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

Lessons from countries

14 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



World Health
Organization



HEALTH
FOR ALL

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

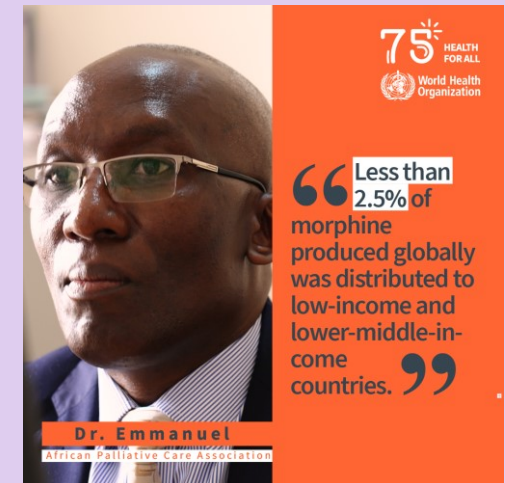
To share three stories from people impacted by access to morphine



<https://www.youtube.com/watch?v=h3klGKSnBq4>



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



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

Today's session



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Former Chair, The Lancet Commission on Palliative Care and Pain Relief

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Presentations

Access to Opioids: The India Story

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Background

India: Poppy growing country

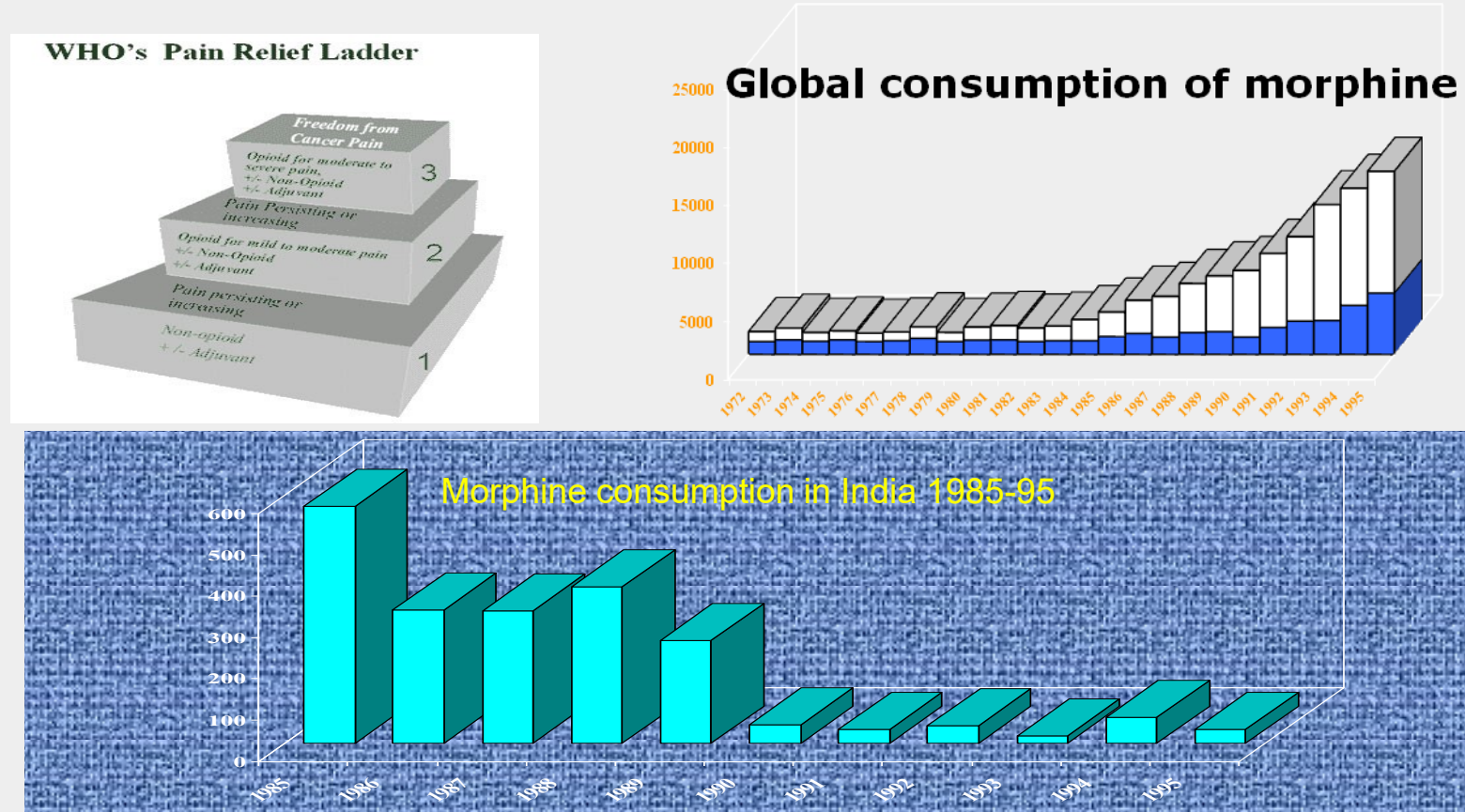
Prior to 1985:

Morphine consumption

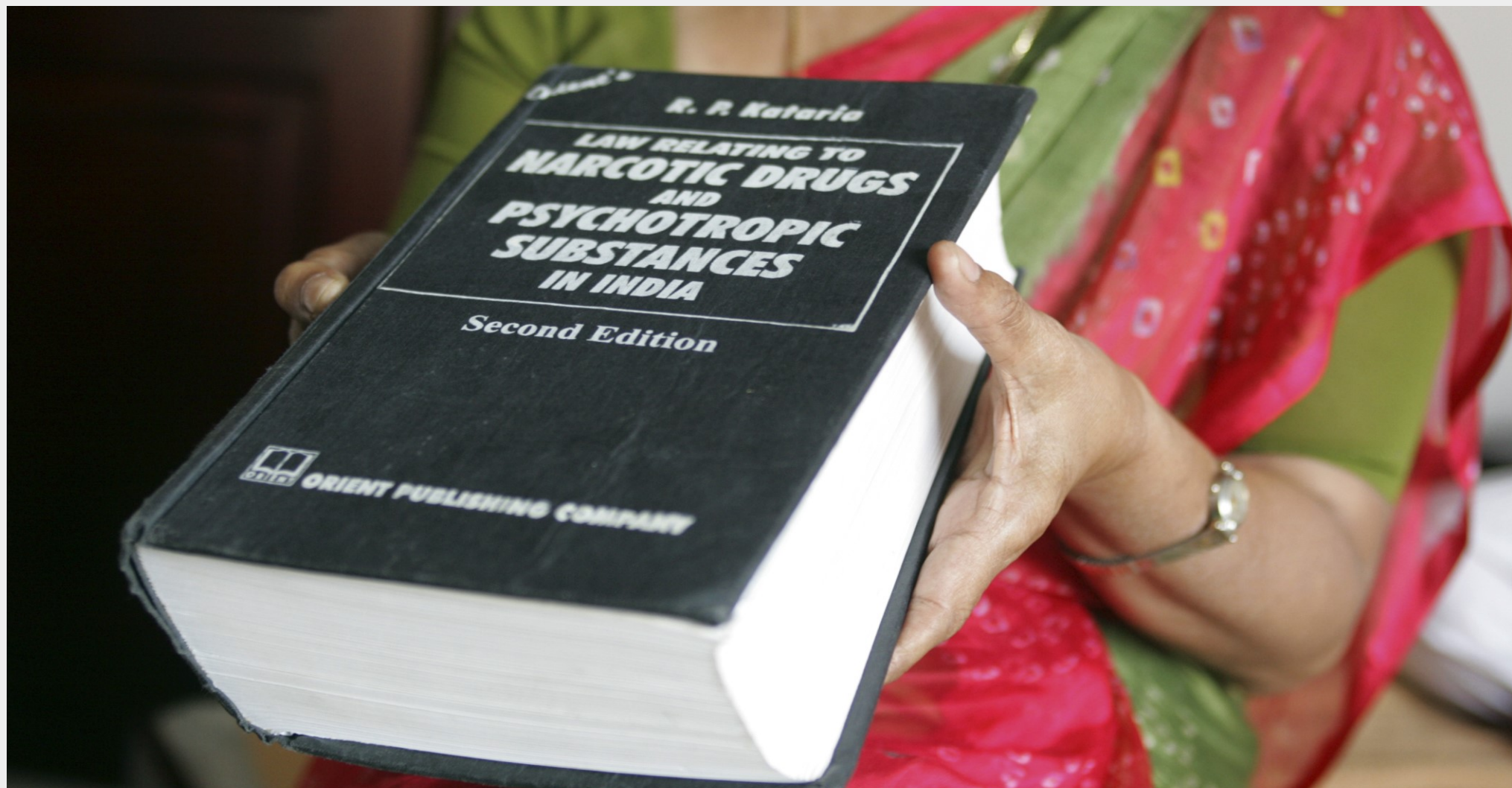
>600 kg, mostly for acute pain



Two opposing forces



1985: The Draconian Narcotic Drugs &
Psychotropic Substances (NDPS) Act



1985: Narcotic Drugs & Psychotropic Substances Act

- Different states - different rules for possession, import, export (across states)
- 3-4 licenses from different departments
- Stringent punishment even for possible clerical errors

THE RESULT:

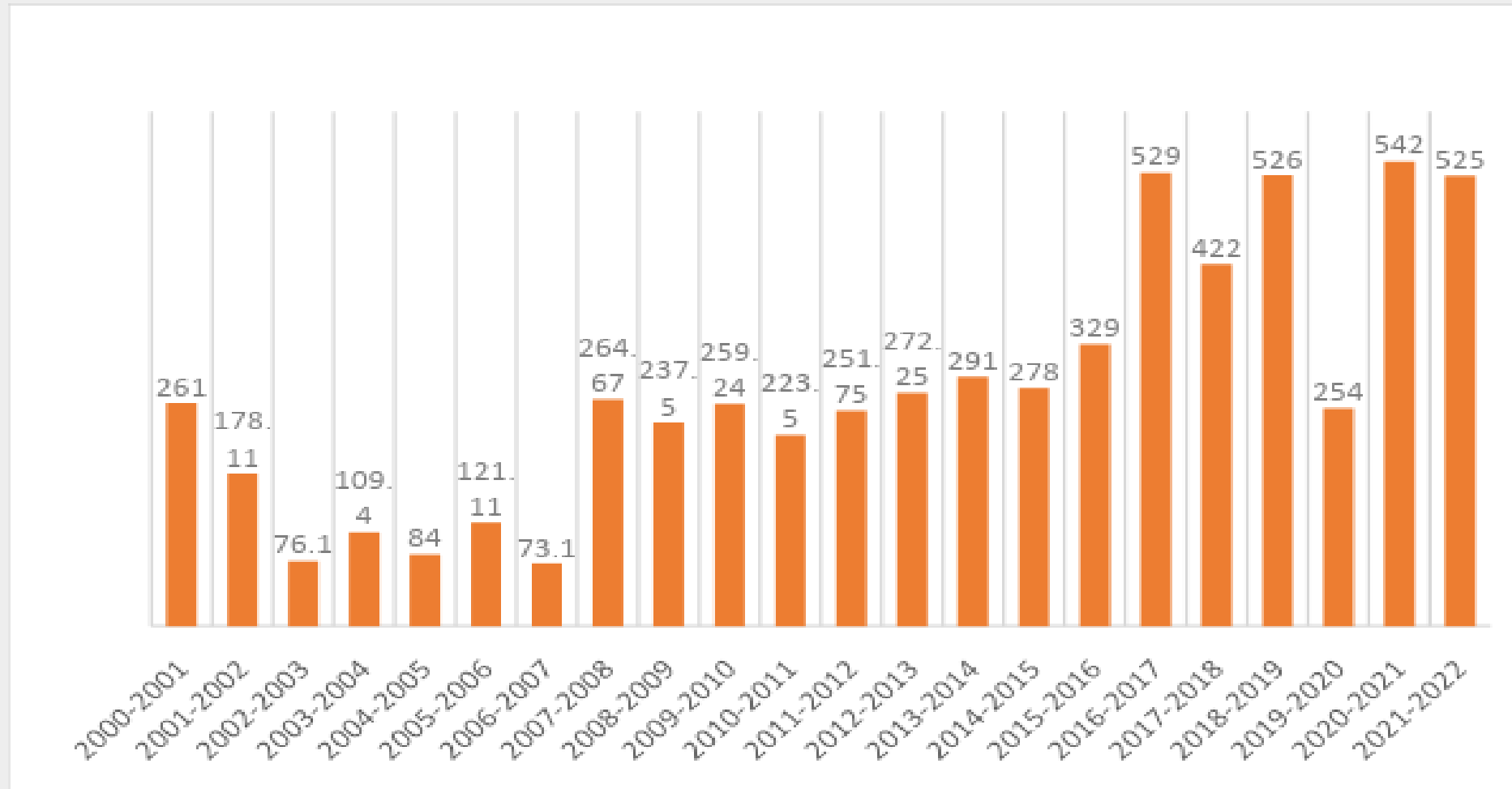
Steep drop in consumption



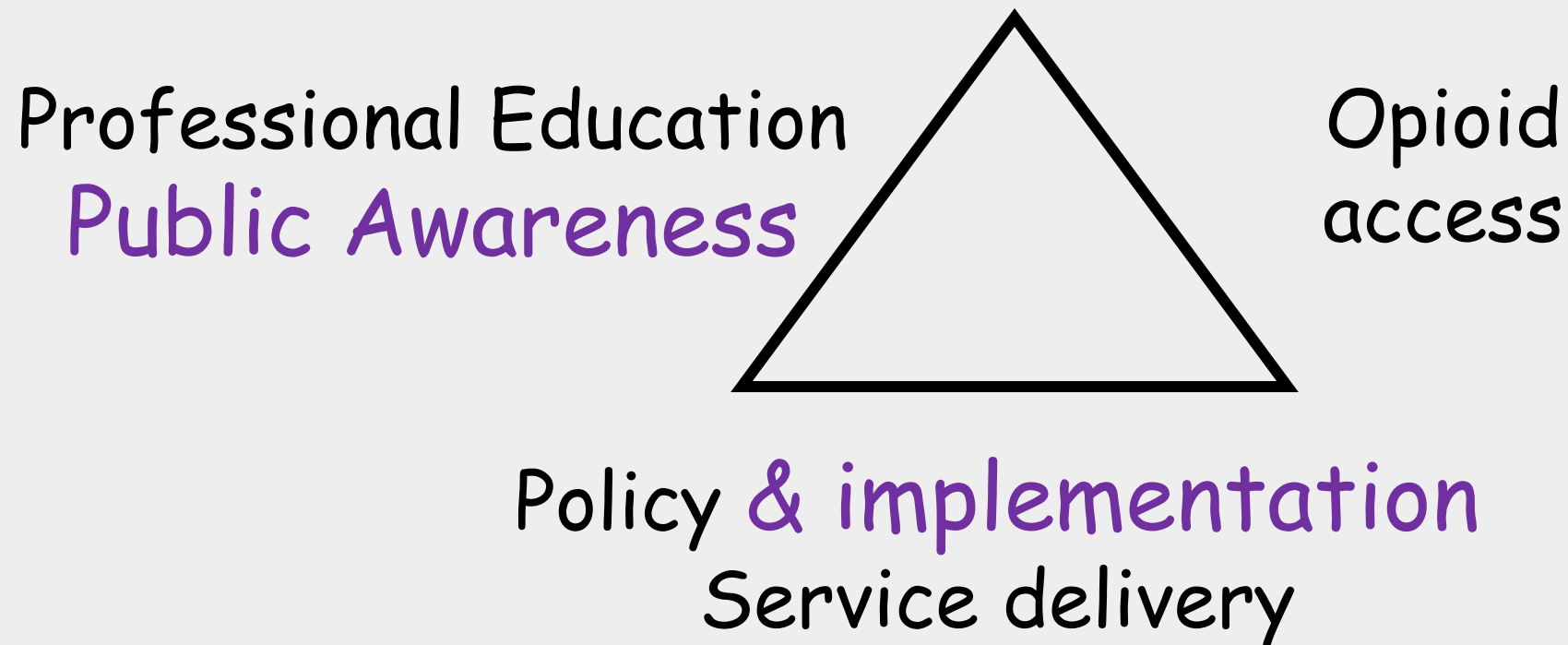
Civil Society Efforts for Opioid Access, 1995 onwards:

- Advocacy with Government of India with international support:
 - WHOCC at Madison Wisconsin
 - Human Rights Watch
- Public interest litigation in Delhi High Court by Mr Ghooi (son of patient) -1997
- Advocacy with 18 state governments
- Public interest litigation in Supreme Court of India, 2008
- Advocacy for legislation by Government of India 2008-2014
- Advocacy for correcting deficiencies – ongoing.

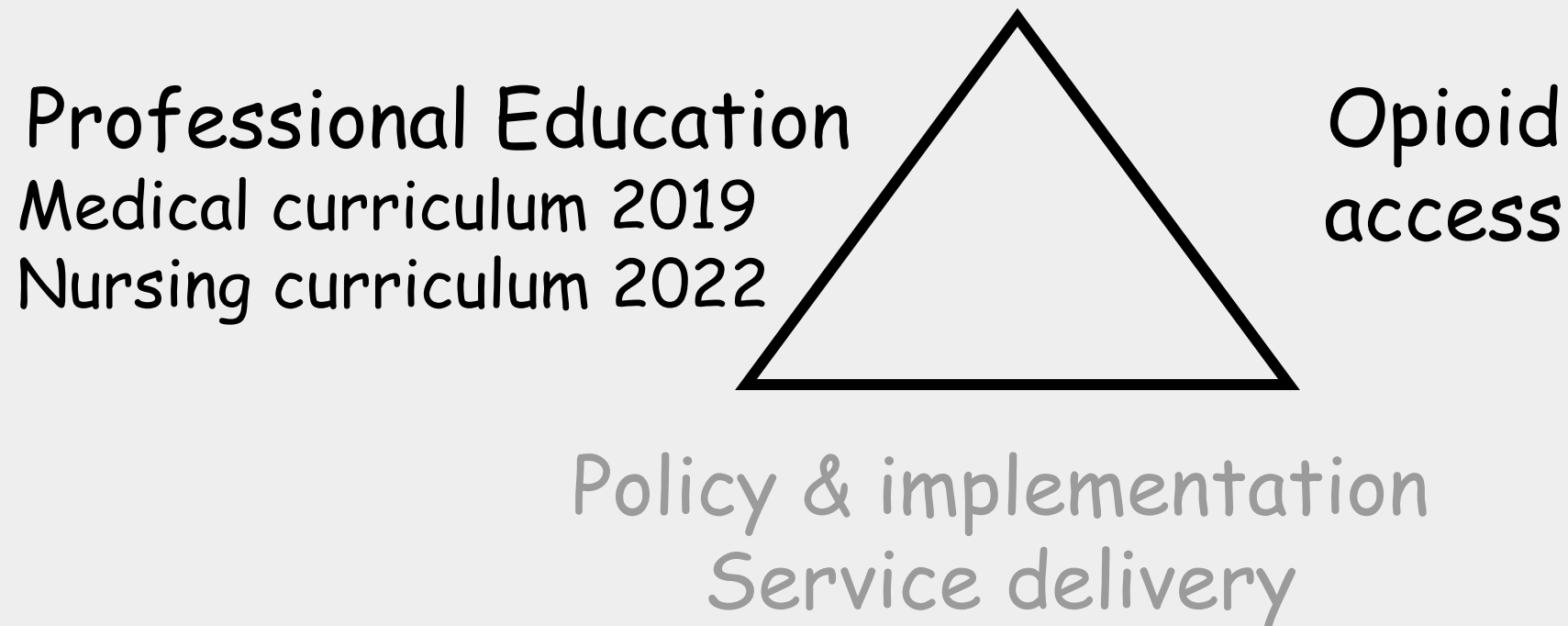
Civil Society Efforts for Opioid Access, 1995 onwards: Morphine consumption



Organization of palliative care: Modified WHO Strategy



Organization of palliative care: Modified WHO Strategy



Organization of palliative care: Modified WHO Strategy



Fears and barriers



Key: Public awareness

REMOVING BARRIERS TO PAIN RELIEF IN LATIN AMERICA THROUGH PROMOTION AND LEADERSHIP



*Latinoamérica
unida en la
atención paliativa*

Marzo | **20**
06 al 09 | **24**
> Cartagena <
Colombia

ALCP

ASOCIACIÓN LATINOAMERICANA
DE CUIDADOS PALIATIVOS

PAOLA MARCELA RUIZ OSPINA

PALLIATIVIST GERIATRIST.

*LEADER OF CONTINUOUS CARE UNIT, SES UNIVERSITY
HOSPITAL OF CALDAS.*

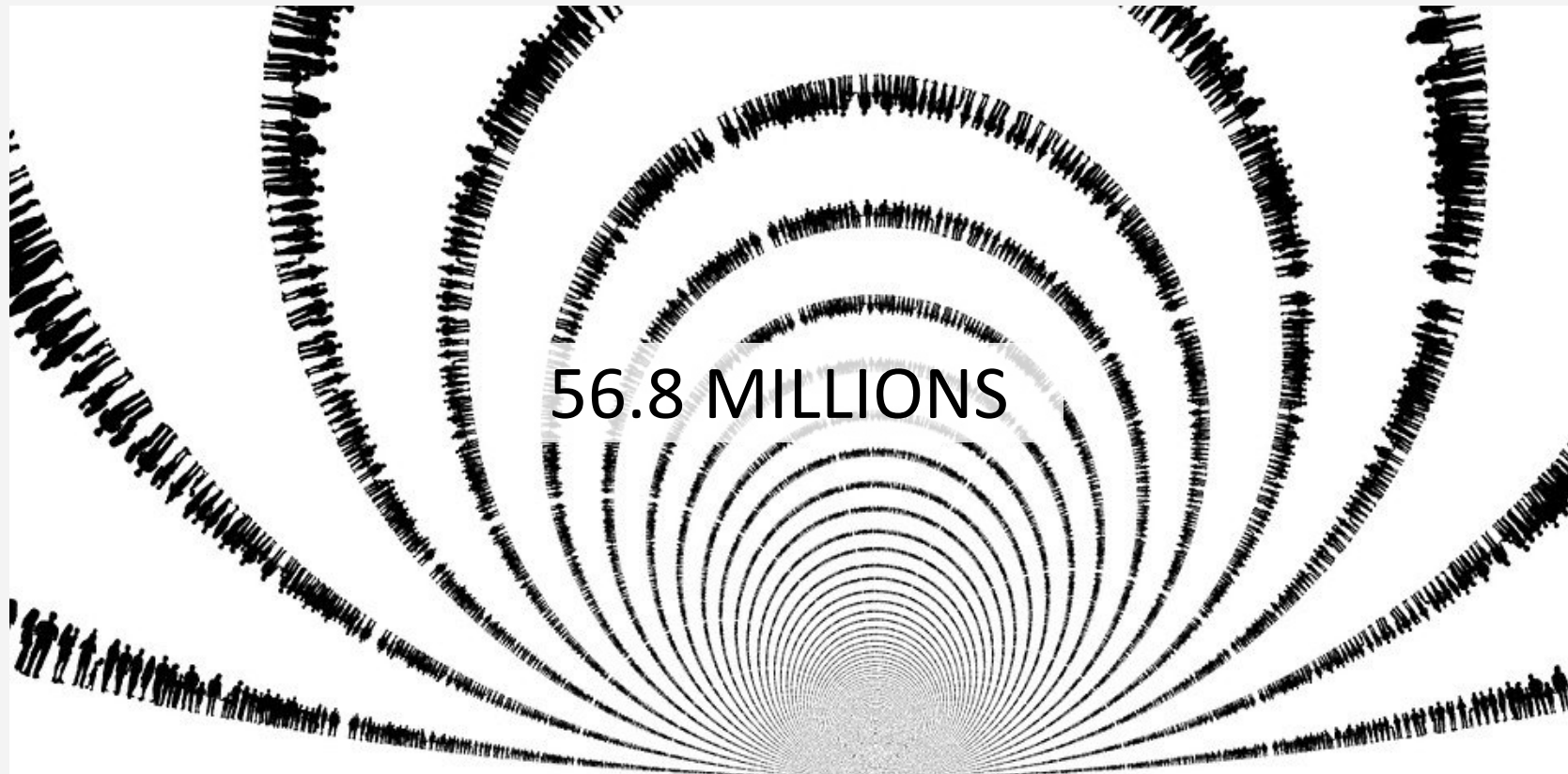
*VIVESSALUD HOME PALLIATIVE CARE PROGRAM
COORDINATOR.*

ASOCUPAC EXPRESIDENT.

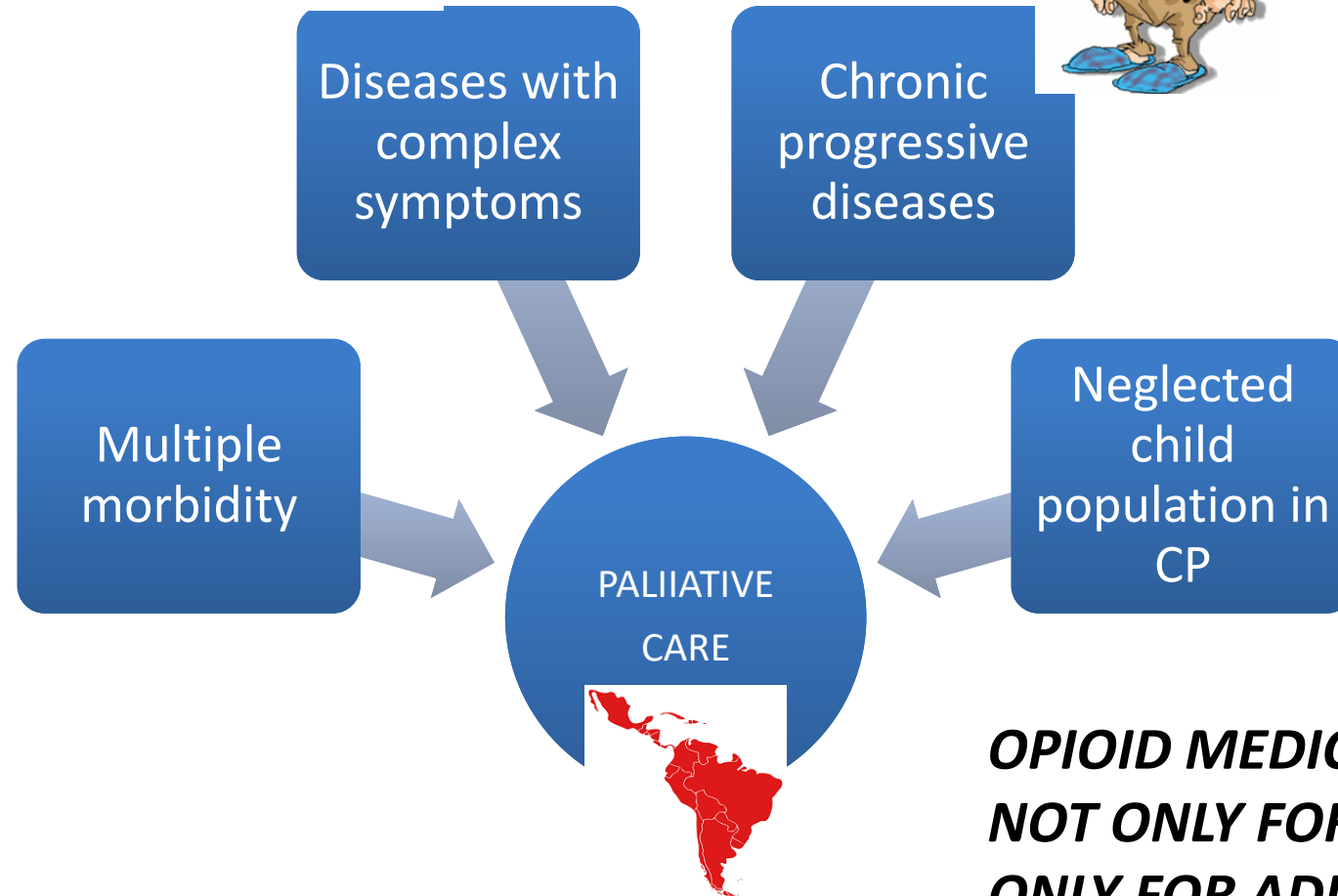
ALCP PRESIDENT



GRATITUDE



SEVERE HEALTH-RELATED SUFFERING (SHS)

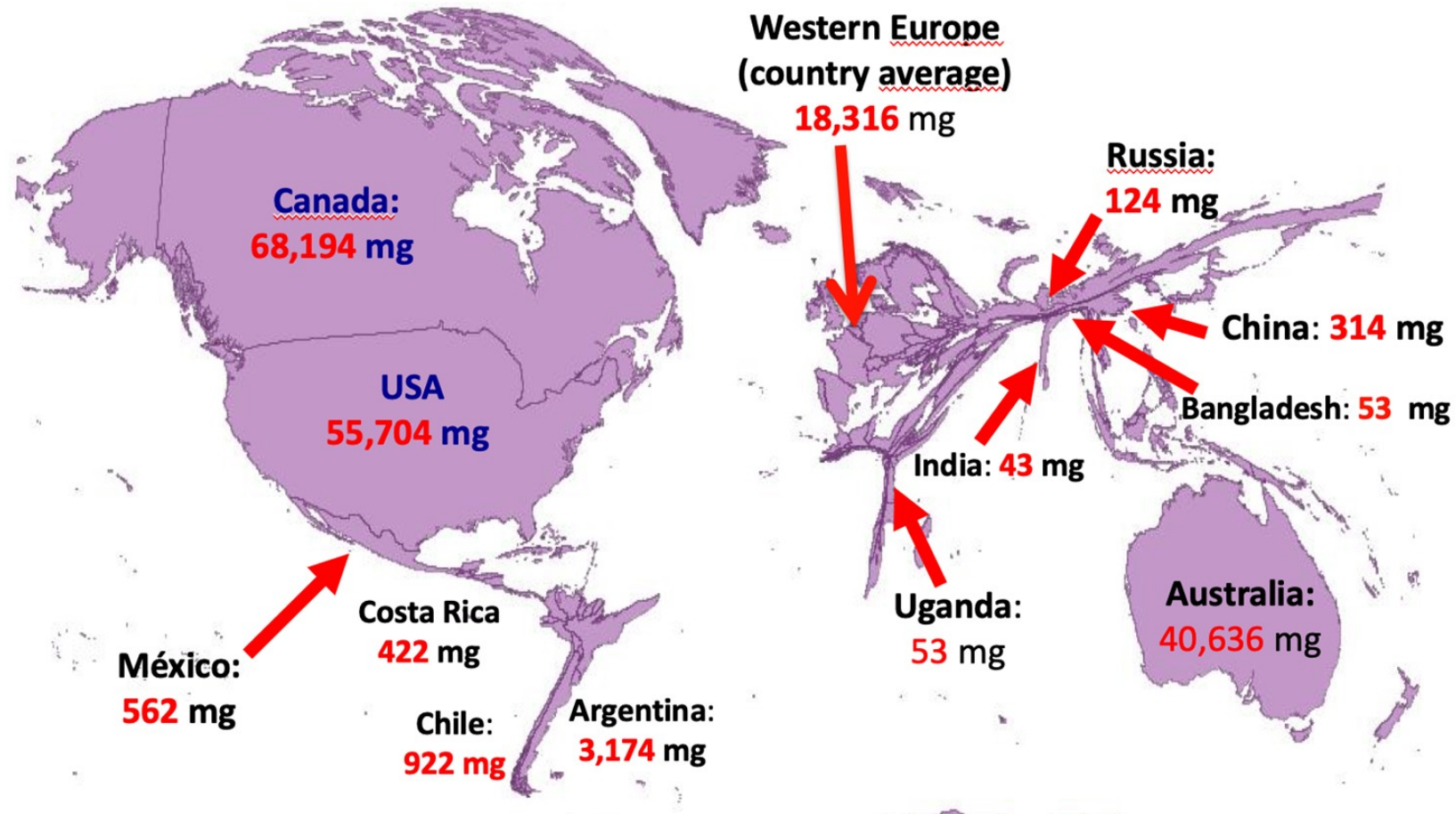


***OPIOID MEDICATIONS:
NOT ONLY FOR PAIN, NOT
ONLY FOR ADULTS!!!***

CURRENT MODEL IN LIGHT OF THE NEED



THERE IS AN IMMENSE SHORTAGE OF PALLIATIVE CARE SERVICES AROUND THE WORLD







NEW WAYS!!!!

ALL COUNTRIES IN THE REGION HAVE IMPROVED IN THE LAST 8 YEARS IN

Education

Investigation

Health policy

Opioid use

Service provision

Vitality (National Associations)

Opioid consumption
in Latin America has
increased in recent
years, but great
inequity persists

Pais	Distribución de opioides DOME/cápita
Argentina	17,1 mg
Bolivia	0,9 mg
Brasil	6,6 mg
Chile	26,3 mg
Colombia	11,2 mg
Costa Rica	8,5 mg
Ecuador	2,5 mg
El Salvador	4,4 mg
Guatemala	2,2 mg
Honduras	1 mg
México	1,7 mg
Panamá	10,8 mg
Perú	4,3 mg
República Dominicana	2,3 mg
Uruguay	12,3 mg
Venezuela	0,2 mg



REGIONAL PROBLEMS

- Most countries have at least 5 types of opioids
- 6 countries in the region (Dominican Republic, Ecuador, El Salvador, Honduras, Paraguay and Trinidad and Tobago) do not have immediate release morphine.
- Some of these countries do have much more expensive formulations, such as extended-release morphine or transdermal fentanyl, the latter present in almost all countries in the region.
- Another problem reported, although essential medicines could be present in the formulary, some countries declared not having the product most of the time.

Bonilla P. Cuidados Paliativos en Latinoamérica. Rev. Nutr. Clin. Metab. 2021;4(2):4-13

COLOMBIA



DATOS GENERALES

Superficie 114.746 km²
 Población [2018] 49.653.000 habitantes
 Total de muertes [2018] 282.000
 Personal médico [2013] 18,2 por 10.000 habitantes
 Enfermería [2013] 10,6 por 10.000 habitantes



GASTO EN SALUD

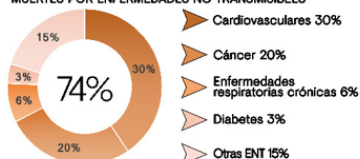
Gasto en salud (% del PIB) [2014] 7,2
 Gastos per cápita totales en salud [2014] 960.866
 Gastos que cubre el Gobierno [2014] 73,3%
 Gasto de bolsillo [2014] 15,4%



VARIABLES MACROECONÓMICAS

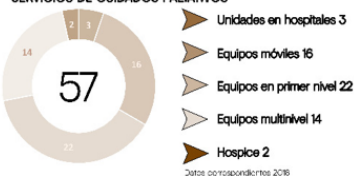
Clasificación del Banco Mundial [2018] Medio Alto
 Índice de Desarrollo Humano (IDH) [2017] 0,746
 Pobreza [2018] 5,7%

MUERTES POR ENFERMEDADES NO TRANSMISIBLES



CIE-10 2018. Datos correspondientes a 2018

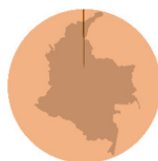
SERVICIOS DE CUIDADOS PALIATIVOS



Datos correspondientes a 2018

NECESIDAD

338.400
 Requieren cuidados paliativos por año



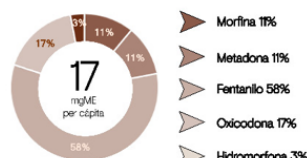
COBERTURA

Capacidad para proveer servicio de cuidados paliativos
0,4%
 Quality of Death index 2015

USO DE ANALGÉSICOS OPIOIDES

Datos correspondientes a 2018
 Uso total de opiáceos (expresado en mg equivalentes de morfina, oral por habitante) y proporción de cada tipo de opiáceo

MEDIA LATINOAMERICANA
 6,7 mgME
 per cápita



Estimación de la colaboración entre prescriptores y reguladores de analgésicos opioides



2 Asociación Nacional de Cuidados Paliativos



✓ Certificación oficial para medicina paliativa
 ✓ Programas de posgrado
 5 Facultades de medicina con cursos de posgrado en cuidados paliativos sobre el total
 60



✓ Ley Nacional de Cuidados Paliativos
 Plan Nacional de Cuidados Paliativos

ALCP ASOCIACIÓN LATINOAMERICANA DE CUIDADOS PALIATIVOS



ALCIÓ
 UNIDAD



INFOGRÁFICOS POR PAÍSES

Colombia

APUNTE HISTÓRICO

Tiberio Álvarez fundó en 1980 la Clínica de Alivio del Dolor y Cuidados Paliativos (Hospital Universitario San Vicente de Paul, Universidad de Antioquia) en Medellín, dando comienzo a los cuidados paliativos en el país y la región. En 1987 Isa Fonnegra creó la Fundación Omega para brindar apoyo a familiares y pacientes con enfermedades terminales en Bogotá. En 1988 Liliana De Lima creó el primer hospicio en La Viga (Cali) con el apoyo de Pedro Bejarano. El Instituto Nacional de Cancerología comenzó en 1995 la primera especialidad médica en Cuidados Paliativos de la región. En 1996 se creó la Asociación Colombiana de Cuidados Paliativos.

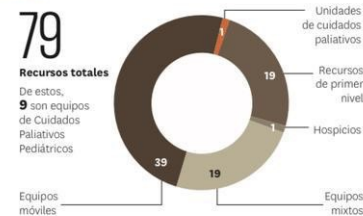
NECESIDAD ACTUAL DE CUIDADOS PALIATIVOS

16%
 de los que lo necesitan, reciben cuidados paliativos



PROVISIÓN DE CUIDADOS PALIATIVOS

1,6
 Recursos asistenciales por millón de habitantes
 0,8
 Recursos para niños por millón de habitantes menores de 15 años



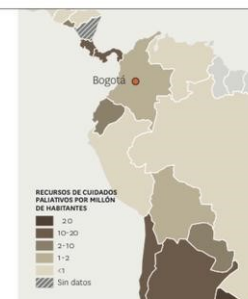
DISTRIBUCIÓN DE OPIOIDES

556,1
 kg



INFORMACIÓN ADICIONAL

Asociación Colombiana de Cuidados Paliativos (ACCP)
 Asociación de Cuidados Paliativos de Colombia (ASOCUPAC)



Datos generales
 Población [2018] 49.464.700 hab.
 Médicos/100.000 hab. [2018] 21,1
 Enfermeros/100.000 hab. [2018] 12,7
Variables socioeconómicas
 PIB per cápita [2018] 6.718,6 \$
 Gasto en salud [% del PIB] [2015] 7,2
 Índice de cobertura sanitaria universal [2017] 76%

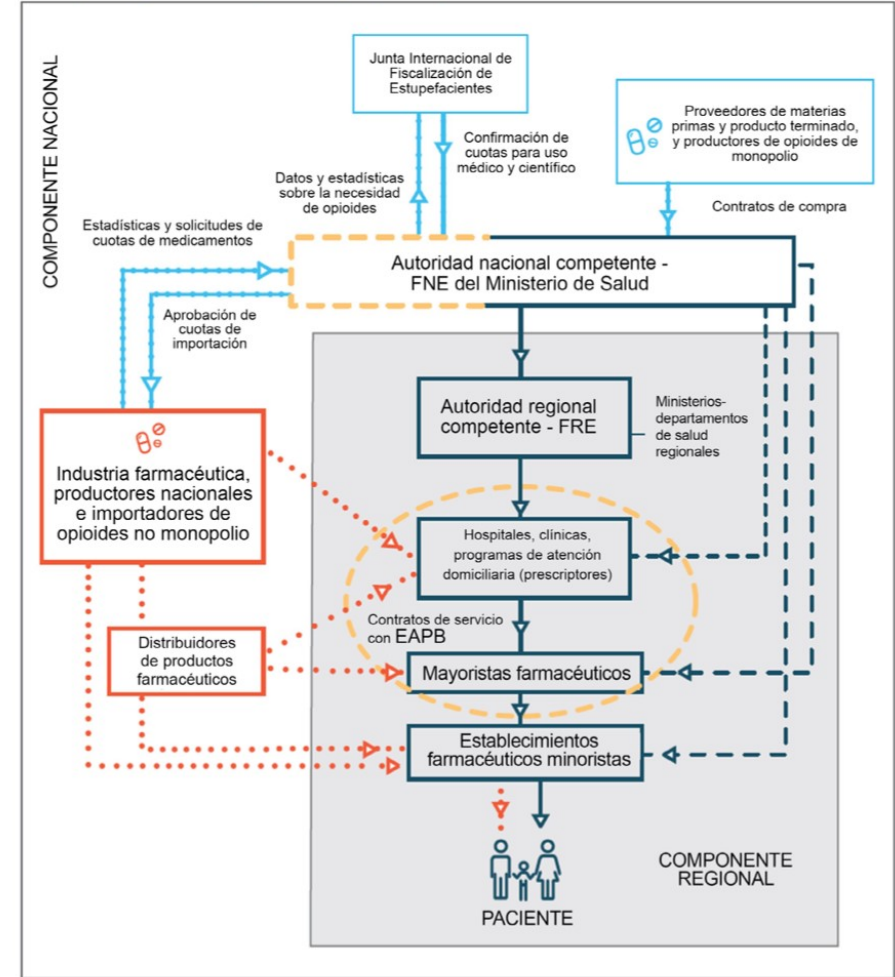
OTROS INDICADORES

Políticas sanitarias
 Estrategia nacional de CP [en proceso]
 Ley nacional específica para CP [SI]
Asociaciones nacionales
 Asociación nacional de CP [SI]
Educación
 Acreditación oficial de la especialización en medicina paliativa [SI]
 Facultades con asignatura independiente de cuidados paliativos





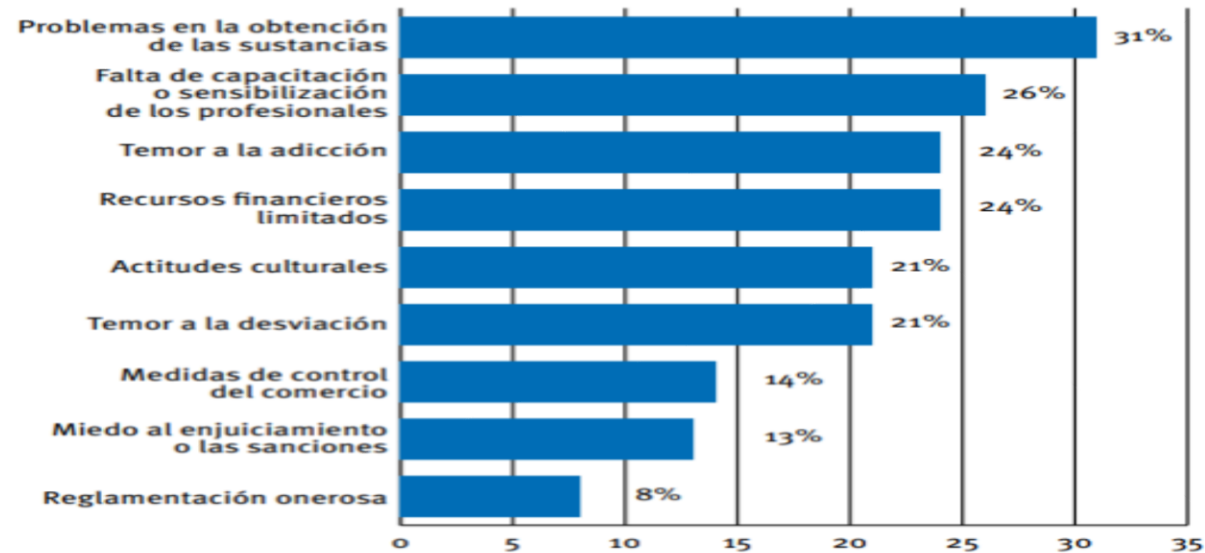
FIGURA 1. Adquisición y distribución de opioides monopolio y no monopolio.



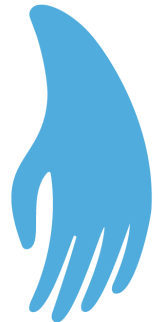
BARRIERS IN ACCESS TO OPIOID MEDICATIONS IN LATIN AMERICA

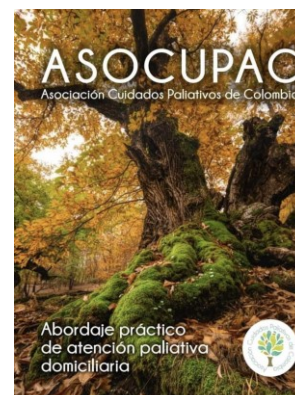


Figura 1. Impedimentos a la disponibilidad mencionados por las autoridades nacionales competentes (2022)



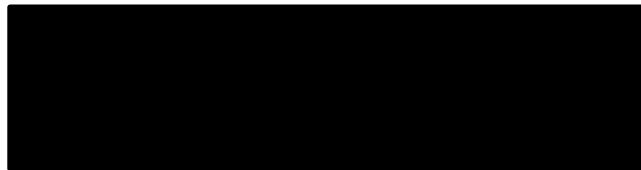
Fuente: Encuesta de la JIFE a los Estados Miembros, 2022.





EDUCATION

ADVOCACY



ASOCIACIÓN LATINOAMERICANA DE CUIDADOS PALIATIVOS

Latinoamérica
unida en la
atención paliativa

Marzo 06-09 | 2024
Cartagena
Colombia



Availability of essential medications for pain and palliative care at all levels of care

General availability of immediate-release oral morphine (in liquid or tablet form) at the primary level of care

Modelo conceptual para el desarrollo de los cuidados paliativos

***THE REAL CRISIS OF OPIOIDS... IN
PALLIATIVE CARE IS NOT HAVING THESE
AVAILABILITY TO MITIGATE
UNNECESSARY HUMAN SUFFERING...***



ALCP

ASOCIACIÓN LATINOAMERICANA
DE CUIDADOS PALIATIVOS



Closing the Global Divide: Palliative Care & Pain Relief

*WHO Webinar III: What can be done to improve safe
access to medical morphine? Lessons from countries
September 14th 2023*

Dr. Felicia Marie Knaul

University of Miami Sylvester Comprehensive Cancer Center, Institute for Advanced Study of
the Americas & Miller School of Med. And, Tómatelo a Pecho, A.C.

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

ALLEVIATING THE ACCESS ABYSS IN PALLIATIVE CARE AND PAIN RELIEF—AN IMPERATIVE OF UNIVERSAL HEALTH COVERAGE

THE LANCET COMMISSION REPORT

The Lancet Commissions

Alleviating the access abyss in palliative care and pain relief— an imperative of universal health coverage: the Lancet Commission report

Felicia Marie Knäul, Paul E Farmer*, Eric L Krakauer*, Liliana De Lima, Afsan Bhadelia, Xiaoxiao Jiang Kwete, Héctor Arreola-Ornelas, Octavio Gómez-Dantés, Natalia M Rodríguez, George A O Alleyne, Stephen R Connor, David J Hunter, Diederik Lohman, Lukas Radbruch, Maria del Rocío Sáenz Madrigal, Rifat Atun†, Kathleen M Foley†, Julio Frenk†, Dean T Jamison†, M R Rajagopal†, on behalf of the Lancet Commission on Palliative Care and Pain Relief Study Group

Executive Summary

In agonising, crippling pain from lung cancer, Mr S came to the palliative care service in Calicut, Kerala, from an adjoining district a couple of hours away by bus. His body language revealed the depth of the suffering.

We put Mr S on morphine, among other things. A couple of hours later, he surveyed himself with disbelief. He had neither hoped nor conceived of the possibility that this kind of relief was possible.

Mr S returned the next month. Yet, common tragedy befell patient and caregivers in the form of a stock-out of morphine.

Mr S told us with outward calm, “I shall come again next Wednesday. I will bring a piece of rope with me. If the tablets are still not here, I am going to hang myself from that tree”. He pointed to the window. I believed he meant what he said.

Stock-outs are no longer a problem for palliative care in Kerala, but throughout most of the rest of India, and indeed our world, we find near total lack of access to morphine to alleviate pain and suffering.

Dr M R Rajagopal, personal testimony

Poor people in all parts of the world live and die with little or no palliative care or pain relief. Starting into this access abyss, one sees the depth of extreme suffering in the cruel face of poverty and inequity.

The abyss is broad and deep, mirroring relative and absolute health and social deprivation. Of the 298·5 metric tonnes of morphine-equivalent opioids distributed in the world per year (average distribution in 2010–13), only 0·1 metric tonne is distributed to low-income countries.¹ The amount of morphine-equivalent opioids distributed in Haiti is 5 mg per patient in need of palliative care per year, which means that more than 99% of need goes unmet. By contrast, the annual distribution of morphine is 55 000 mg per patient in need of palliative care in the USA and more than 68 000 mg per patient in need of palliative care in Canada—much more than is needed to meet all palliative care and other medical needs for opioids on the basis of estimates of the Commission (figure 1).

The fact that access to such an inexpensive, essential, and effective intervention is denied to most patients in low-income and middle-income countries (LMICs) and in particular to poor people—including many

poor or otherwise vulnerable people in high-income countries—is a medical, public health, and moral failing and a travesty of justice. Unlike so many other priorities in global health, affordability is not the greatest barrier to access, and equity-enhancing, efficiency-oriented, cost-saving interventions exist.

The global health community has the responsibility and the opportunity to close the access abyss in the relief of pain and other types of suffering at end-of-life and throughout the life course, caused by life-limiting and life-threatening health conditions. However, unlike many other essential health interventions already identified as priorities, the need for palliative care and pain relief has been largely ignored, even for the most vulnerable populations, including children with terminal illnesses and those living through humanitarian crises, and even in the Sustainable Development Goals (SDGs).² Yet palliative care and pain relief are essential elements of universal health coverage (UHC).

Several barriers explain this neglect: the focus of existing measures of health outcomes—major drivers of policy and investment—on extending life and productivity with little weight given to health interventions that alleviate pain or increase dignity at the end of life;³ opioidophobia, which refers to prejudice and misinformation about the appropriate medical use of opioids;⁴ the focus, in medicine, on cure and extending life and a concomitant neglect of caregiving and quality of life near death;^{5,6} limitations on patient advocacy due to the seriousness of illnesses; the focus on preventing non-medical use of internationally controlled substances without balancing the human right to access medicines to relieve pain;^{7,8} and the global neglect of non-communicable diseases, which account for much of the need for palliative care.⁹

Global health is devoid of the investments, interventions, and indicators that are essential to ensure universal access to safe, secure, and dignified care at the end of life or to the palliation of pain and suffering. With this Report, we aim to remedy these limitations by: (1) quantifying the heavy burden of serious health-related suffering (SHS) associated with a need for palliative care and pain relief (section 1); (2) identifying and costing an Essential Package Of Palliative Care And Pain Relief Health Services (the Essential Package) that would alleviate this burden (section 2); (3) measuring the unmet need for one of the most essential components of the

Lancet 2018; 391: 1391–454
Published Online
October 12, 2017
[http://dx.doi.org/10.1016/S0140-6736\(17\)31513-8](http://dx.doi.org/10.1016/S0140-6736(17)31513-8)
This online publication has been corrected. The corrected version first appeared at thelancet.com on March 9, 2018.
See Comment page 1338

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The Lancet Commissions

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For WHO's 2015 Global Health Estimates see http://www.who.int/globalhealth/global_health_estimates/en

For additional online material see <http://www.thelancet.com>

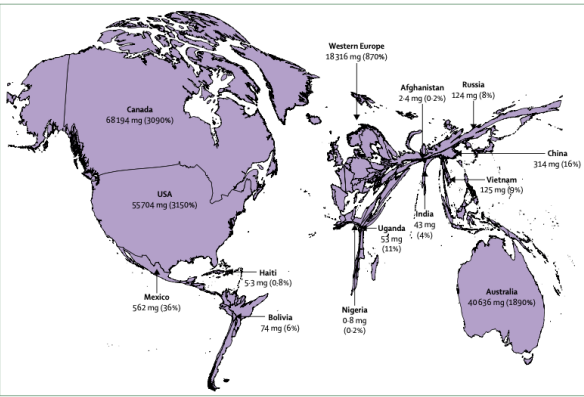


Figure 1: Distributed opioid morphine-equivalent (morphine in mg/patient in need of palliative care, average 2010–13), and estimated percentage of need that is met for the health conditions most associated with serious health-related suffering
Source: International Narcotics Control Board and WHO Global Health Estimates, 2015. See additional online material for methods.

package—inexpensive, immediate-release oral and injectable morphine (section 2); and (4) outlining national and global health-systems strategies to expand access¹⁰ to palliative care and pain relief as an integral part of UHC by applying a balanced approach that ensures adequate attention to both the medical needs of all patients and the risk of non-medical use (section 3).¹¹ Our findings and recommendations are summarised in five key messages (panel 1).

Alleviating SHS is a global health and equity imperative

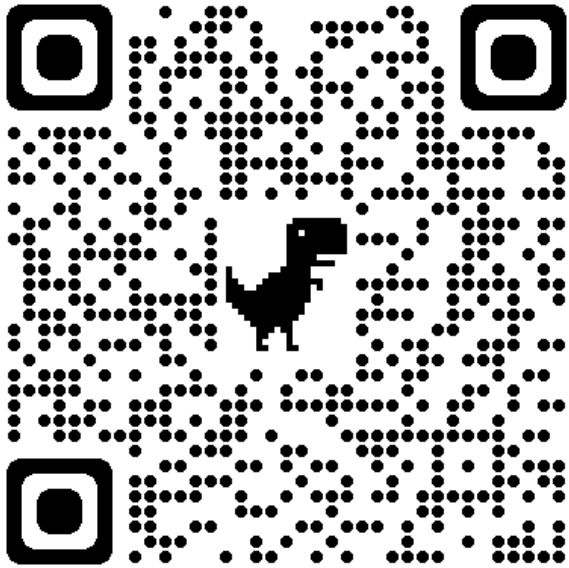
The Commission developed a new conceptual framework for measuring the global burden of SHS. Suffering is health-related when it is associated with illness or injury of any kind. Suffering is serious when it cannot be relieved without medical intervention and when it compromises physical, social or emotional functioning. Palliative care should be focused on relieving the SHS that is associated with life-limiting or life-threatening conditions or the end of life. We analysed the 20 health conditions and 15 symptoms typically associated with these health conditions that cause most of the burden of SHS. We undertook this far-reaching analysis of health conditions because we recognise and uphold the importance of including previously neglected diseases within the realm of palliative care.

More than 25·5 million people who died in 2015—45% of the 56·2 million deaths recorded worldwide—experienced SHS. Of those, more than 80% of the people who died with SHS in 2015 were from developing regions, and the vast majority lack access to palliative care and pain relief.

Every year almost 2·5 million children die with SHS and more than 98% of these children are from developing regions. In high-income countries, children account for less than 1% of all deaths associated with SHS, whereas in low-income countries, children account for more than 30% of all deaths associated with SHS. Yet we also estimate that in low-income countries at least 93% of child deaths associated with SHS are avoidable.

Including both those who die in a given year and the many who live with life-threatening or life-limiting health conditions, we estimate that more than 61 million people are affected by SHS. More than 80% of these patients live in LMICs where palliative care and pain relief is scarce or non-existent.

The annual burden measured in days of physical and psychological SHS is huge—more than 6 billion days, or up to 21 billion days worldwide, depending on symptom overlap. Although HIV and cancer rank highest overall among conditions accounting for both number of people who experience SHS and the total days with SHS, even in



OUTLINE

- 1. Global need: Serious Health-related Suffering (SHS)**
- 2. Intervention: an essential package**
- 3. Access to opioid medicines: DOME**
- 4. Unmet need, Access to pain relief: DOME/SHS**
- 5. Strengthening health systems for and with access to pain relief and palliative care**

GLOBAL BURDEN OF SERIOUS HEALTH-RELATED SUFFERING (2019)

26+ million deaths

- Half of the 55 million global deaths

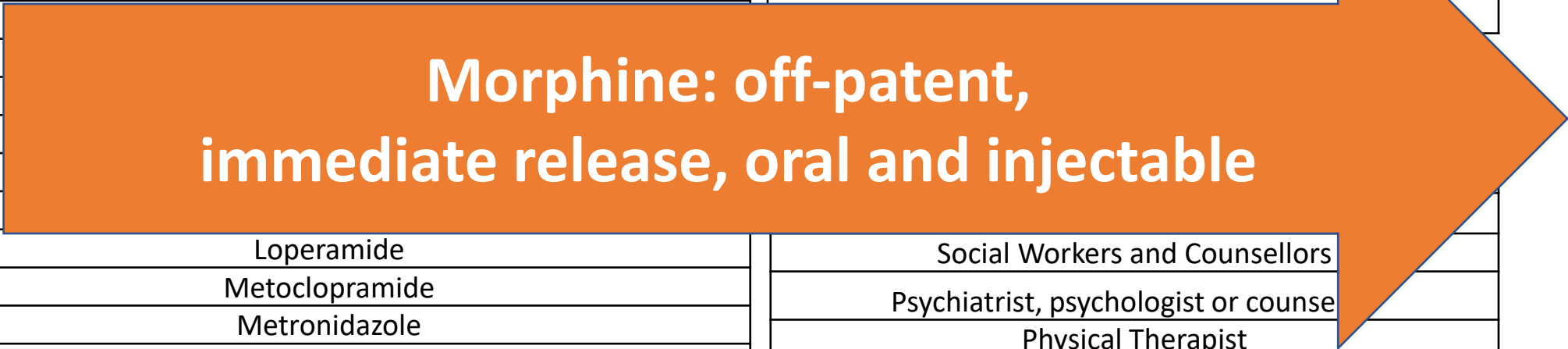
42+ million people experienced SHS

- Non-decedents

At least 68+ million people worldwide:
80% in LMICs



INTERVENTION: ESSENTIAL, MOST BASIC PACKAGE

Medicine	Medical Equipment
Amitriptyline	Pressure Reducing Mattress
Bisacodyl (Senna)	Nasogastric drainage or feeding tube
Dexamethasone	Urinary catheters
Diazepam	Opioid lock box
Diphenhydramine (chlorpheniramine, cyclizine, or dimenhydrinate, oral & injectable)	Flashlight with rechargeable battery
Fluconazole	Adult diapers/ Cotton and Plastic
	
Loperamide	Social Workers and Counsellors
Metoclopramide	Psychiatrist, psychologist or counsellor
Metronidazole	Physical Therapist
Morphine	Pharmacist
Naloxone Parenteral	Community Health Workers
Omeprazole oral	Clinical Support Staff
Ondasetron	Non-Clinical Support Staff
Paracetamol oral	
Petroleum jelly	

Aligned with Sustainable Development Goals (SDGs): Should be made universally accessible by 2030

DISTRIBUTED OPIOID MORPHINE-EQUIVALENT (DOME)

- Morphine,
- Pethidine
- Codeine
- Oxycodone
- Hydromorphone
- Fentanyl

Country-reported
data from the
International
Narcotics Control
Board

Conversion to ME:, 0.25, 83.33, 1.33, 5, 0.417

AS A % OF TOTAL DOME, 1990 AND 2019

1990

2019

% Pethidine & Codeine



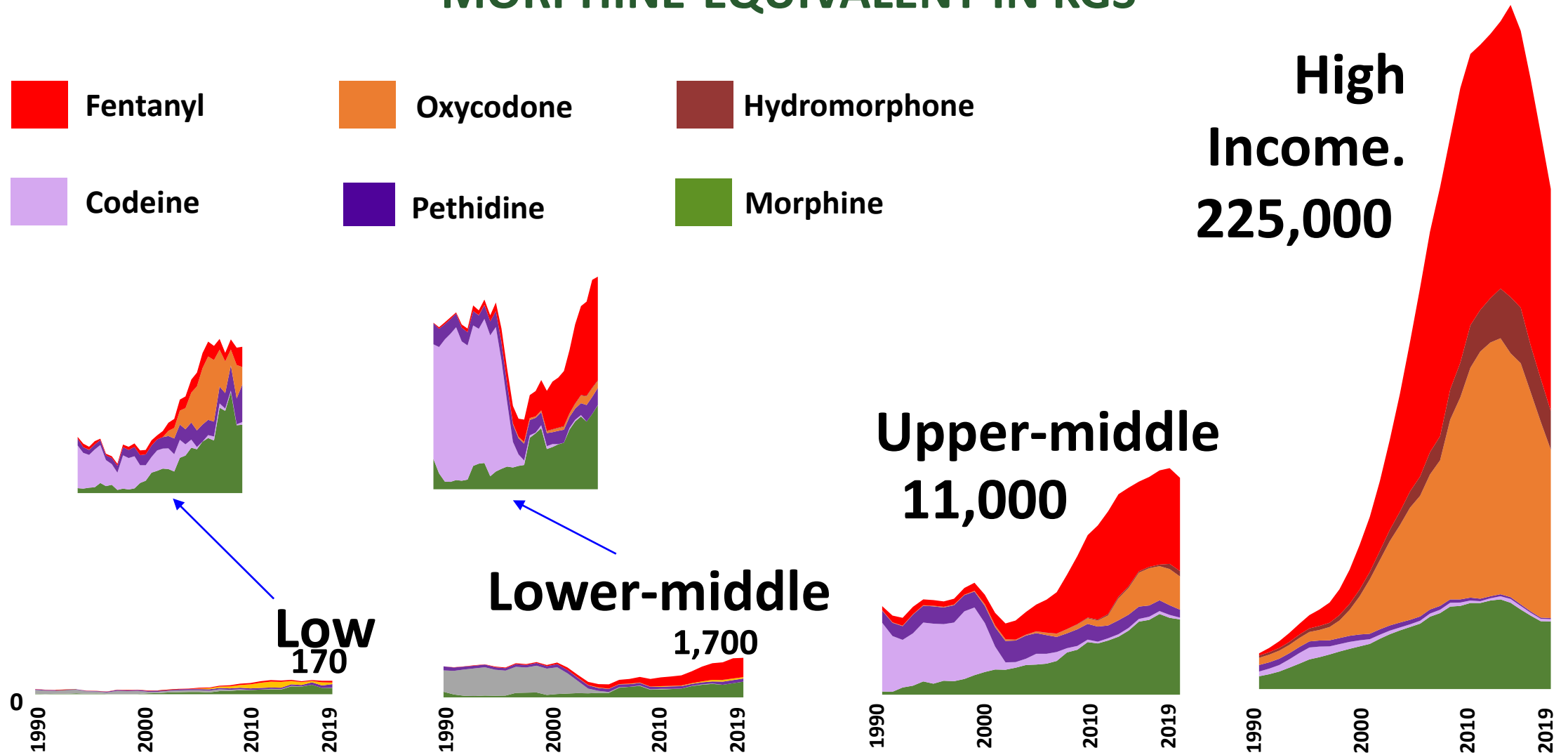
% Morphine



% Fentanyl + oxycodone + hydromorphone

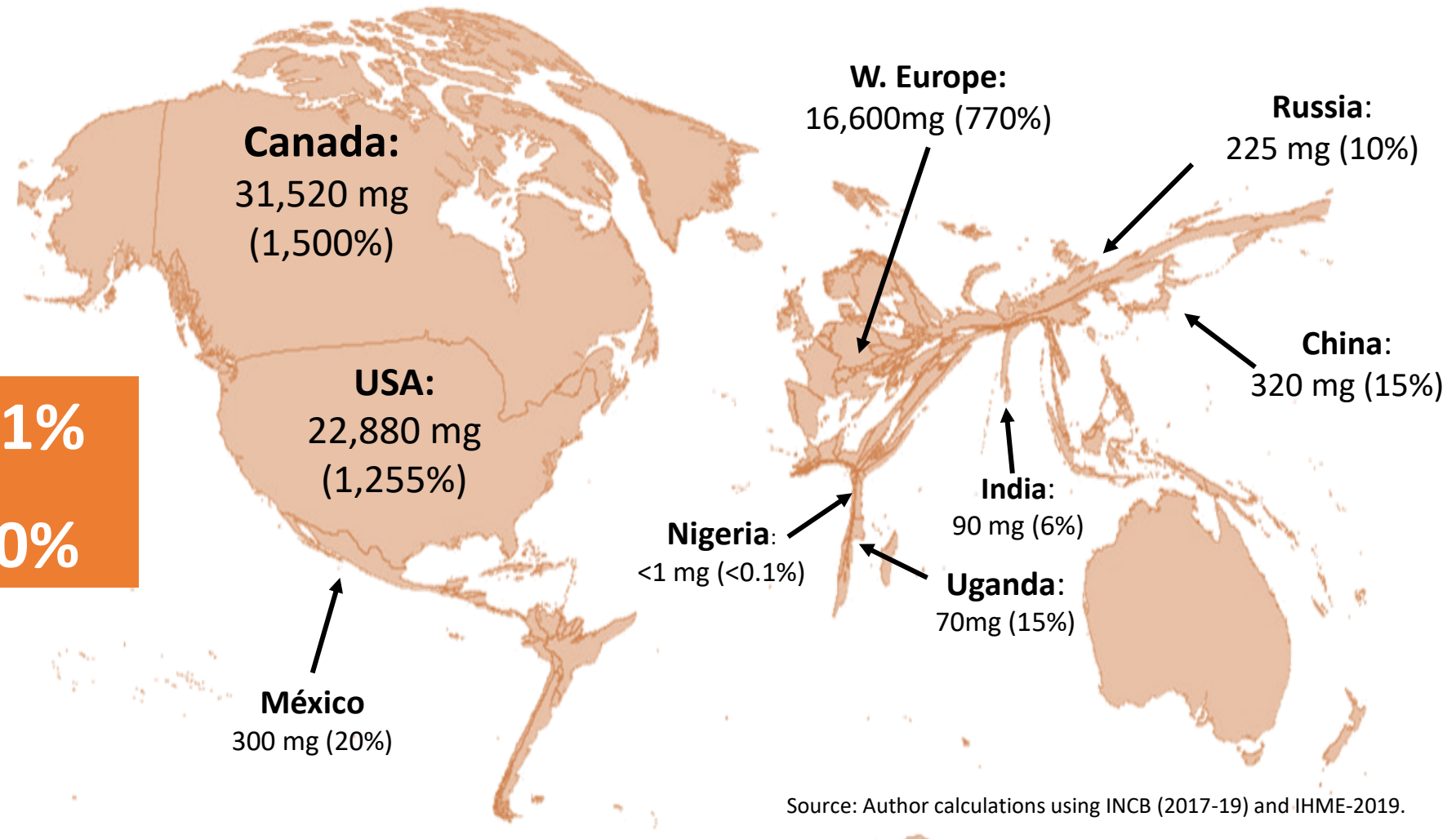


DISTRIBUTED OPIOIDS: BY INCOME REGION, 1990-2019, MORPHINE-EQUIVALENT IN KGS



THE GLOBAL PAIN DIVIDE: DISTRIBUTED OPIOID MORPHINE-EQUIVALENT (DOME, MG/PATIENT) & % OF SHS PALLIATIVE CARE NEED, 2019

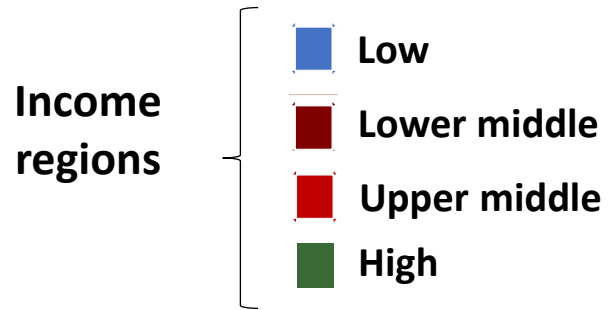
- The 50% poorest: <1%
- The 10% richest: 90%



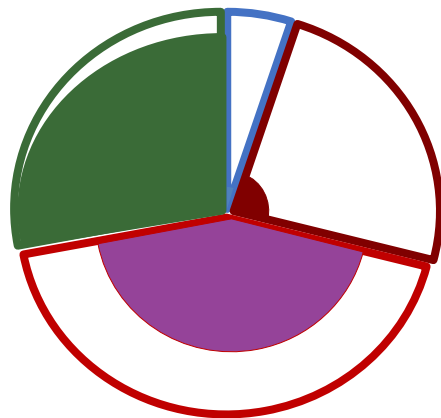
Source: Author calculations using INCB (2017-19) and IHME-2019.

TOTAL MEDICAL AND PALLIATIVE CARE UNMET NEED FOR OPIOID ANALGESICS (IN DOME), 2019

BENCHMARK: WESTERN EUROPE HIGH-INCOME

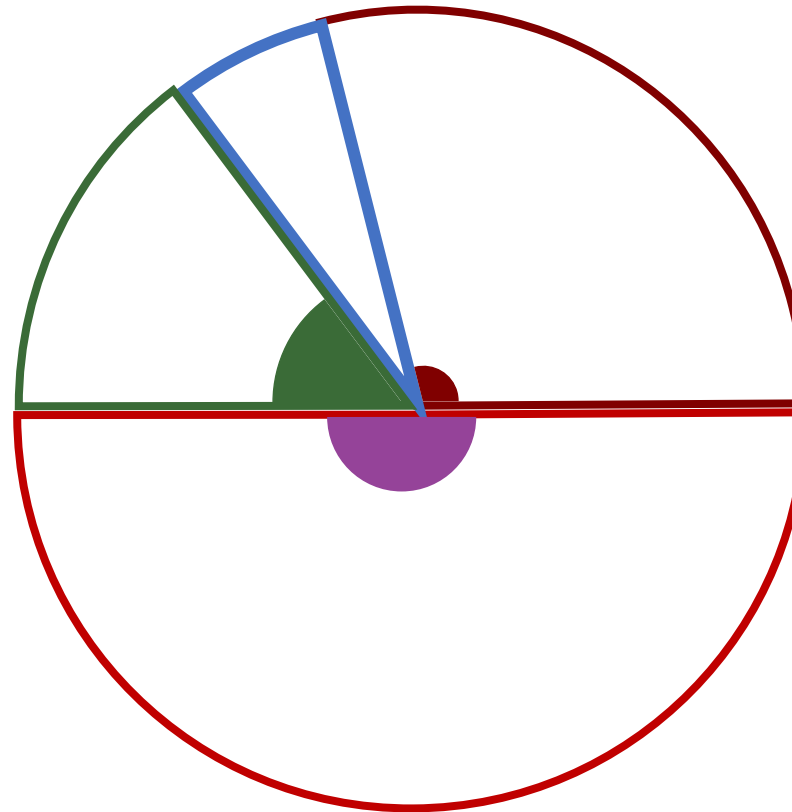


Palliative Care need



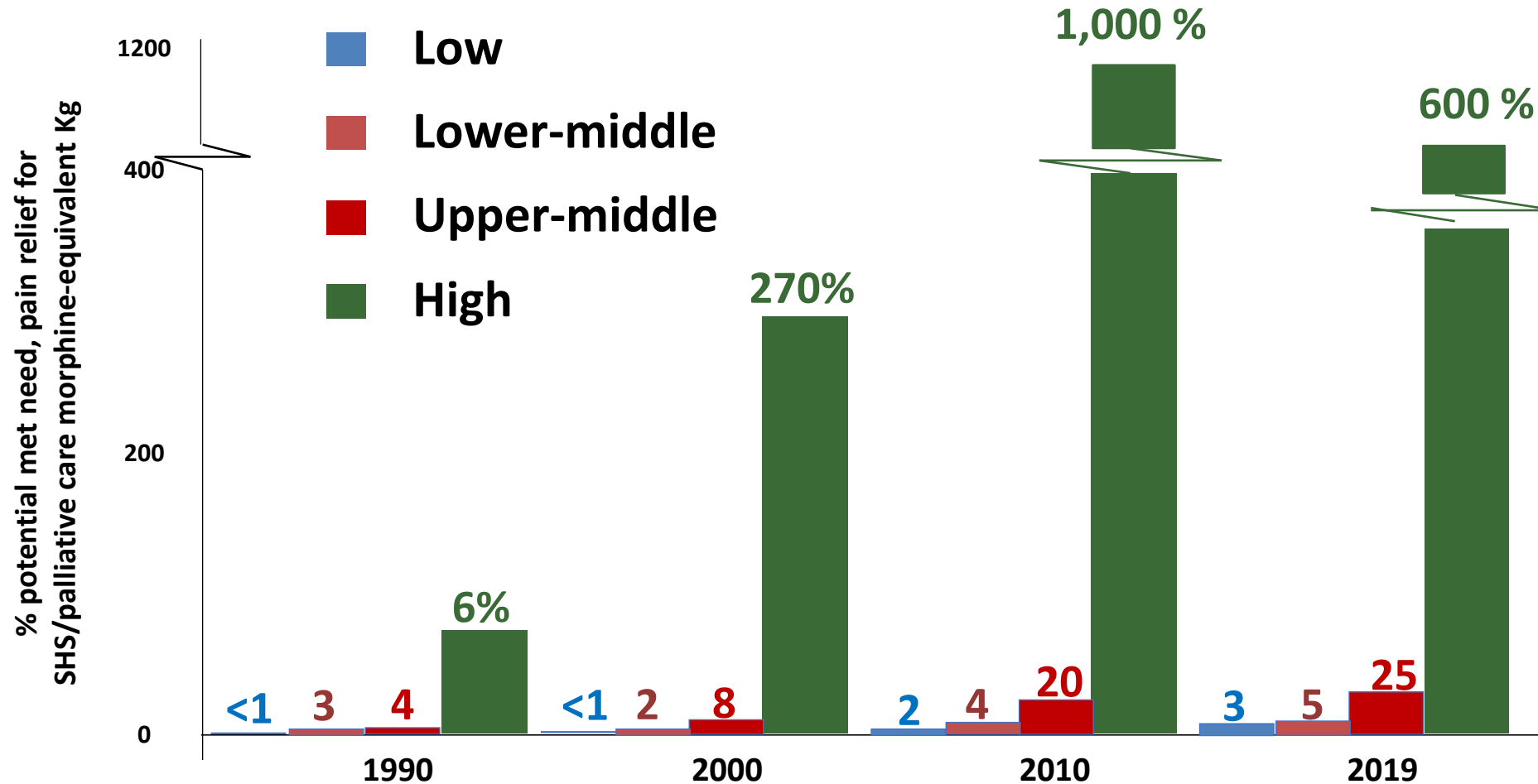
Unmet
need,
60% =
52/85
tons

Projected total need



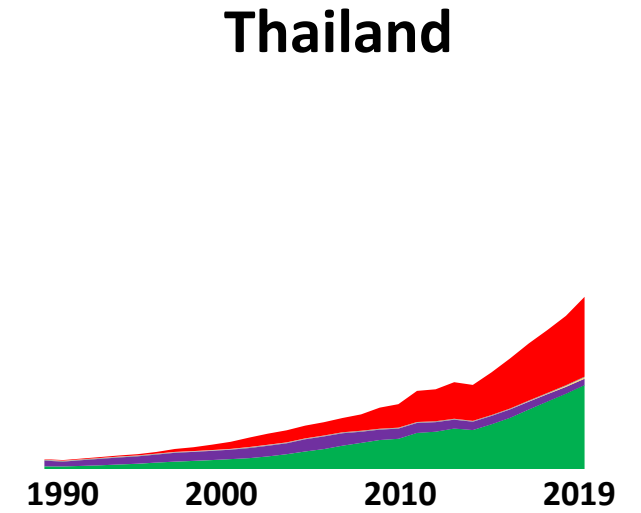
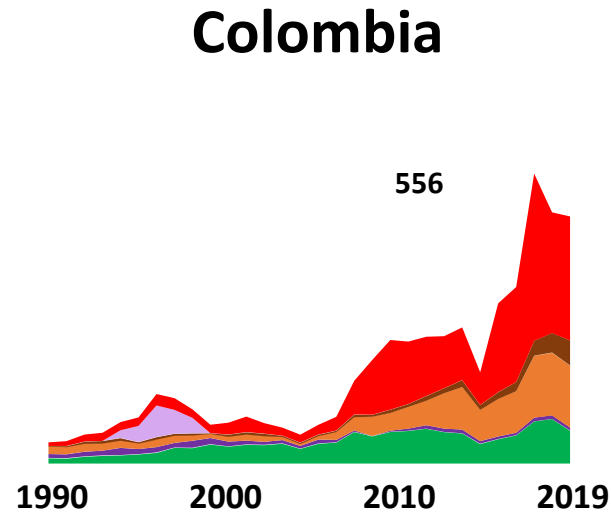
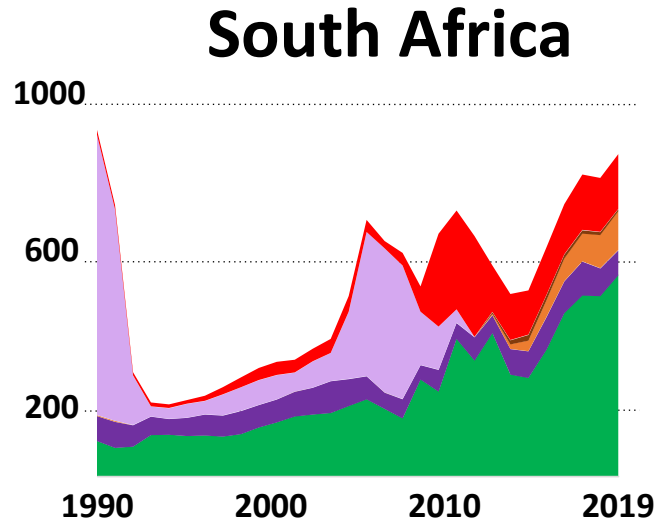
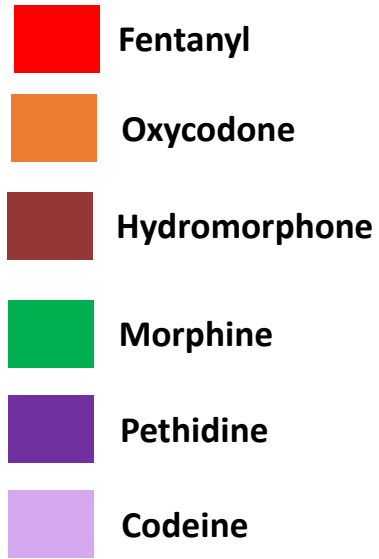
Unmet need,
95%:
639/671
metric tons

Potential Met Need Based on Morphine Equivalent: Income groups (% , 1990 to 2019)

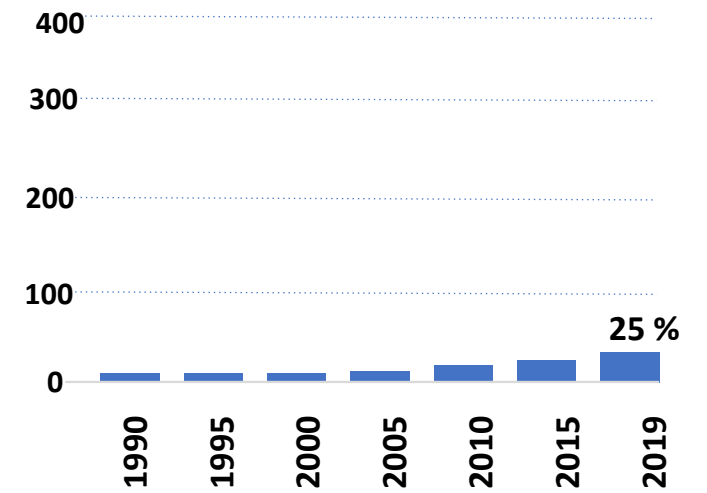
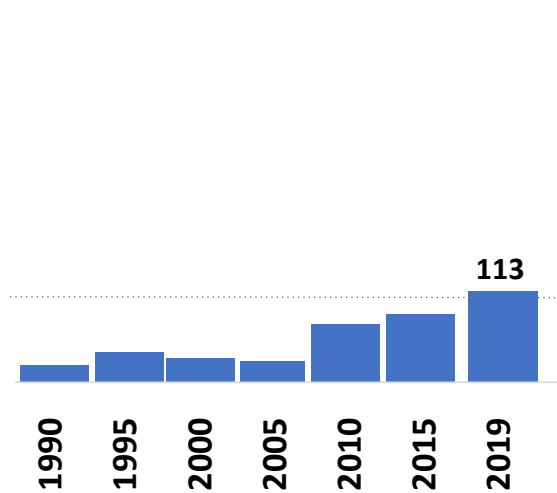
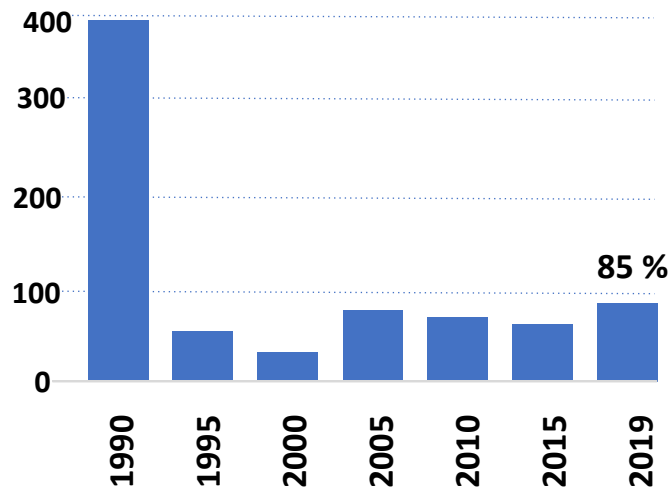


DOME by Medicine versus SHS

South Africa, Colombia, Thailand (1990-2019)



% Potential met need: palliative care pain relief (SHS)



**Annual estimated cost of closing the pain divide:
meeting global palliative care need using morphine (DOME)**

- **Price paid: *\$US600 million***
 - **At best international prices: *\$US145 million***
- (2015)**

Universal Health Coverage

UHC: All people must obtain the health services they require—prevention, promotion, treatment, rehabilitation, and palliative care—without risk of impoverishment (WHO).

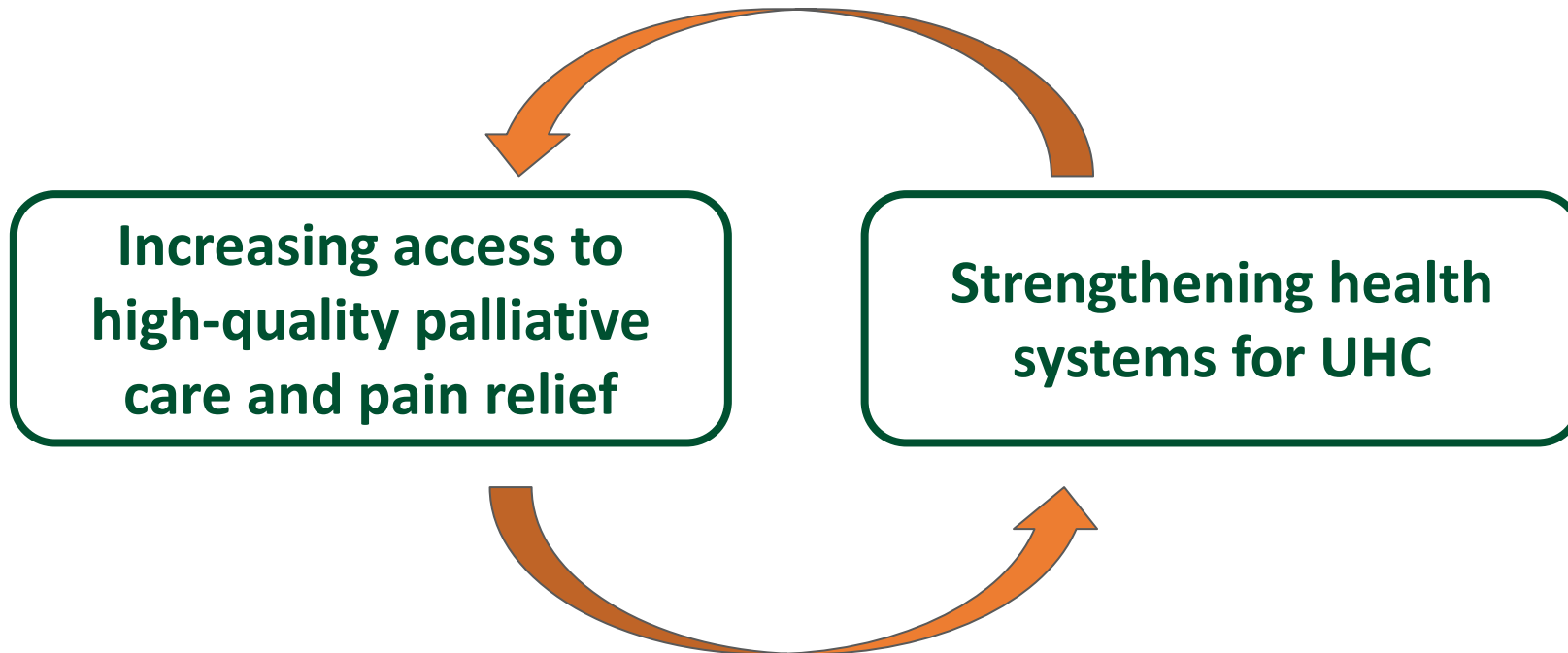
Through health system strengthening and health reform
undertaken in the difficult context of epidemiological transition and fragmented health systems

Without access to pain relief and palliative care neither UHC nor SDG3 can be achieved

Palliative care and pain control have been ignored in most countries

PALLIATIVE CARE AND PAIN RELIEF AND HEALTH SYSTEMS

Strong health systems require strong palliative care and pain relief systems – and vice-versa. This symbiotic, mutually reinforcing relationship should be cultivated and leveraged using diagonal approaches to substantively advance universal health coverage.



INTEGRATE INTO UHC

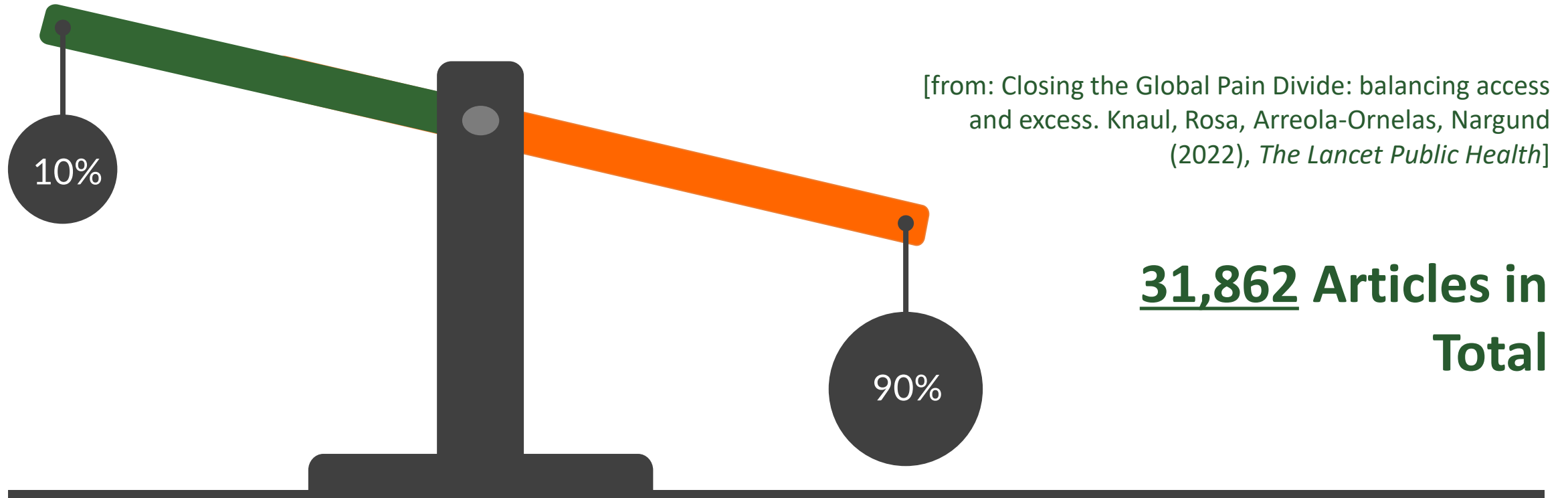
BY STRENGTHENING HEALTH SYSTEMS *BY FUNCTION*

Stewardship	Financing	Delivery	Human Resources
<i>Priority setting:</i> national health agenda	Explicit inclusion in national insurance & social security	Develop and implement secure opioid supply chain and ensure prescription practices	General competency mandatory component of ALL health professional curricula
<i>Planning:</i> comprehensive guidelines, programs	Guarantee public funding with specific budget allocations; start with EP	Establish hub-and-spoke distribution networks	Establish as a recognized medical & nursing specialty
In sub-national health agenda	Develop pooled purchasing for competitive prices	Integrate: <u>all</u> levels of care and disease-specific programs	
<i>Planning:</i> Developing scaleable, state-wide programmes			
<i>Regulation:</i> integrated guidelines that encompass all providers			
<i>Monitoring and evaluation of performance</i>			
<i>Intersectoral advocacy</i>			

**A balanced approach is essential –
adequate attention to medical needs of all
patients, and management of risk of non-
medical use**

....Yet....

THE GLOBAL PAIN DIVIDE IN SCIENCE AND LITERATURE: A BIBLIOMETRIC REVIEW



Opioid Access and Pain Disparities

Only 7% of the research focuses on disparities and inequity in access to palliative care and pain medication

Opioid Addiction and Use Disorder

93% of research articles focus on opioid misuse, showing that research is driven by experiences in the US and Canada

NEXT STEPS IN OUR RESEARCH WITH IAHPHC AND THE “HUB”

- Serious Health-related Suffering 3.0

- Packages: beyond the essential, minimum and differentiate for children

- Measure real value to patients and families of universal access to palliative care and pain relief:
SALYs

Pain is a pandemic.

The opioid crisis is an epidemic.

A balanced approach dedicated to
access without excess

In global and national governance and policy is
key to remedying
the huge burden of needless suffering
that plagues our world.



The North American Opioid Crisis and the Need for Global Balance

WHO Webinar on the Report “Left Behind in Pain”

KEITH HUMPHREYS

CHAIR, STANFORD LANCET COMMISSION ON THE NORTH AMERICAN OPIOID CRISIS

ESTHER TING MEMORIAL PROFESSOR, STANFORD UNIVERSITY

SENIOR CAREER RESEARCH SCIENTIST, VA HSR&D

Twitter: @KeithNHumphreys

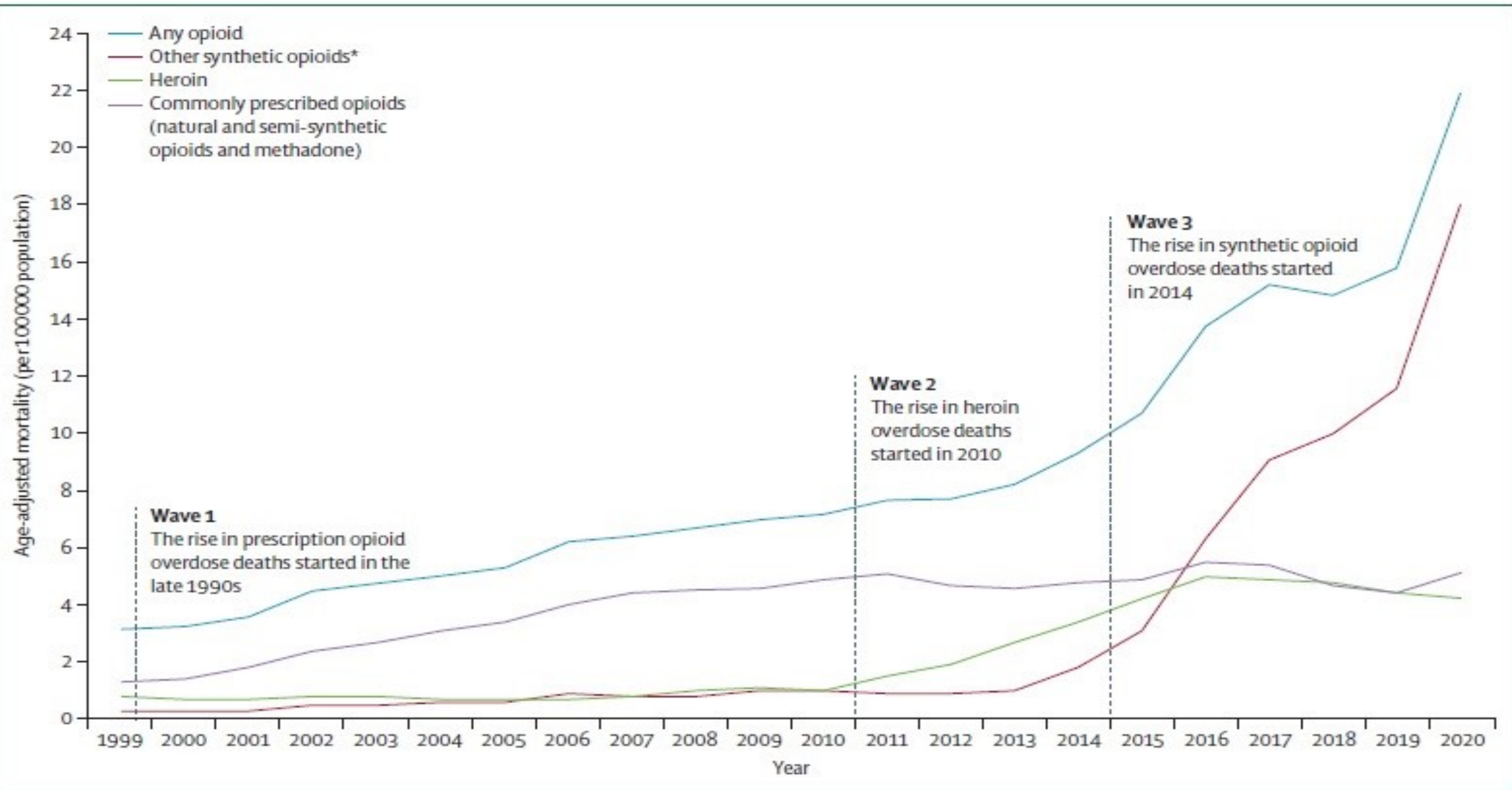
Commission Disclosures

- ▶ Philanthropically funded
- ▶ Commissioners volunteered the time
- ▶ Nothing in the Commission's Report necessarily reflects the official views of Stanford University, the VA, The Lancet, or any organization that employs or supports the work of commissioners.

Commission Members

- ▶ Christina Andrews, Ph.D.
- ▶ Jonathan Caulkins, Ph.D.
- ▶ Mariano Florentino Cuéllar, J.D., Ph.D.
- ▶ Yasmin Hurd, Ph.D.
- ▶ Erin Krebs, M.D.
- ▶ Anna Lembke, M.D.
- ▶ Lisa Larrimore Ouellette, J.D., Ph.D.
- ▶ Chelsea Shover, Ph.D.
- ▶ Amy Bohnert, Ph.D.
- ▶ Margaret Brandeau, Ph.D.
- ▶ Jonathan Chen, M.D., Ph.D.
- ▶ David Juurlink, M.D., Ph.D.
- ▶ Howard Koh, M.D.
- ▶ Sean Mackey, M.D., Ph.D.
- ▶ Brian Suffoletto, M.D.
- ▶ Christine Timko, Ph.D.

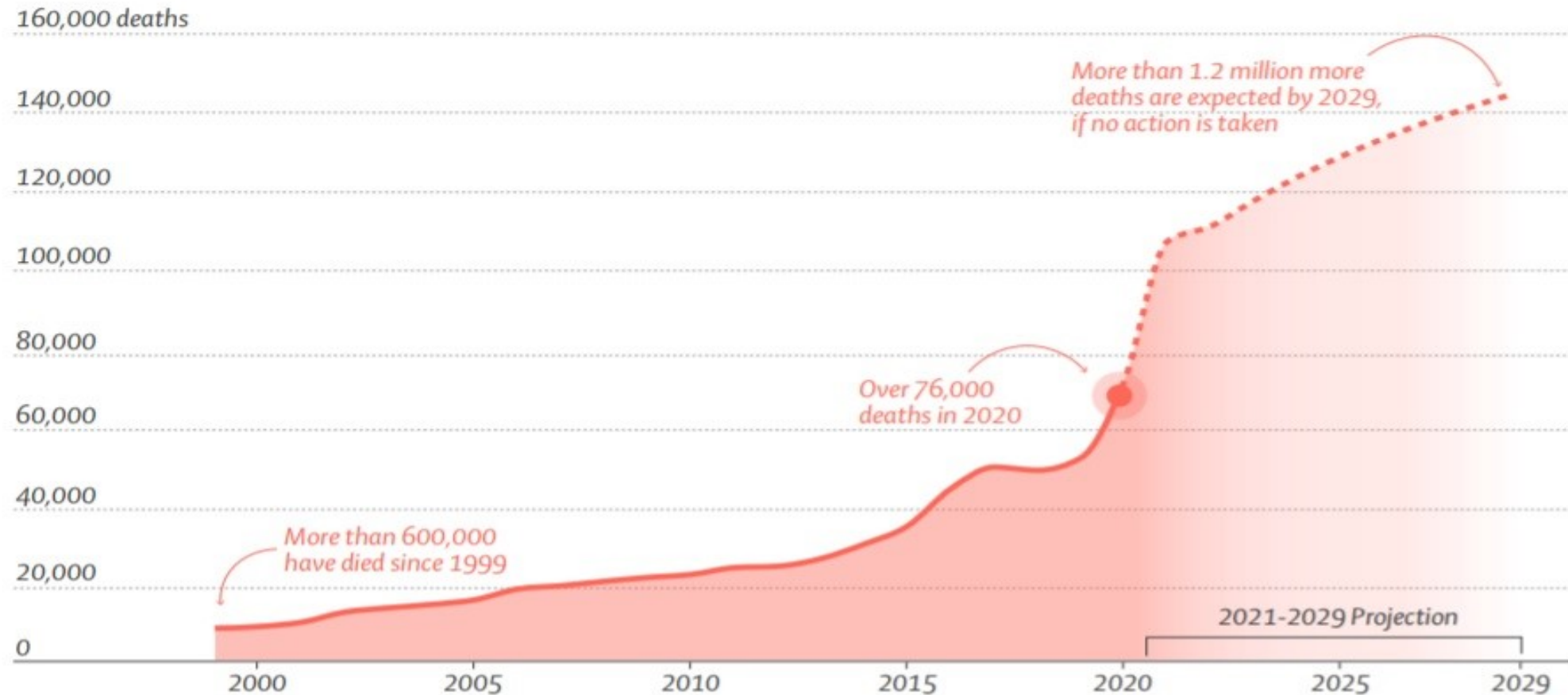
Advisors: Professors Richard Frank, Anne Case, Shelly Greenberg
Special Thanks to: SAMHSA Deputy Assistant Secretary Tom Coderre



The opioid crisis: 1.2 million additional deaths expected in North America by 2029


Without urgent interventions the number of deaths will grow exponentially, and the epidemic will expand globally.

Deaths from opioid overdose in North America

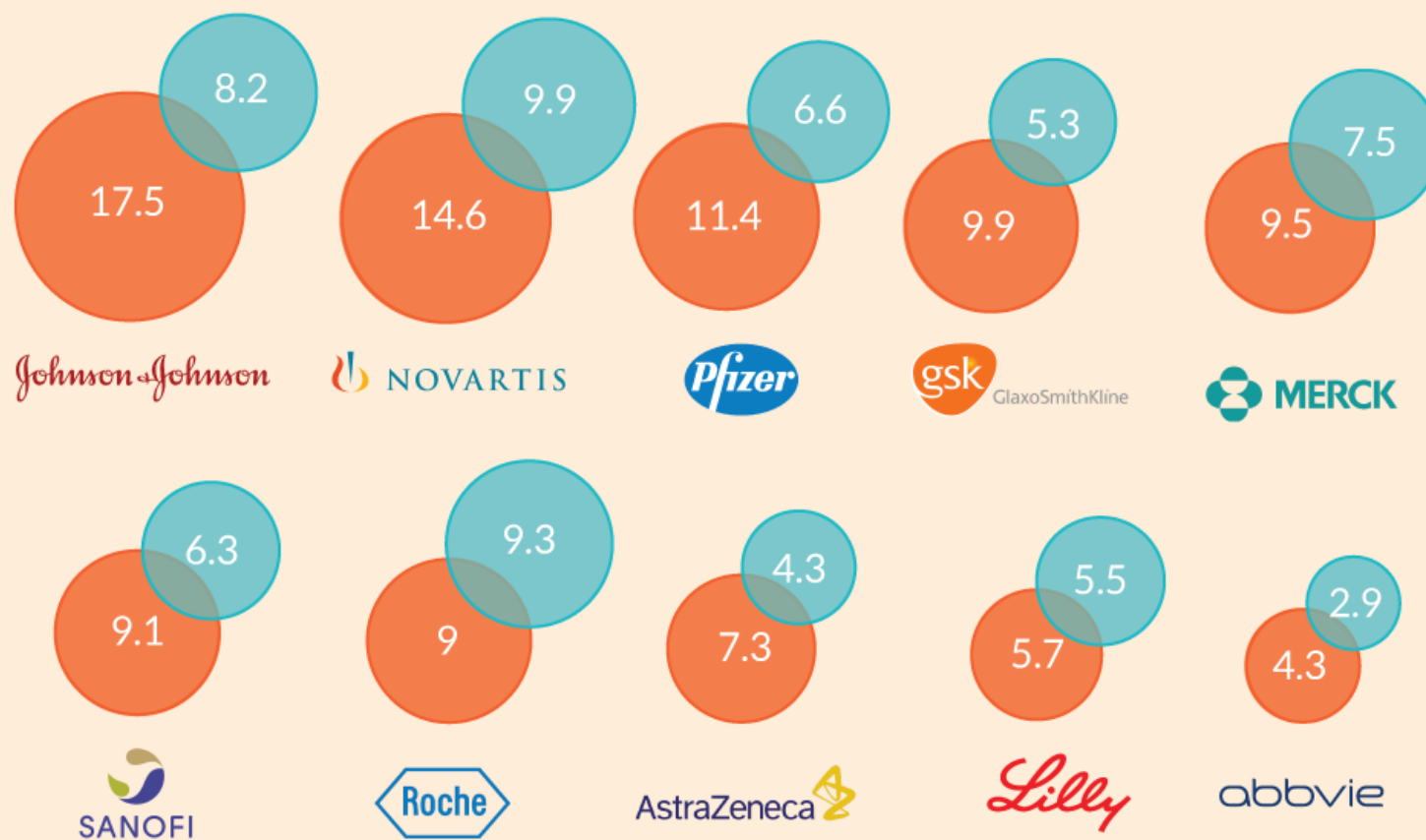


Origin of Crisis: Commission Analysis



- ▶ Initiated in time of legitimate concern about poor pain management
 - ▶ Exploited by opioid manufacturers and distributors
 - ▶ Enabled by failures in regulation, law, health care policy/practice
- 

HOW MUCH DOES BIG PHARMA SPEND ON: SALES & MARKETING vs. RESEARCH & DEVELOPMENT



IN US \$ BILLION, FOR 2013



DOLLARS FOR DOCTORS

American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics

Sens. Baucus and Grassley demand evidence of financial support from the drug industry to nonprofit groups that advocate use of opioid painkillers, including the newly defunct American Pain Foundation.

by Charles Ornstein and Tracy Weber, May 8, 2012, 8:57 p.m. EDT

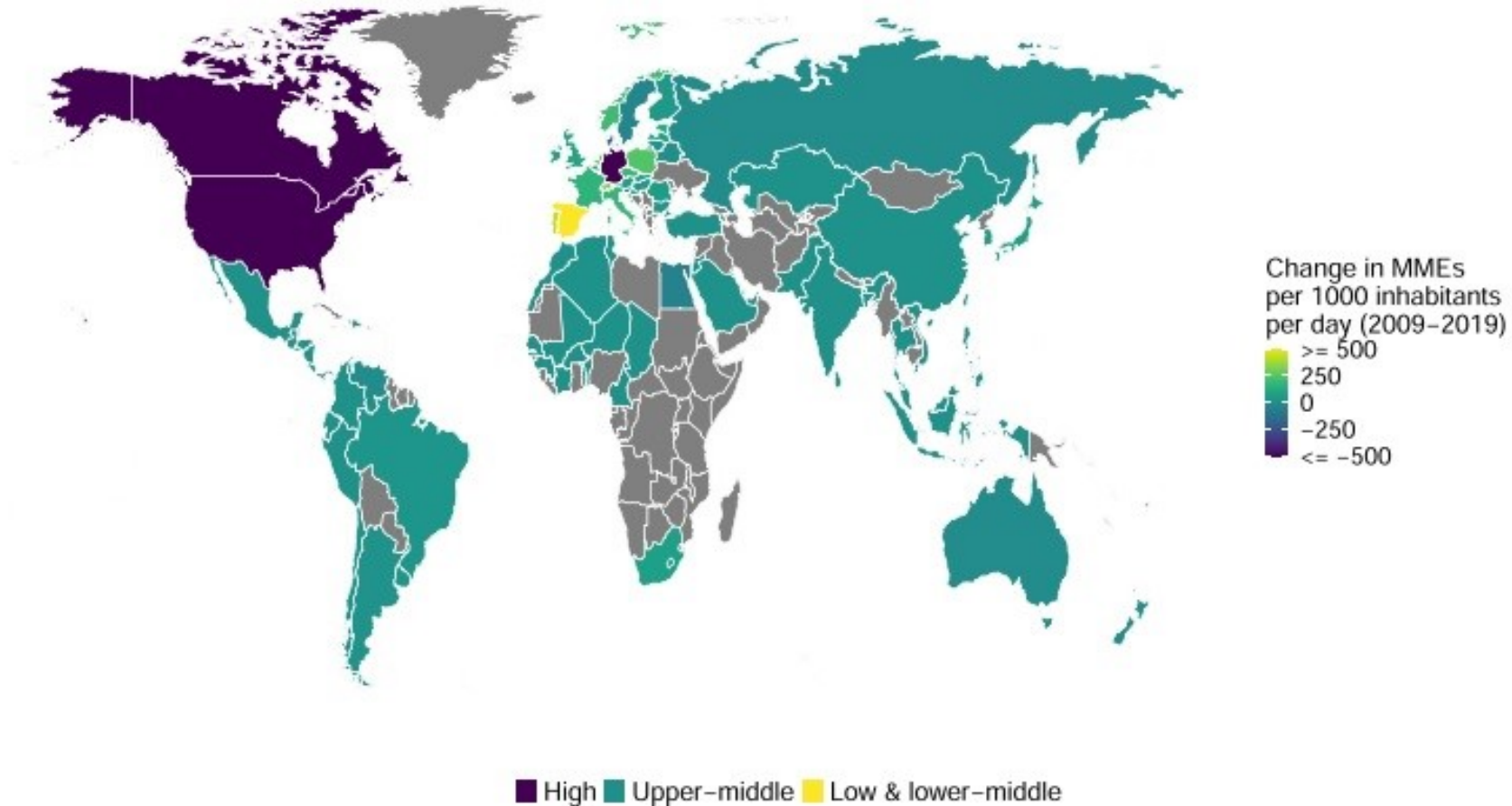


And yet, the opioids remain essential medicines that we cannot do without



And Excess is only one type of Crisis

S. Jayawardana et al. / EClinicalMedicine 42 (2021) 101198



Key Conclusion:

Challenge is to expand access while avoiding corruption, profit-seeking and regulatory failure



OxyContin goes global — “We’re only just getting started”

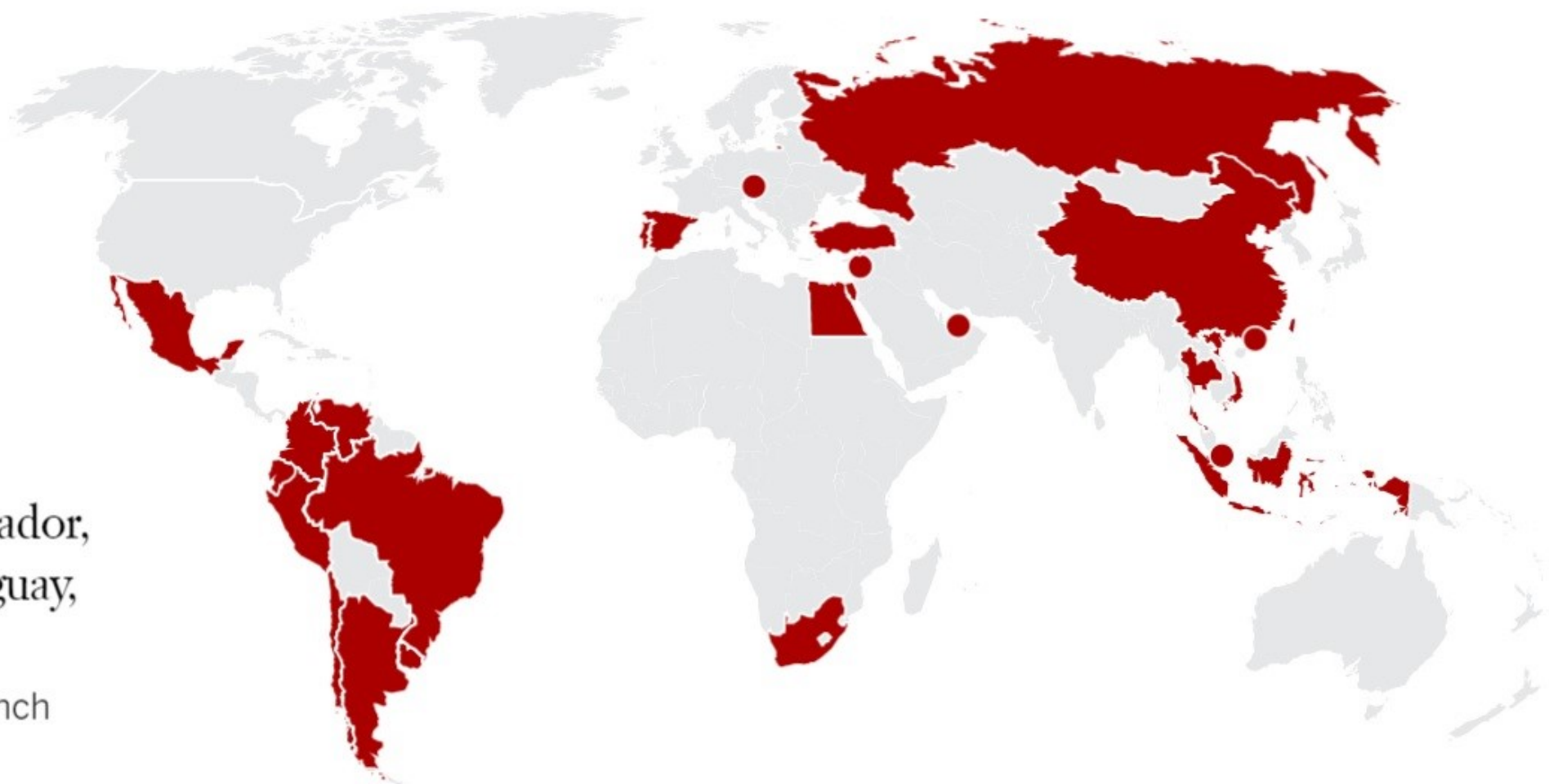
By HARRIET RYAN, LISA GIRION AND SCOTT GLOVER

DEC. 18, 2016

Up next

Chile, Ecuador,
Peru, Uruguay,
Venezuela

Plans to launch
operations



Recommendation adapted from The Lancet Commission on Palliative Care and Pain Relief

- ▶ Distribute free, generic morphine for analgesia to hospitals and hospices in low-income nations

Key Point

- ▶ The balance between the benefits and costs of opioids is more likely to be achieved when the profit motive is not dominant

For more information: [opioids.Stanford.edu](https://opioids.stanford.edu)

opioids.stanford.edu



Stanford University

Stanford

Stanford-Lancet Commission on the North American Opioid Crisis

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Lukas Radbruch

Chair of Palliative medicine at the University of Bonn

Director of the department of Palliative medicine at the University Hospital Bonn,
Germany.



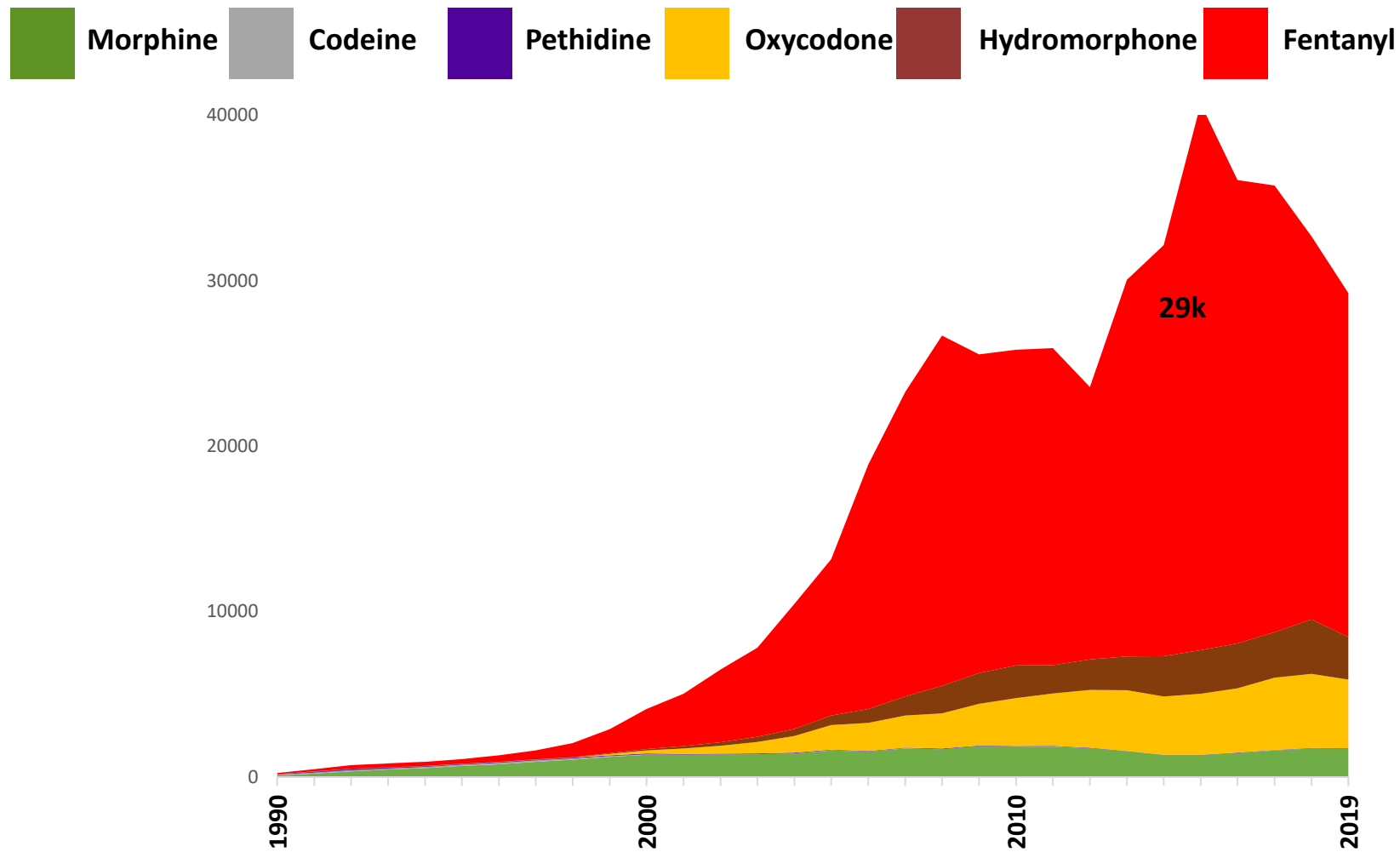
Opioids

High dosage

Transdermal fentanyl
12 x 2.4 mg/d
= 28.8 mg/d
= 2,880 mg/d morphine eq



Distributed opioids in Morphine Equivalent Germany (kg, 1990-2019)



Knaut et al. Lancet Group on Pain Relief and Pall Care

Deaths from Opioids Overdose

US 2015

Palliative care needs covered by opioids: 3147%

Deaths from opioids overdose: 33,000

Overdose deaths/Mio inhabitants: 102.9

Most frequent: heroin

Illicit fentanyl and carfentanyl

Prescription opioids: fraud and theft

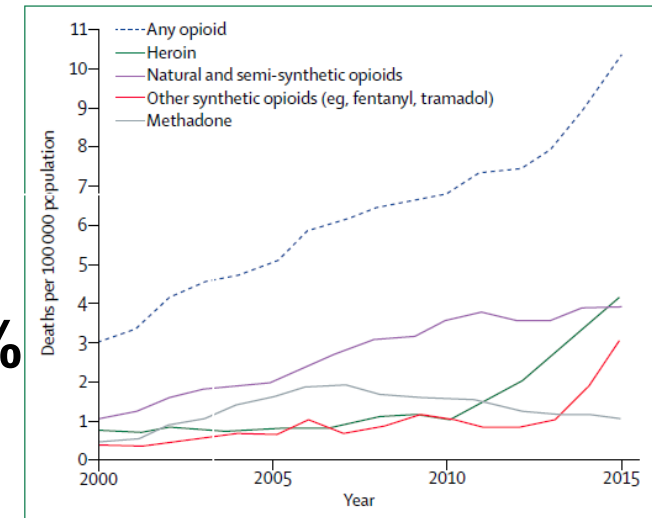


Figure 4: Deaths from opioids overdose, by type of opioid, in the USA, 2000–15
Source: Centers for Disease Control and Prevention, National Center for Health Statistics (Underlying Cause of Death 1999–2015, CDC WONDER Online Database, December, 2016).

Germany 2015

Palliative care needs covered by opioids: 1474%

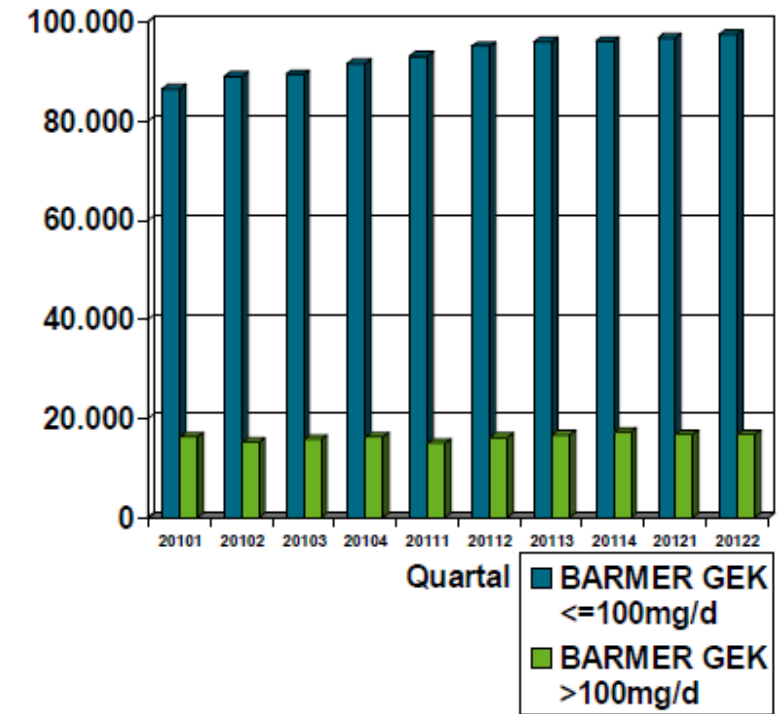
Deaths from opioids overdose: 223

Overdose deaths/Mio inhabitants: 2.7

Most frequent: heroin

Barmer Sickness Fund

Evaluation of 870,000 Patients in 2012



**Opioid prescriptions in three quarterly periods
for 1.3% of all patients**

**Approx. 15% with more than 100 mg per day ME: male, younger patients,
somatoform disorders, depression**

Mental / behavioural disorders:

inpatient treatment needed for 71 patients (0.008%)

**risk factors: male, younger, somatoform disorder, higher dosages,
prescription of tranquilizer**

LONTS Guidelines

Opioids are one drug-based treatment option for (...) therapy of chronic osteoarthritis, diabetic polyneuropathy, postherpetic neuralgia and low back pain

For all other clinical presentations, short- and long-term therapy with opioid-containing analgesics should be evaluated on an individual basis.

Long-term therapy with opioid-containing analgesics is associated with relevant risks (sexual disorders, increased mortality)

Schwerpunkt

English version of „Empfehlungen der aktualisierten Leitlinie LONTS. Langzeitanwendung von Opioiden bei chronischen nicht-tumorbedingten Schmerzen“
DOI 10.1007/s00482-014-1463-x
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¹ Medizinisches Versorgungszentrum (Schmerztherapie, Palliativmedizin, Psychiatrie, Psychotherapie) Saarbrücken – St. Johann, Saarbrücken; ² Klinik Innere Medizin I (Gastroenterologie, Hepatologie, Stoffwechsel- und Infektionskrankheiten, Psychosomatik), Klinikum Saarbrücken GmbH, Saarbrücken; ³ Klinik für Psychosomatische Medizin und Psychotherapie, Technische Universität München, München; ⁴ Orthopädie am Grünen Turm Ravensburg, Ravensburg; ⁵ Allgemeinmedizinische Praxis, Pforzheim; ⁶ Abteilung für Allgemeinmedizin und Versorgungsforschung, Universitätsklinikum Heidelberg, Heidelberg; ⁷ Klinik für Neurologie/Schmerztherapie, Bezirksklinikum Ansbach, Ansbach; ⁸ Klinik für Anästhesiologie und Intensivmedizin, Universität zu Lübeck, Lübeck; ⁹ Clinical Analysis, Research and Application, Kleinmachnow; ¹⁰ Abteilung für Schmerzmedizin, Berufsständeschaftliches Universitätsklinikum Bergmannsheil GmbH, Bochum; ¹¹ Schmerz-OS e.V. Groß Gröden; ¹² Klinik für Palliativmedizin, Universitätsklinikum Bonn, Bonn; ¹³ Malteser Krankenhaus Seeliger Gerhard Bonn/Rhein-Sieg, Bonn; ¹⁴ Universitäts-Schmerz-Centrum, Universitätsklinikum Carl Gustav Carus, Dresden; ¹⁵ Klinik für Anästhesiologie mit Schwerpunkt operative Intensivmedizin, Charité – Universitätsmedizin Berlin, Berlin; ¹⁶ Department Orthopädie, Unfallchirurgie und Paraplegiologie, Konservative Orthopädie/Schmerztherapie, Ambulanz und Tagesklinik, Universitätsklinikum Heidelberg, Heidelberg; ¹⁷ Klinik für Geriatrie und Intensivmedizin, Diakonissenkrankenhaus Mannheim, Mannheim; ¹⁸ Klinische Psychologie, Technische Universität Darmstadt, Darmstadt; ¹⁹ Klinik für Neurologie, Technische Universität München, München; ²⁰ Schmerz-Tagesklinik und -Ambulanz, Universitätsmedizin Göttingen, Göttingen

Recommendations of the updated LONTS guidelines

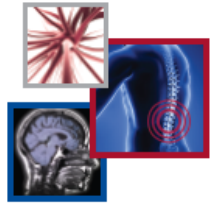
Long-term opioid therapy for chronic noncancer pain



Opioid Indications

Chronic pain

Do	Don't
Cancer pain Palliative care patients Pain with Arthrosis (Diabetic) polyneuropathy Post-zoster pain	Somatoform pain disorders Low back pain Fibromyalgia Headache Rheumatoid arthritis Parkinson Spinal injury



The opioid epidemic and the long-term opioid therapy for chronic noncancer pain revisited: a transatlantic perspective

Winfried Häuser^{*1,2}, Frank Petzke³, Lukas Radbruch⁴ & Thomas R Tölle⁵

Practice points

A Transatlantic Perspective

Recent US and German systematic reviews differ in their appraisal, with a more positive view in Europe and a negative one in the USA.

LtOT should only be performed in patients which responded to an opioid trial (opioid responders).

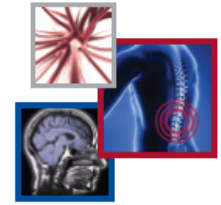
Opioids should not be used for fibromyalgia, irritable bowel syndrome or somatoform pain disorder.

Opioid analgesics remain an important option for the drug treatment of carefully selected patients with chronic osteoarthritis pain, low back pain and neuropathic pain.

A Transatlantic Perspective US disadvantages

The opioid epidemic and the long-term opioid therapy for chronic noncancer pain revisited: a transatlantic perspective

Winfried Häuser^{*12}, Frank Petzke³, Lukas Radbruch⁴ & Thomas R Tölle⁵



Physician-related:

lack of access to multicomponent therapy; ease of prescribing opioids compared with other pain therapies

Patient-related:

Focus on pain rather than on psychological distress as a target; on pain relief than on functional improvement;

Society-related:

human right to have access to pain treatment interpreted as right to access opioid therapy; better insurance coverage for medications than for psychological pain therapies; aggressive marketing of sustained opioids

University Hospital Bonn

Palliative Care Unit: Strongbox





Dr Stephen R Connor

Executive Director,
Worldwide Hospice Palliative
Care Alliance, London UK

WHO Webinar:

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

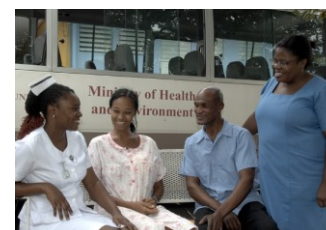
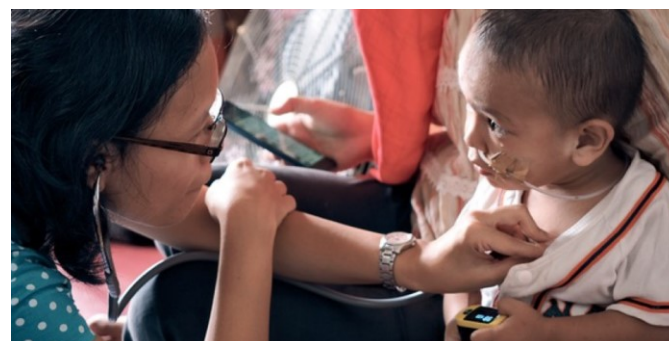
PRESENTATION:

Lack of access to pain relief “amounts to torture”: Putting human rights at the center of government policy on access



Global Atlas of Palliative Care

2nd Edition



The need for palliative care - a global perspective

- Almost 57 million need PC
(Not including COVID)
 - **25.7M at EOL**
- 82.5% LMIC
- 67% 50+ / 7% children
- >18 die million in pain
- + >100 million grieving people – 1 billion attend funerals



Palliative care, including pain relief, is increasingly recognized under international and regional human rights law.

- 1) the first human rights treaty to explicitly recognize the right to palliative care, the Inter-American Convention on the Rights of Older Persons (2012-15);
- 2) the first World Health Assembly resolution on palliative care (2014);
- 3) a report by the UN Special Rapporteur on Torture with a focus on denial of pain treatment (2009, 2013);
- 4) addressing the availability of controlled medicines at the UN General Assembly Special Session on the World Drug Problem (2016).



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Press Release

The Americas Becomes First Region in the World to Have an Instrument for the Promotion and Protection of the Rights of Older Persons

Protected Rights: States Parties shall take steps to ensure that public and private institutions offer older persons access without discrimination to comprehensive care, including palliative care...

Ensure that medicines recognized as essential by the World Health Organization, including controlled medicines needed for palliative care, are available and accessible for older persons.

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

“Affirming that access to palliative care and to essential medicines for medical and scientific purposes manufactured from controlled substances, including opioid analgesics such as morphine, in line with the three United Nations international drug control conventions, contributes to the realization of the right to the enjoyment of the highest attainable standard of health and well-being”



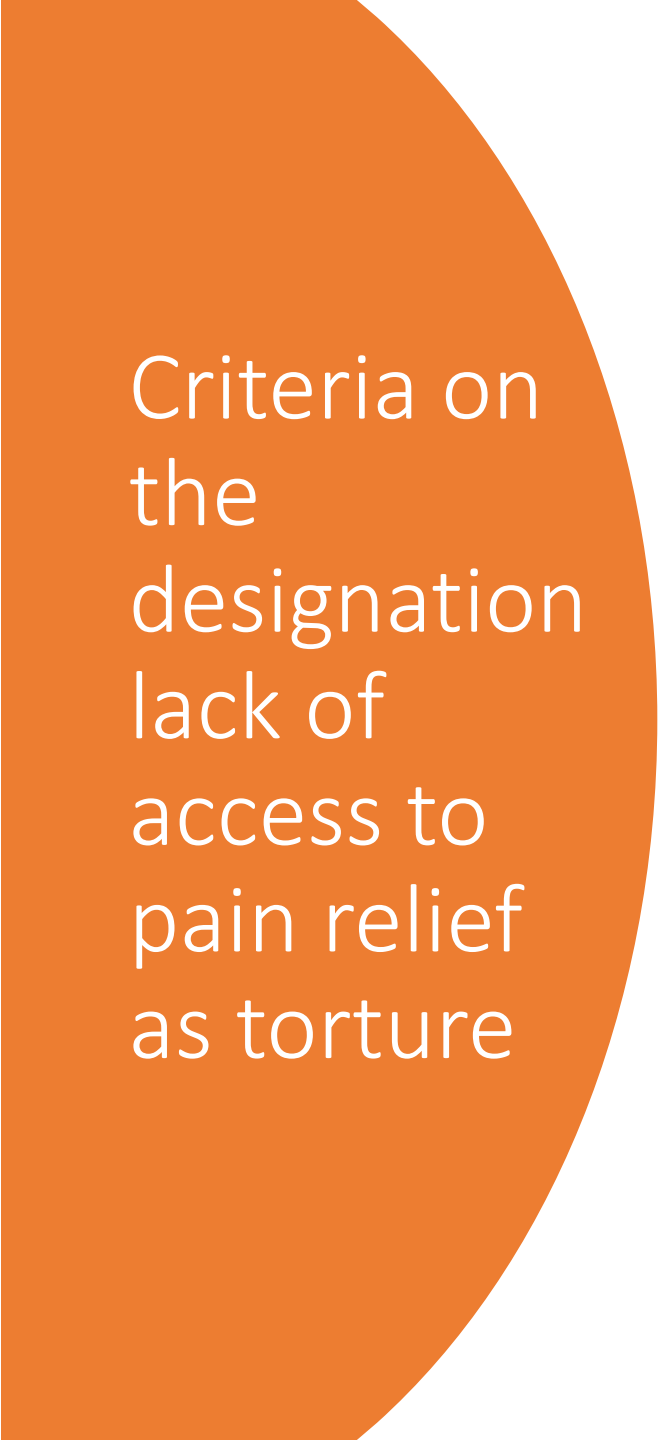
UNITED NATIONS
HUMAN RIGHTS
OFFICE OF THE HIGH COMMISSIONER

Special Rapporteur on Torture

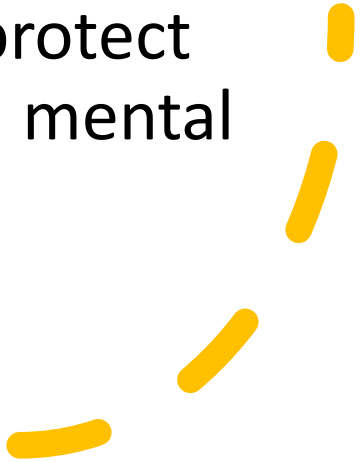
- “the de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment.”
Special Rapporteur on Torture, Professor Manfred Nowak (2009)



- “Governments must guarantee essential medicines—which include, among others, opioid analgesics—as part of their minimum core obligations under the right to health and take measures to protect people under their jurisdiction from inhuman and degrading treatment.”
- —*UN Special Rapporteur on Torture, 2013*

A large orange semi-circle graphic on the left side of the slide, containing the title text.

Criteria on the designation lack of access to pain relief as torture

- “the suffering is severe and meets the minimum threshold under the prohibition against torture and ill-treatment”;
 - “the State is, or should be, aware of the suffering, including when no appropriate treatment was offered”; and
 - “The Government failed to take all reasonable steps to protect individuals' physical and mental integrity.”
- 
- A decorative yellow dashed line graphic in the bottom right corner of the slide.

UNGA Special Session on the World Drug Problem (2016)

- In 2016, the UN General Assembly Special Session on the World Drug Problem adopted a consensus document that, for the first time, included a stand-alone section on controlled medicines and called for countries to take steps to ensure their availability
- “Operational recommendations on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion”





UNODC

United Nations Office on Drugs and Crime

OUTCOME DOCUMENT OF THE 2016 UNITED NATIONS GENERAL ASSEMBLY SPECIAL SESSION ON THE WORLD DRUG PROBLEM

**OUR JOINT COMMITMENT TO EFFECTIVELY ADDRESSING
AND COUNTERING THE WORLD DRUG PROBLEM**

**UNGASS
2016**

**SPECIAL SESSION OF THE UNITED NATIONS GENERAL ASSEMBLY
ON THE WORLD DRUG PROBLEM**



INTERNATIONAL NARCOTICS CONTROL BOARD



Availability of Internationally Controlled Drugs:
**Ensuring Adequate Access for
Medical and Scientific Purposes**

*Indispensable, adequately available
and not unduly restricted*

The Right to the Highest Attainable Standard of Health

- General Comment 14,
**Committee on Human Rights
ICESCR**. 2000. P.34.
- In particular, States are under the obligation to respect the right to health by, inter alia, refraining from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and **palliative health services**

Palliative Care: A Critical Component of the Right to Health

It is critical to provide “attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity.” —**UN Committee on Economic, Social and Cultural Rights, 2000**

Palliative care is a recognized component of the right to the highest attainable standard of health, which is protected in article 12 of the International Covenant on Economic, Social and Cultural Rights, and in article 24 of the **Convention on the Rights of the Child**.

Global Health Policy Progress

- Advocacy for Palliative Care has resulted in inclusion of palliative care in key UN policy documents:
 - 1990's WHO Definition of Palliative Care (PC)
 - 2013 Inclusion of PC in the UN Universal Health Coverage Continuum
 - 2016 UN Gen Ass Spec Session World Drug Problem
 - 2014 World Health Assembly Resolution on Palliative Care
 - 2017 World Health Assembly Resolution on Cancer
 - 2017 World Health Assembly Resolution on Dementia
 - 2018 Astana Declaration on Primary Care
 - (2023 Pandemic Treaty)

Summary

- Palliative care and pain relief are considered a part of the right to health, though it is explicitly mentioned in only a few enforceable instruments.
- The focus is on the responsibility of governments to provide education, policy, and essential medicines, not on individual clinicians

The greatest evil is physical pain – St Augustine





Thank you!

For questions about this presentation contact me at
sconnor@thewhpca.org

Panel discussion



In your view, why
access to morphine
for medical purposes
has been such an
intractable problem?



In your view, what should be the main elements of the **roadmap** to improve **safe access** to morphine by 2030?



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**

Q&A with the audience

Thank you