylbromide, oral and injectable
Haloperidol, oral and injectable
Ibuprofen (naproxen, diclofenac, or meloxicam), oral
Lactulose (sorbitol or polyethylene glycol), oral
Loperamide, oral
Metaclopramide, oral and injectable
Metronidazole, oral – to be crushed for topical use
Morphine, oral immediate release and injectable
Naloxone, injectable
Omeprazole oral
Ondansetron, oral and injectable (Only at hospitals that provide cancer chemotherapy or radiotherapy)
Oxygen
Paracetamol, oral
Petroleum jelly

Essential Package of PC: **Equipment**

- Necessary for relief of at least one type of physical or psychological suffering.
- Inexpensive
- Simple to use with basic training
- Small enough to ship and store easily.

Essential medical equipment for palliative care
Pressure Reducing Mattress
Nasogastric drainage & feeding tube
Urinary catheters
Opioid lock box, only for hospitals & clinics
Flashlight with rechargeable battery (if no access to electricity)
Adult diapers/ Cotton and plastic

Efforts to control illicit, non-medical use of opioids should include:

- Supply chain security
- Harm reduction
- Evidence-based treatment of opioid use disorder (a mental illness)

Efforts to control illicit, non-medical use of opioids should NOT interfere with efforts to assure access to opioids for medical uses:

- Treatment of pain
- Treatment of opioid use disorder

African Palliative Care Association

Guidelines for Ensuring Patient Access to, and Safe Management of, Controlled Medicines

Detailed guidelines on secure handling of controlled medicines from manufacture or importation to the patient in the hospital or at home.

Editors: Joranson D, Maurer M, Mwangi-Powell, F.

http://integratepc.org/wp-content/uploads/2013/05/patient_access1.pdf

DCP3: Opioid Access at Each Level of Healthcare Systems …

- **2nd & 3rd Level (Referral) Hospitals**
  - All doctors who care for patients with moderate or severe pain or terminal dyspnea should have at least basic training in pc and should be able to prescribe opioids for inpatients and outpatients.
  - Inpatient and outpatient pharmacies should have all essential palliative medicines including oral morphine.
- **1st Level (District) Hospitals**
  - All doctors at district hospitals who care for patients with moderate or severe pain or terminal dyspnea should have at least basic training in pc and should be able to prescribe opioids for inpatients and outpatients.
  - Hospital pharmacies should have all essential palliative medicines including oral morphine.
  - At least one outpatient pharmacy in each district should dispense oral morphine by prescription.

… DCP3: Opioid Access at Each Level of Healthcare Systems

- **Community Health Centers:**
  - If staffed by one or more doctors, clinical officers, or assistant doctors, at least one should have at least basic training in pc and should be able to prescribe opioids for outpatients.
  - In some settings, specially trained nurses may prescribe opioids.
  - In general, pharmacy should stock oral and injectable morphine (unless high risk of theft or violence).
- **Home care:**
  - Community health workers (CHWs), if available, can be trained to recognize and report:
    - Inadequately controlled pain
    - Improper use of opioids
  - Home visits by doctor or nurse from community health center as needed for assessment and adjustment of opioid regimen.

Uganda: Liquid morphine brought to cancer patient at home by palliative care team nurse.