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

Lessons from countries

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

World Health Organization

75 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

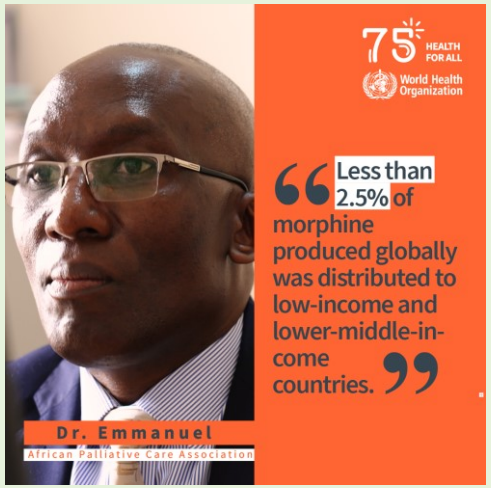
https://www.who.int/publications/i/item/9789240075269

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

World Health Organization 75 HEALTH FOR ALL

Today's session

Rumalie (Mae) Corvera
Palliative Medicine Specialist, Asian Hospital and Medical Centre, Asian Cancer Institute, the Philippines
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President, National Hospice and Palliative Care Council of the Philippines

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Clinical nurse specialist, Balsam-the Lebanese Center for Palliative Care,
American University of Beirut Medical Centre, Lebanon

Emmanuel Luyirika
Executive Director, The African Palliative Care Association, Uganda

Suzanne Nielsen
Professor and Deputy Director, Monash Addiction Research Centre, Monash University, Australia

Xiaohong Ning
Director and Associate Professor, Center for Palliative Care Medicine
Peking Union Medical College Hospital, China

Presentations

Improving Access to Morphine in the Philippines

Challenges in reaching people across the islands

Dr. Rumalie A. Corvera

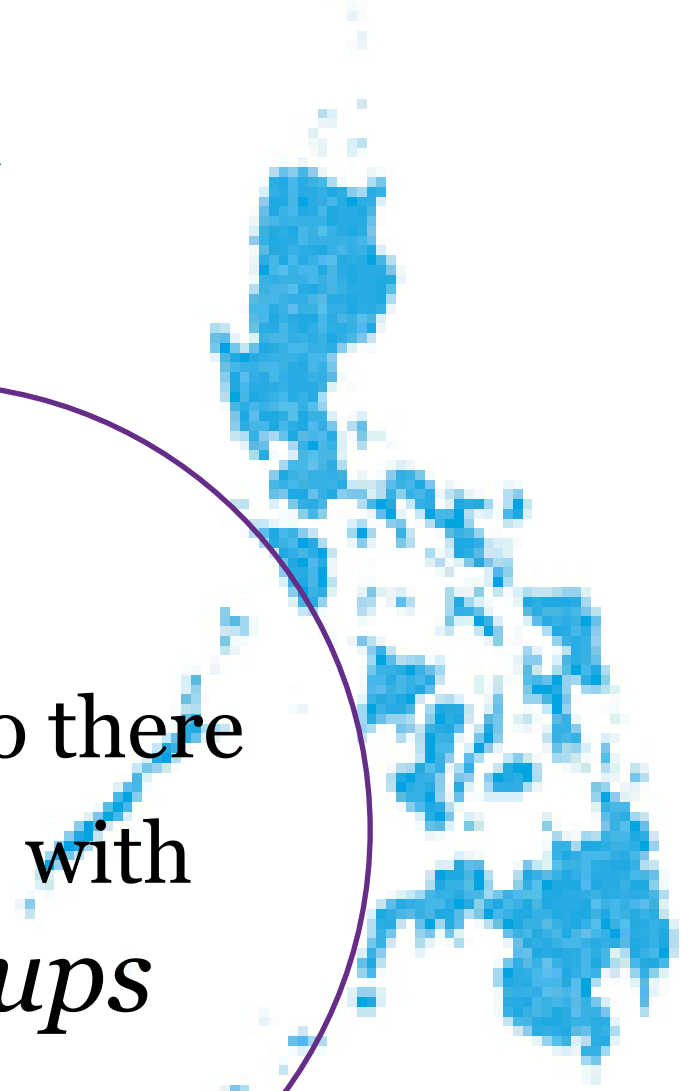
President, National Hospice and Palliative Care Council of the Philippines

Objectives

- To share a snapshot of the Philippines as an Archipelago and how it affects healthcare delivery throughout the country in general.
- To describe the consequences of limited Morphine access in cancer care and health-related suffering.
- To share highlights of how improved access to Morphine in the Philippines was addressed through capacity building and advocacy for Palliative Care.
- To share the new and present challenges of Morphine access in the country through the voice of Pain and Palliative Medicine specialists and government.

The Philippine Archipelago, People and Healthcare

Within about *2000* habitable of the total *7641 islands* of our archipelago there are approximately *117.3 M people*, with around *175 ethnolinguistic groups*



The Philippine Archipelago, People and Healthcare

- *Decentralized system* of government reflected in the governance and structure of the health care system.

- The distribution of health infrastructure as well as human resources is heavily skewed towards the National Capital Region and Luzon. This physical imbalance is *compounded by unequal financial access to health service*

The Philippine Archipelago, People and Healthcare

A cross-sectional study was conducted at a representative cancer center in the Philippines, enrolling 351 cancer patients. Approximately 3 out of 5 patients did not receive adequate pain control, and one-third of patients experienced severe pain.

The under treatment of pain discovered in this study (59% of cancer patients) is alarming"

The experience of pain among cancer patients at the university of the Philippine General Hospital Cancer Institure- A cross sectional study. Harold Nathan C. Tan, Rogelio Nona Velasco, Lance Isidore Garcenila Catedral, Michael Ducusin San Juan, Corazon Ngelangel, and Emiliano CalvoJournal of Clinical Oncology 2021 39:15_suppl, e24078-e24078

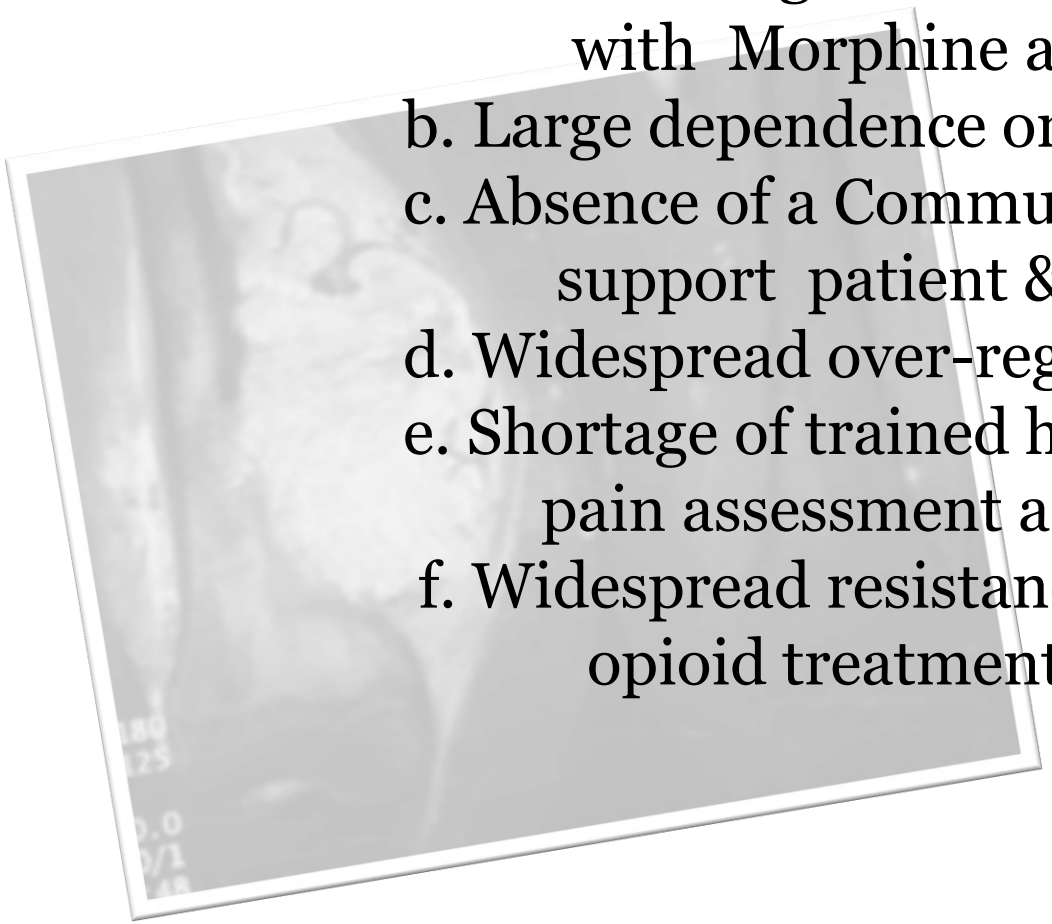
The Philippine Archipelago, People and Healthcare

"In the Philippines, a lower-middle income country in Southeast Asia of over 110 million people, up to 75% of patients with cancer suffer from inadequate pain relief."

-Ho FDV, De Luna DV, Cubarrubias DLPF, Ong EP, Abello RMR, Ansay MFM, Taliño MKV, Robredo JPG, Eala MAB, Dee EC. Palliative and Supportive Care in the Philippines: Systems, Barriers, and Steps Forward. J Palliat Care. 2023 Feb

Historical Challenges

a. The lack of general knowledge of and experience with Morphine among health care workers.
b. Large dependence on charitable donations for their supply.
c. Absence of a Community-based health care program to support patient & family.
d. Widespread over-regulation of opioid use.
e. Shortage of trained health care workers thus inadequacies in pain assessment and knowledge about managing pain.
f. Widespread resistance among patients and physicians toward opioid treatment.



National Progress

Improving access to Morphine for patients in need, primarily through *capacity building* and *advocating for the integration of Palliative and Hospice Care into our health care system*.

Historical Milestones

1987

- The Pain Society of the Philippines was formed

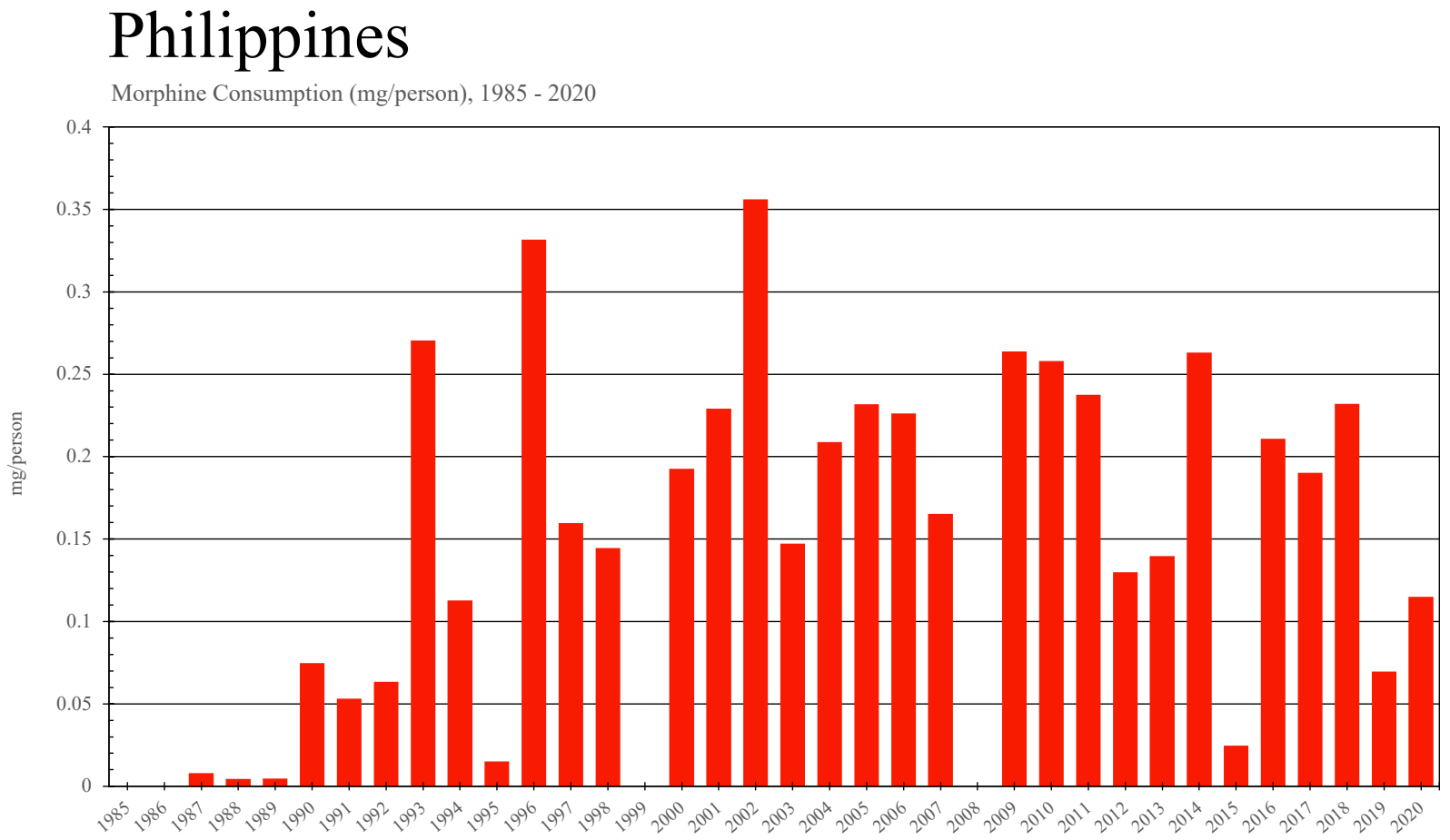
1989

- Pain control was integrated into the Philippine Cancer Control Program
- Morphine available to DOH accredited hospitals
- Hospice and Palliative Care was integrated into the Family Health Care Program of the Department of Family and Community Medicine (DFCM) of the University of the Philippines - Philippine General Hospital (UP-PGH)

2003

- National Hospice and Palliative Care Council of the Philippines (Hospice Philippines) was formed

Historical Milestones



Sources: International Narcotics Control Board (data); The World Bank (population)
Created by: Walther Global Palliative Care & Supportive Oncology, Indiana University Simon Comprehensive Cancer Center, 2022

Historical Milestones

2010

- Presidential Proclamation No. 2016 s. 2010 declaring Hospice Philippines as one of the major conduits of the Department of Health in the Distribution of Morphine.

2012

- The Philippine Society of Hospice and Palliative Medicine (PSHPM) was established and was recognized as a Sub-Specialty Society under the Philippine Academy of Family Physicians (PAFP).

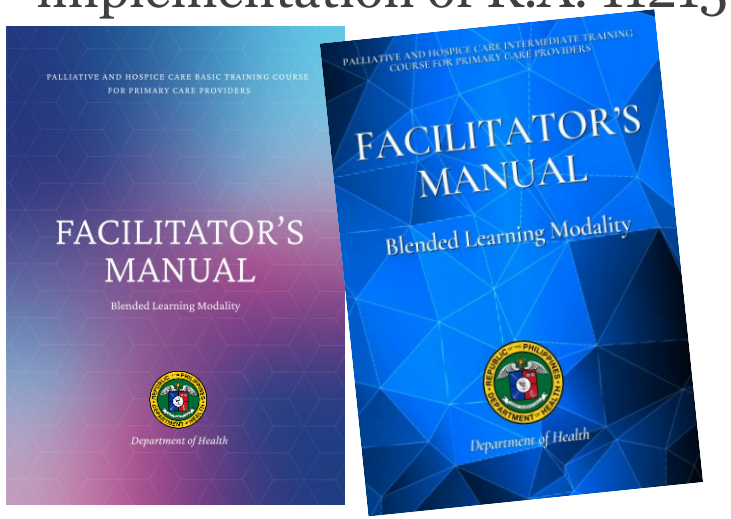
2015

- The Philippines Department of Health had an Administrative Order 2015-0052 also known as the National Policy for Palliative and Hospice Care in the Philippines that was signed and circulated on December 21, 2015

Historical Milestones

2020

- The Department of Health released Department Order 2020-1431 which aims for the Development of *Manual of Operations, Procedures and Standards and Training Modules* and Piloting in Selected Advance Implementation Sites of the National Palliative and Hospice Care Program, this is in light of the implementation of R.A. 11215 and R.A. 11223



National Progress

National Laws and Policies Related to Palliative and Hospice Care

Administrative Orders

- AO 2011-0004 Guideline for distribution and monitoring of Morphine sulfate
- AO 2015-0052 National Policy on Palliative and Hospice Care in the Philippines

Republic Acts

- RA 11215 National Integrated Cancer Control Act;
- RA 11223 Universal Health Care/UHC Act;

Philippine National Objectives for Health 2017-2020

- Access to essential quality health products and services shall be ensured at appropriate levels of care *including palliative care in the comprehensive essential health service package* and specialized health services for all life stages

National Progress

Palliative and Hospice Care Provisions in the Philippines

Government

- Philippine General Hospital*
- Phil. Children's Medical Centre
- National Children’s Hospital
- Southern Philippines Medical Centre*
- National Kidney and Transplant Institute*
- Davao Regional Medical Center *
- JBL Memorial Regional Center *
- Cagayan Valley Medical Centre
- Valenzuela Medical Center

National Progress

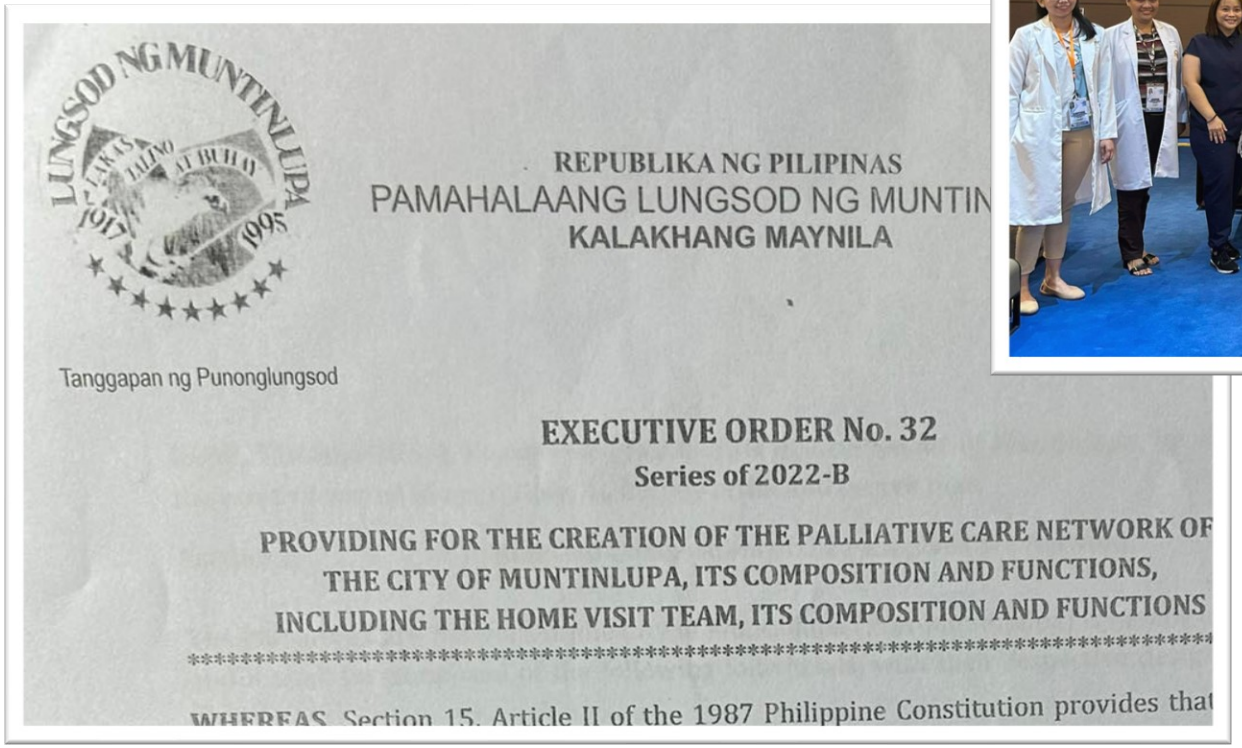
Palliative and Hospice Care Provisions in the Philippines

Private

- Makati Medical Center*
- Asian Hospital and Medical Centre *
- The Medical City*
- St. Lukes Global ; St. Lukes Quezon City
- Manila Medical Center
- FEU*
- University of Sto. Thomas Hospital
- Tagaytay Medical Center
- Tagaytay Medical Center
- Cardinal Santos
- Chong HUA Hospital
- Siliman Medical Center
- University Hospital CDO
- St. Paul's & Quailed Iloilo
- De La Salle Health Sciences Institute
- Healthserv Los Baños Medical Centre

National Progress

Local Government Unit Provider



LUNGSOD NG MUNTINLUPA

Tanggapan ng Punonglungsod

REPUBLIKA NG PILIPINAS
PAMAHALAANG LUNGSOD NG MUNTIN
KALAKHANG MAYNILA

EXECUTIVE ORDER No. 32
Series of 2022-B

PROVIDING FOR THE CREATION OF THE PALLIATIVE CARE NETWORK OF THE CITY OF MUNTINLUPA, ITS COMPOSITION AND FUNCTIONS, INCLUDING THE HOME VISIT TEAM, ITS COMPOSITION AND FUNCTIONS

****

WHEREAS, Section 15, Article II of the 1987 Philippine Constitution provides that

REPUBLIC OF THE PHILIPPINES
City of Muntinlupa

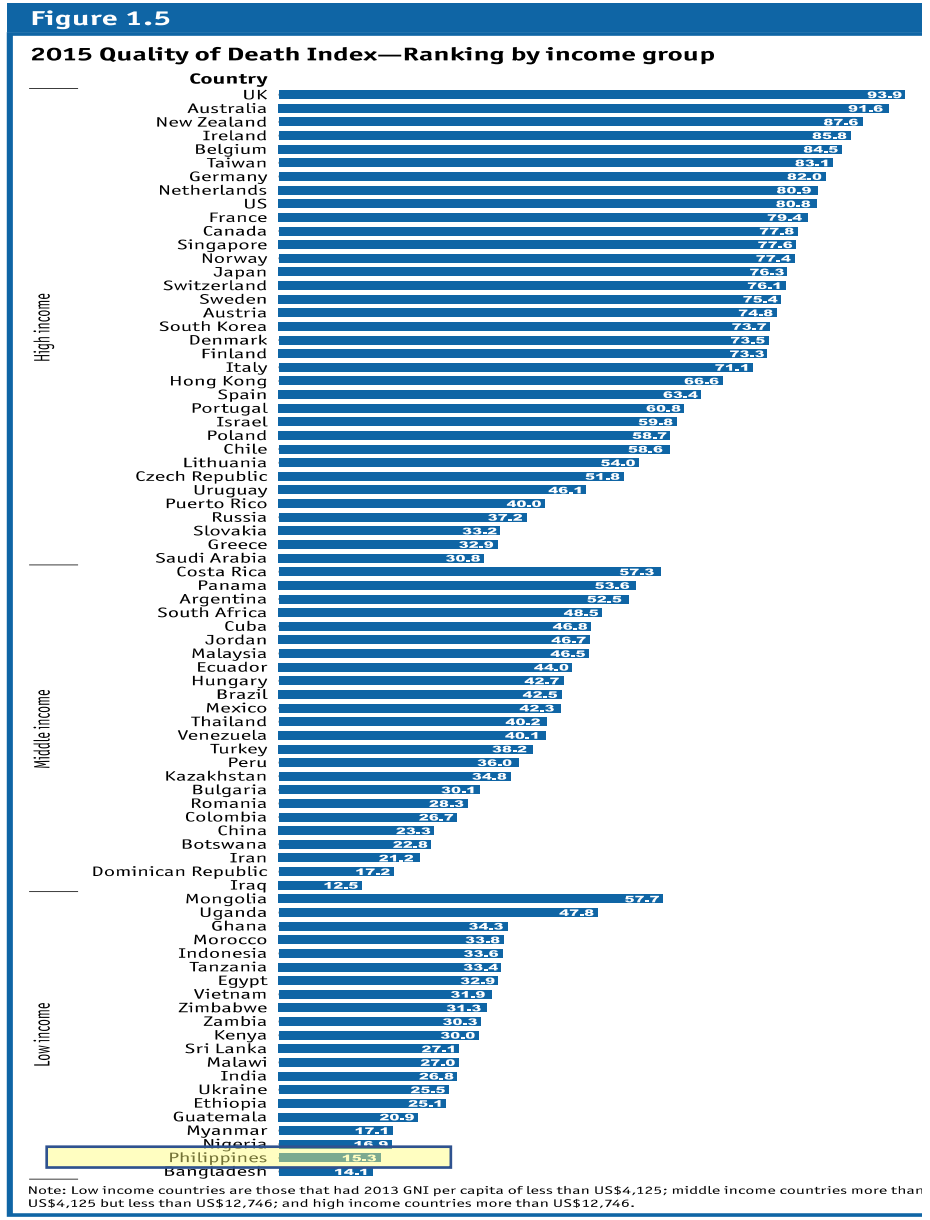
Palliative Med Muntinlupa

The first LGU-championed program as a product of long-term commitment, planning and partnerships

Outcomes

Philippines was number 78,
third from the lowest next to Iraq
and Bangladesh in the 2015
Quality of Death Index by
a Economist Intelligence Unit report
because of these factors:

- Severe shortage of specialized palliative care professionals
- Lack of government-led strategy for the development and promotion of national palliative care
- Limited number of government subsidies or programs for individuals accessing palliative care services
- Limited public understanding and awareness of palliative care services.



Outcomes

Cross Country Comparison of Expert Assessments of the Quality of Death and Dying 2021

Eric A. Finkelstein, PhD, Afsan Bhadelia, PhD, Cynthia Goh, MBBS, Drishti Baid, BA, Ratna Singh, MA,Sushma Bhatnagar, MD, and Stephen R. Connor, PhD

Philippines is number 38

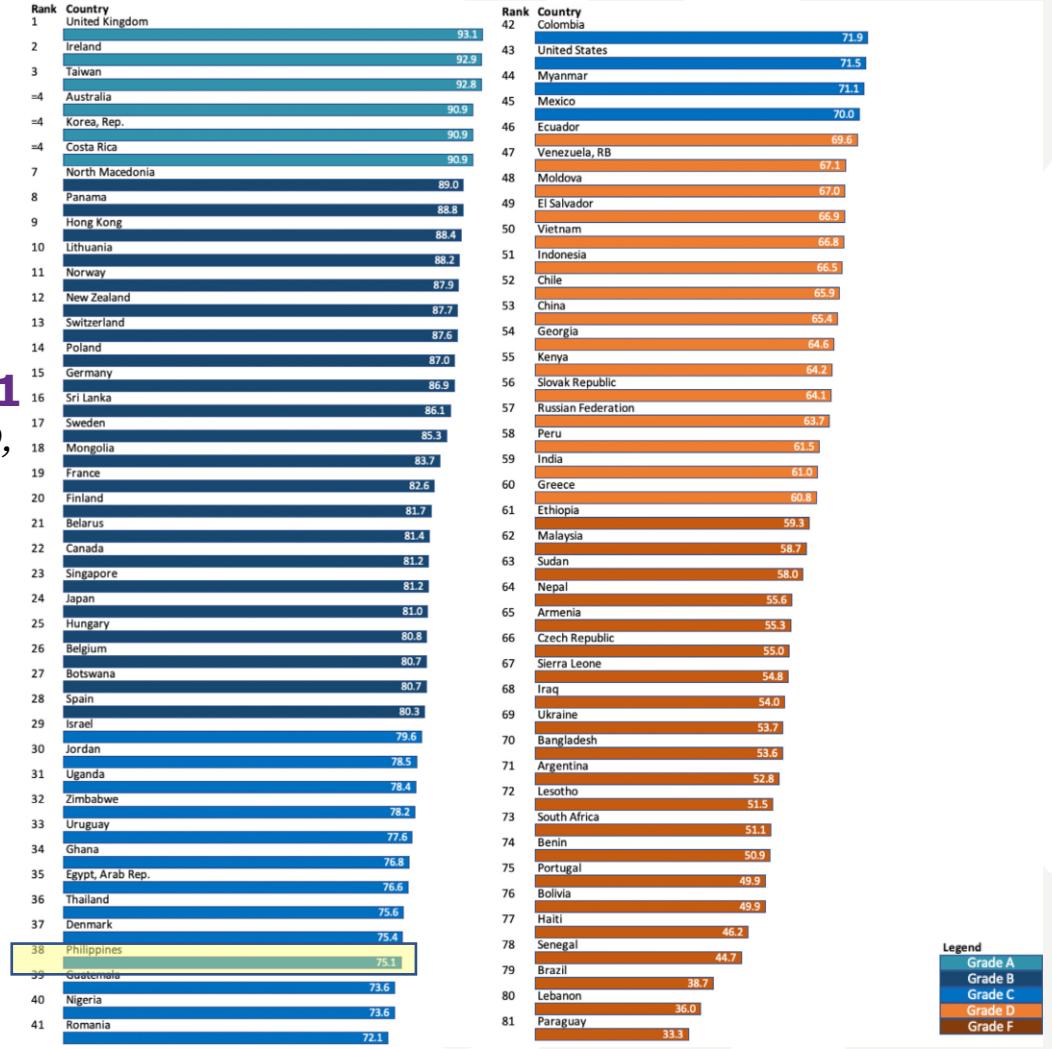


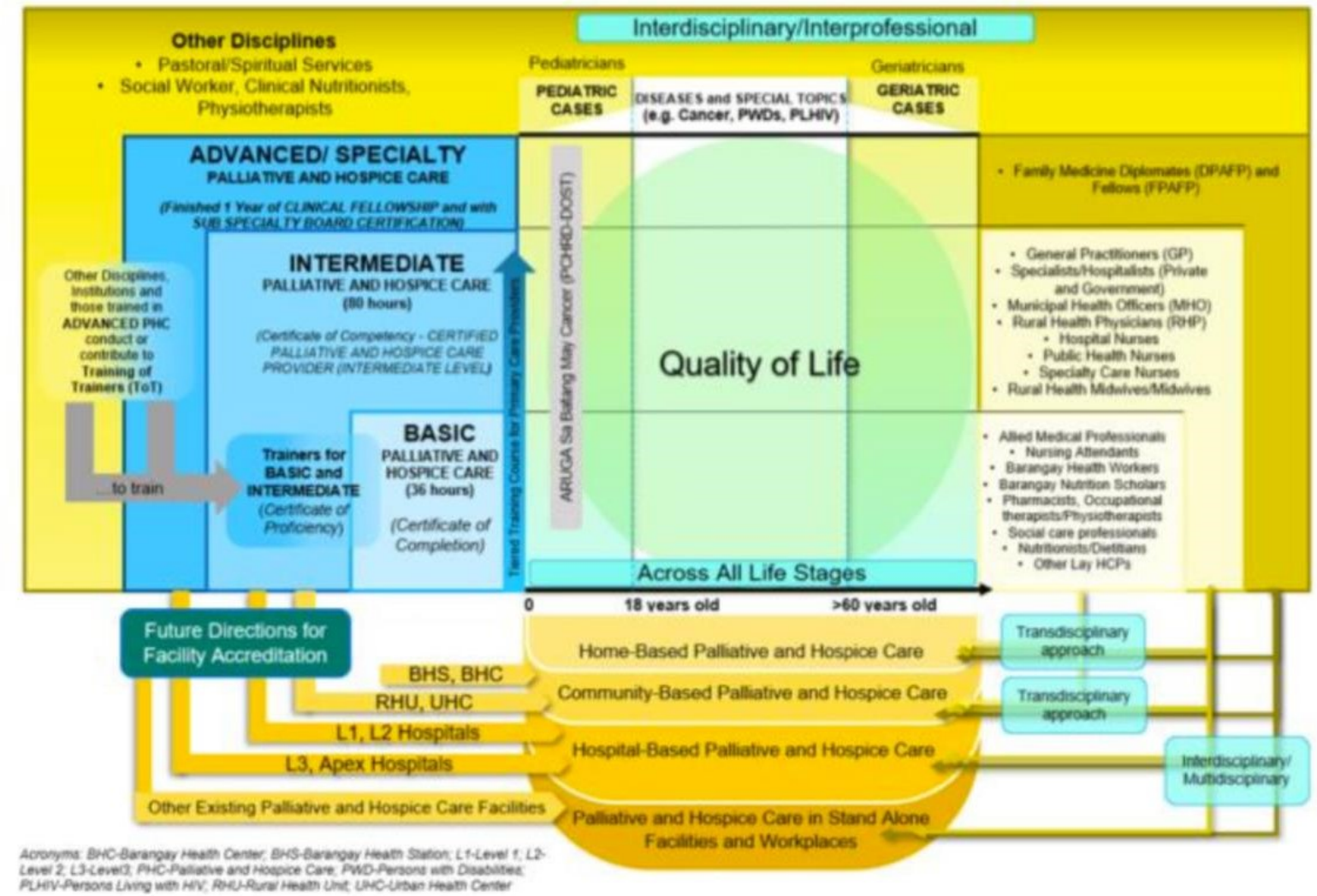
Fig. 3. Rankings of countries (and Hong Kong and Taiwan) based on input from country experts.

Moving Forward

Present Challenges

a. Policies which create barriers for legitimate access to morphine.
b. Compliance to Regulations result to excessive paperwork, which may cause the delay to the availability of morphine.
c. Supply Chain Issues
d. Inadequate healthcare facilities, particularly in underserved areas or regions with limited resources, can impact patients' access to appropriate pain management, including morphine.
e. Knowledge Gap

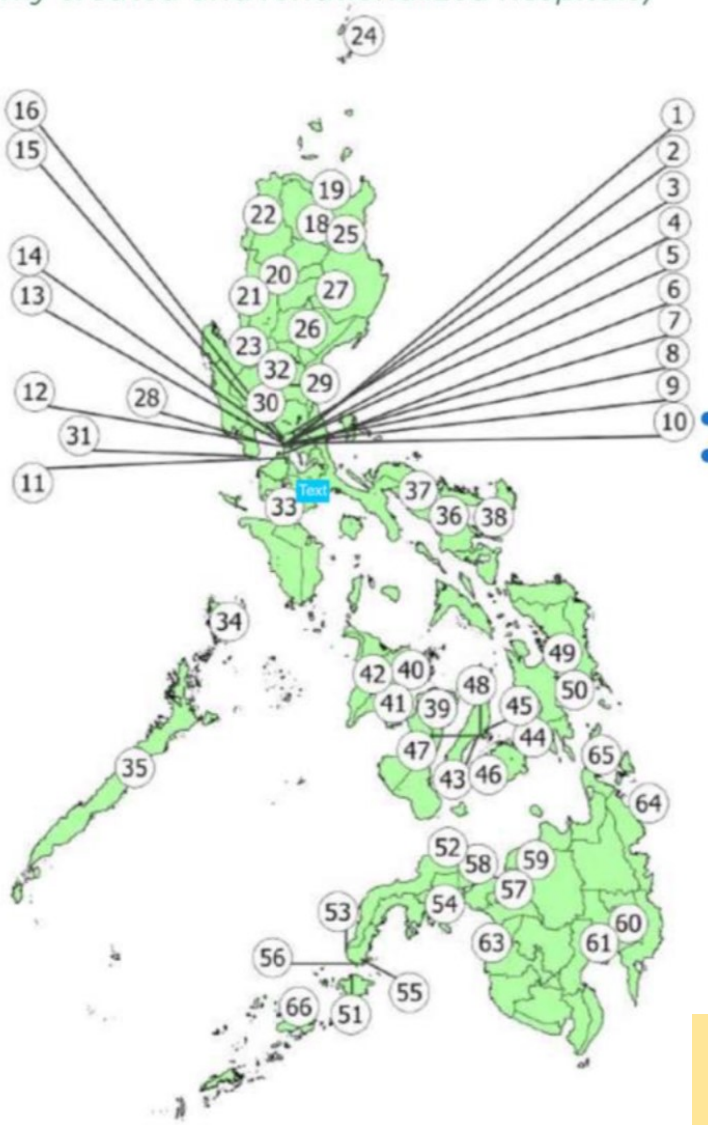
National Palliative and Hospice Care Training Program Framework



Distribution of DOH hospitals

(excluding GOCCs, extension, newly created and renationalized hospitals)

1) AMANG RODRIGUEZ MEMORIAL MEDICAL CENTER
2) DR. JOSE FABELLA MEMORIAL HOSPITAL
3) DR. JOSE N. RODRIGUEZ MEMORIAL HOSPITAL
4) EAST AVENUE MEDICAL CENTER
5) JOSE R. REYES MEMORIAL MEDICAL CENTER
6) LAS PIÑAS GENERAL HOSPITAL & SATELLITE TRAUMA CENTER
7) NATIONAL CENTER FOR MENTAL HEALTH
8) NATIONAL CHILDREN'S HOSPITAL
9) PHILIPPINE ORTHOPEDIC CENTER
10) QUIRINO MEMORIAL MEDICAL CENTER
11) RESEARCH INSTITUTE FOR TROPICAL MEDICINE
12) RIZAL MEDICAL CENTER
13) SAN LAZARO HOSPITAL
14) SAN LORENZO RUIZ GENERAL HOSPITAL
15) TONDO MEDICAL CENTER
16) VALENZUELA MEDICAL CENTER
17) BAGUIO GENERAL HOSPITAL AND MEDICAL CENTER
18) CONNER DISTRICT HOSPITAL
19) FAR NORTH LUZON GENERAL HOSPITAL AND TRAINING CENTER
20) LUIS HORA MEMORIAL REGIONAL HOSPITAL
21) ILOCOS TRAINING AND REGIONAL MEDICAL CENTER
22) MARIANO MARCOS MEMORIAL HOSPITAL AND MEDICAL CENTER
23) REGION I MEDICAL CENTER
24) BATANES GENERAL HOSPITAL
25) CAGAYAN VALLEY MEDICAL CENTER
26) REGION II TRAUMA AND MEDICAL CENTER
27) SOUTHERN ISABELA MEDICAL CENTER
28) BATAAN GENERAL HOSPITAL AND MEDICAL CENTER
29) DR. PAULINO J. GARCIA MEMORIAL RESEARCH & MEDICAL CENTER
30) JOSE B. LINGAD MEMORIAL GENERAL HOSPITAL
31) MARIVELES MENTAL WELLNESS AND GENERAL HOSPITAL
32) TALAVERA GENERAL HOSPITAL
33) BATANGAS MEDICAL CENTER
34) CULION SANITARIUM AND GENERAL HOSPITAL
35) OSPITAL NG PALAWAN
36) BICOL MEDICAL CENTER
37) BICOL REGION GENERAL HOSPITAL AND GERIATRIC MEDICAL CENTER



38) BICOL REGIONAL TRAINING AND TEACHING HOSPITAL
39) CORAZON LOCSIN MONTELIBANO MEMORIAL REGIONAL HOSPITAL
40) DON JOSE S. MONFORT MEDICAL CENTER EXTENSION HOSPITAL
41) WESTERN VISAYAS MEDICAL CENTER
42) WESTERN VISAYAS SANITARIUM
43) CEBU SOUTH MEDICAL CENTER
44) DON EMILIO DEL VALLE MEMORIAL HOSPITAL
45) EVERSLEY CHILDS SANITARIUM AND GENERAL HOSPITAL
46) GOVERNOR CELESTINO GALLARES MEMORIAL HOSPITAL
47) SAINT ANTHONY MOTHER AND CHILD HOSPITAL
48) VICENTE SOTTO MEMORIAL MEDICAL CENTER
49) EASTERN VISAYAS REGIONAL MEDICAL CENTER
50) SCHISTOSOMIASIS RESEARCH AND CONTROL HOSPITAL
51) BASILAN GENERAL HOSPITAL
52) DR. JOSE RIZAL MEMORIAL HOSPITAL
53) LABUAN GENERAL HOSPITAL
54) MARGOSATUBIG REGIONAL HOSPITAL
55) MINDANAO CENTRAL SANITARIUM
56) ZAMBOANGA CITY MEDICAL CENTER
57) AMAI PAKPAK MEDICAL CENTER
58) MAYOR HILARION A. RAMIRO SR. MEDICAL CENTER
59) NORTHERN MINDANAO MEDICAL CENTER
60) DAVAO REGIONAL MEDICAL CENTER
61) SOUTHERN PHILIPPINES MEDICAL CENTER
62) COTABATO REGIONAL AND MEDICAL CENTER
63) COTABATO SANITARIUM
64) ADELA SERRA TY MEMORIAL MEDICAL CENTER
65) CARAGA REGIONAL HOSPITAL
66) SULU SANITARIUM

Institutionalized Palliative Care Services	**Consultative Provision of Palliative Care** ***(Presence of Palliative Medicine Specialist is part of Hospital Staff)***

Key Goals and Strategies

1. Supply Chain Resilience through sustainable Private-Public partnership
2. Foster collaboration among policymakers, healthcare professionals, patient advocates, and other stakeholders to ensure a comprehensive and inclusive approach to policy- making.
3. Invest in research and development activities to explore alternative sources or formulations of morphine.
4. Offer comprehensive training programs for healthcare professionals involved in the prescribing, administration, and monitoring of Morphine and to involved government agencies Patient Access and Support

Priority Tasks

1. A series of dialogues between the Philippine Dangerous Drug Board (DDB), Department of Health together with Pain and Palliative Medicine Societies , Hospice Philippines, Licensed pharmaceutical companies, for purposes of :
   - Reinforcing control measures and systems for Opioid Access and Monitoring
   - Establishing electronic versions of the special DOH form for prescribing Regulated Drugs, with primary emphasis on cancer patients and individuals requiring controlled substances for the management of severe pain, seizures, and related symptoms.
   - Exploring actual proposals for Public-Private Partnership towards maintaining the supply chain, especially for patients who cannot afford to purchase regulated medications.
2. Organizing collaborative efforts to educate relevant government bodies, pharmacies, and medical professionals, with the overarching goal of enhancing capacity for ensuring proper access to and monitoring of controlled substances. One such activity would be the **International Narcotics Control Board (INCB)** ***Learning Project3*** that assists member States to improve availability of internationally controlled essential medicines. (https://www.incb.org/incb/en/project-learning/e-learning-modules_main.html)

“Resilience, in a sense, is applied optimism”

-Kate O’Neill

Acknowledgements

For their most valued insights and contributions to this talk

1. Members of the following Professional Societies and Organizations:
    Philippine Society of Hospice and Palliative Medicine
    Pain Society of the Philippines
    Hospice Philippines
    Home Health Care Providers of the Philippines
    Asia Pacific Hospice Palliative Care Network
    Union for International Cancer Control
    Philippine Oncology Nurses Association

2. Dangerous Drug Board of the Philippines .

References

1. Philippine Statistics Authority website
2.Left behind in pain: extent and causes of global variations in access to morphine for medical use and actions to improve safe access. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.
3. The experience of pain among cancer patients at the University of the Philippine: Philippine General Hospital Cancer Institute – A cross sectional study ;Harold Nathan C. Tan, Rogelio Nona Velasco, Lance Isidore Garcenila Catedral, Michael Ducusin San Juan, Corazon Ngelangel, and Emiliano Calvo;Journal of Clinical Oncology 2021 39:15_suppl, e24078-e24078
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6. Cancer Pain Management Insights and Reality in Southeast Asia: Expert Perspectives From Six Countries; Francis O. Javier, Cosphiadi Irawan, Marzida Binti Mansor, Wimonrat Sriraj, Kian Hian Tan, and Dang Huy Quoc Thinh Journal of Global Oncology 2016 2:4, 235-243
7. THE 2015 QUALITY OF DEATH INDEX RANKING PALLIATIVE CARE ACROSS THE WORLD An Economist Intelligence Unit study, commissioned by the Lien Foundation KEY FINDINGS INFOGRAPHIC
8. Cross Country Comparison of Expert Assessments of the Quality of Death and Dying 2021
Eric A. Finkelstein, PhD, Afsan Bhadelia, PhD, Cynthia Goh, MBBS, Drishti Baid, BA, Ratna Singh, MA,Sushma Bhatnagar, MD, and Stephen R. Connor, PhD
9. International Narcotics Control Board (data); The World Bank (population)
Created by: Walther Global Palliative Care & Supportive Oncology, Indiana University Simon Comprehensive Cancer Center, 2022

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Improving access to morphine “a culturally tough medicine”: Experiences from China

Ning Xiaohong
Palliative Medicine Center of PUMCH
2023.9.12

CHINA：Cultural Challenges Associated with Morphine

➢ Cultural Perspective on Pain Management

- Expressing pain openly is often seen as a sign of weakness

➢ Stigma Surrounding Opioid Medications

- Morphine, have been stigmatized due to their potential for addiction and abuse.
- China experienced two Opium Wars, casting a certain psychological shadow regarding the use of opioid medications like morphine is left

➢ Lack of Education and Awareness

- Do not have sufficient knowledge about the use of morphine
- Lack of education and awareness result in misconceptions and fears surrounding its use.

[1]支梦佳,魏兴梅,高翔等.我国阿片类镇痛药物临床使用现状分析[J].药物流行病学杂志,2018,27(06):400-405.DOI:10.19960/j.cnki.issn1005-0698.2018.06.010.

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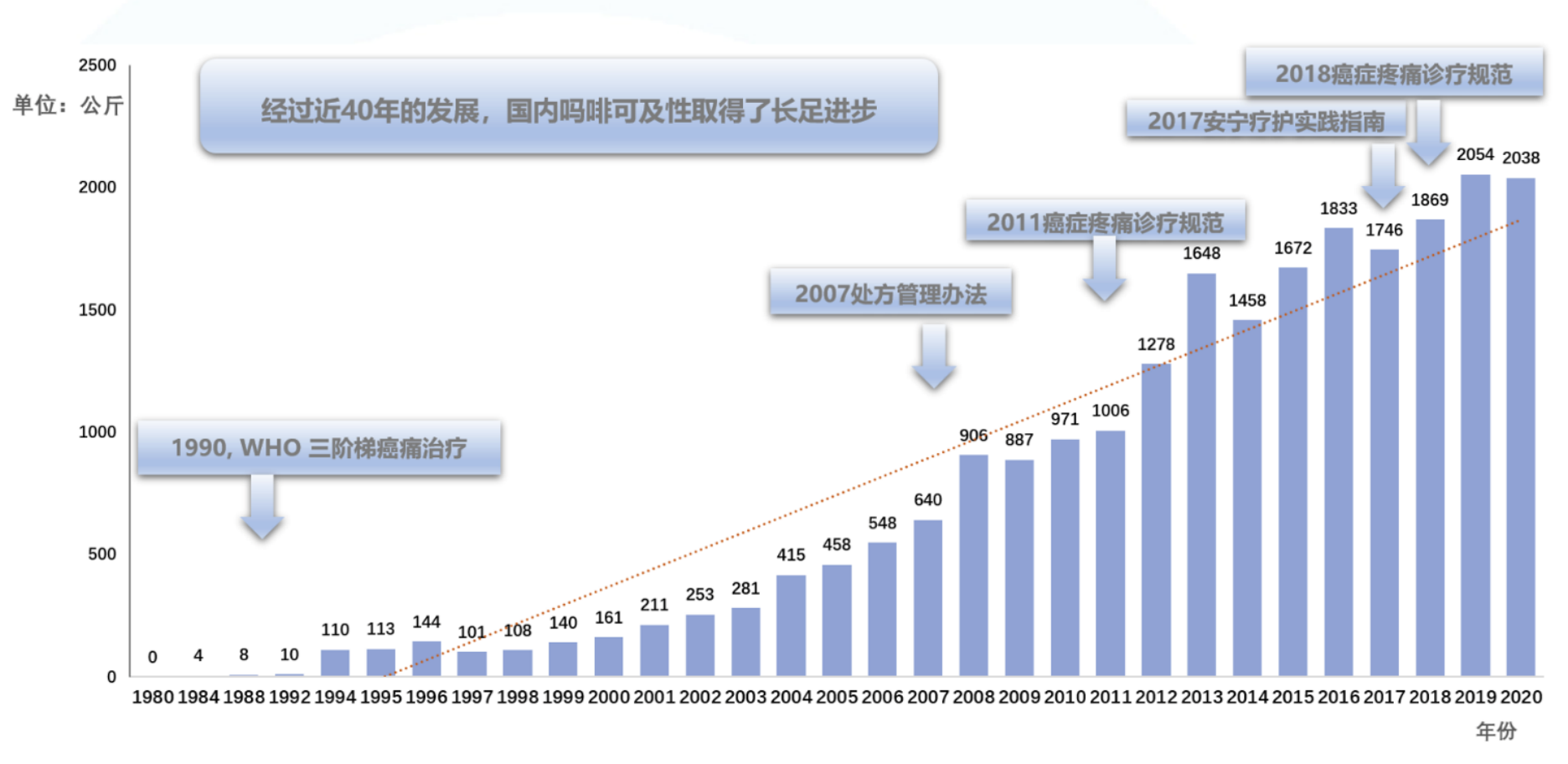
Trend of medical morphine consumption in China

- Since the introduction of the World Health Organization's **three-step cancer pain treatment approach in the 1990s**, the clinical use of opioid drugs in China has consistently aligned with international standards.
- The annual total consumption of medical morphine in China has gradually increased from **less than 10 kg in the 1980s to 2038 kg in 2020.**



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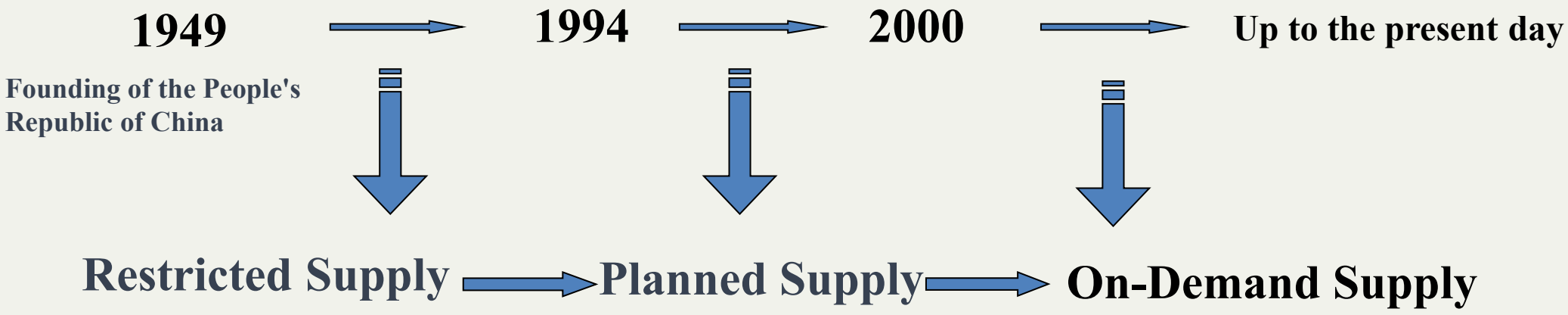
A relatively positive trend in the use of narcotic analgesics for pain management in China

- According to data from the annual report of INCB [1,2]， the morphine consumption in China in 2018 was 2.1 times higher than that in 2009
- Over the past decade, there has been a significant overall increase in morphine consumption in China.
- However, its share in global consumption has only increased from 2.04% to 4.20%.
- There remains a severe shortage of opioid analgesics, especially in the treatment of chronic pain, particularly cancer pain control.阿片药物的使用量相当于实际需求的16%。

[1] INCB. Narcotic Drugs Technical Publications2019[EB/OL].http://www.incb.org/documents/Narcotic-Drugs/Technical- Publications/2019/Narcotic_Drugs_Technical_Publication_2019_ web.pdf.
[2] INCB. Narcotic Drugs Technical Publications2014[EB/OL].http://www.incb.org/documents/Narcotic-Drugs/Technical Publications/2014/Narcotic_Drugs_Report_2014.pdf.

A Review of the Regulations on the Supply and Management of Anesthetic Drugs



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A series of policies and management measures to regulate the use of morphine.

- Medical institutions have implemented a record-keeping management system for anesthetic drugs and Class I psychotropic drugs, in addition to injectable solutions.

Challenges Faced in Improving Morphine Access

Currently no restrictions from policies on the use of anesthetic drugs

But， both hospitals and doctors lack enthusiasm.

- the variety and specifications of anesthetic drugs in hospitals are not comprehensive, and each hospital has different drug management regulations, limiting the number of types and specifications of a particular drug.
- doctors perceive a significant responsibility when prescribing anesthetic drugs, leading to their reluctance to do so.
- Doctors worry about the Addiction and side effect of opioids.
- Off label use of morphine should be supported officially, eg, to use morphine at end stage refractory dyspnea.
- ……

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Ways for improving morphine usage

- Relax the restrictions on the types and specifications of opioids
- Inspector of pain management by the relevant department
- Education of medical students and physicians on pain management and opioid use

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Thank you all for being here and listening.

Why we made our own morphine liquid and talked to the policeman: Experience from East Africa

Dr Emmanuel Luyirika

Executive Director,

African Palliative Care Association

APCA's Strategic Objectives

1. To increase the **knowledge and awareness of palliative & comprehensive chronic care** linked to advocacy through & collaboration with all stakeholders *(Including the Triennial Conference, African Ministers of Health Palliative Care Session, Webinars, Social Media, etc.)*

2. To support **the improvement of health systems in Africa through the integration of palliative and comprehensive chronic care at all levels** (***Essential Palliative Care Medicines and Technologies, Palliative Care Training and Education, Palliative Care Policy development, Palliative Care Service Delivery- Small Grants)***

3. To build **an evidence base for palliative and comprehensive chronic care** in Africa

4. To ensure **sustainability palliative care as a discipline and approach to comprehensive chronic care in** Africa

History of the low-cost morphine production model

- In 1993 Dr Anne Merriman started Hospice Africa Uganda and started local morphine reconstitution model

- This was followed in 2004 with a statutory instrument that allows appropriately trained nurses and clinical officers to prescribe oral morphine

Dr Anne Merriman founder of Hospice Africa Uganda with Dr Stephen Watiti a key survivor and palliative care advocate at the August 2022 African Conference Kampala, Uganda

Progress towards a national oral morphine reconstitution model

- In 1998 Dame Ruth Sims and Dr Veronica Moss of Mildmay UK started Mildmay Uganda an HIV facility was as a partnership between Uganda Government and Mildmay Mission Hospital UK with DFID and later CDC funding

- Mildmay Uganda also started its local oral morphine reconstitution using the "Kitchen sink" approach

- Uganda then moved to a centralized reconstitution model

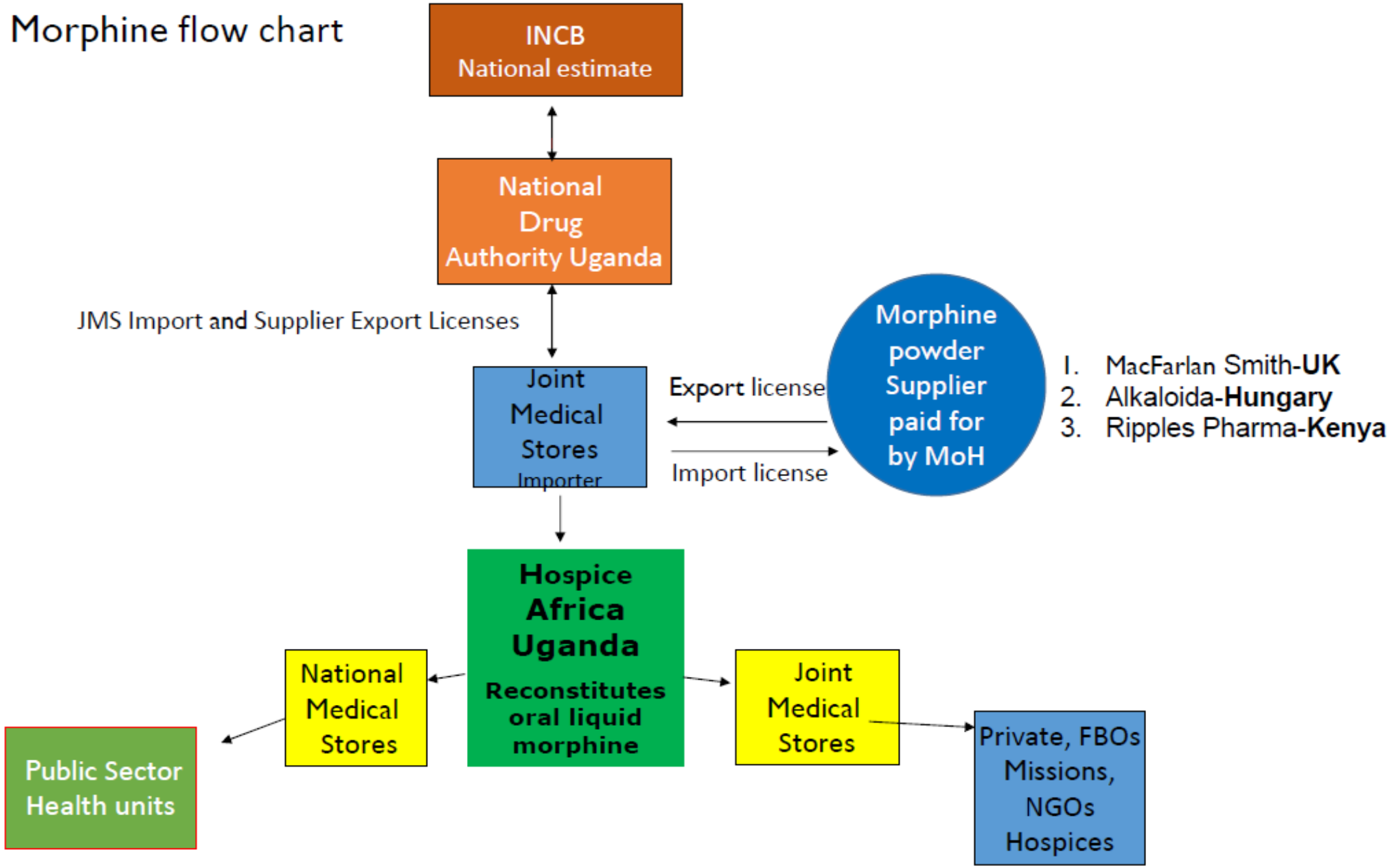
Dr Veronica Moss with a child after starting the Uganda programme (Photo Credit: Mildmay UK)

The Ugandan Model of Low Cost Oral Liquid Morphine Production

This model being expanded in sub-Saharan Africa started in Uganda. It is a whole system of strategic partnership for local opioid production:

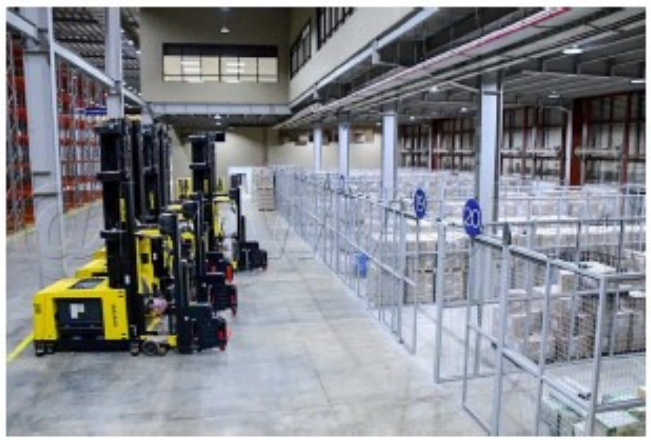
- **Funding** – *Ministry of Health*
- **Procurement** – *Joint Medical Stores (FBO owned by Catholic and Anglican Churches)*
- **Production** – *Hospice Africa Uganda (NGO)*
- **Warehousing/ storage** – *National Medical Stores (Govt)*
- **Distribution** – Joint Medical Stores & National Medical Stores
- **Training of prescribers** including nurses/ clinical officers – *Hospice Africa Uganda & Makerere University with support from, MOH & PCAU. APCA provides scholarships for training*
- **Accreditation of sites** – *Palliative Care Association of Uganda (PCAU)*
- **Dispensing** at health facilities and in patients homes
- Administration of medicines at home
- **National Committee** – All stakeholders hosted by MoH every 3 months; PCAU & MoH ensure Narcotics Police involvement

Morphine flow chart



Morphine Solution ingredients

- Food grade colour: Ponceau Red and DC Apple Green
- Sodium Benzoate (preservative)
- Morphine Sulphate powder
- Purified water



Ponceau Red colouring

DC Apple Green colouring

Morphine Sulphate-Active ingredient

Water purification plant

Current formulations produced in Uganda

- Oral Morphine Solution 1mg/ml 500ml (Green)
- Oral Morphine Solution 1mg/ml 250ml (Green)
- Oral Morphine Solution 10mg/ml 250ml (Red)


UG 5320M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Why Oral liquid morphine?

- Easier for titrating doses
- Limitation for illicit use (the liquid cannot be converted into products for illicit use)
- Easier to manufacture
- It's a cheaper option (a whole bottle costs less than $3)
- Improves access for children and even patients with swallowing difficulties

The role of non-physician prescribers of opioids: nurses and clinical officers (medical assistants)

Authority to prescribe Restrictions on prescribing Narcotic Analgesic Drugs to be prescribed Requirements for prescribing

MINISTRY OF HEALTH

STATUTORY INSTRUMENTS

SUPPLEMENT No. 13 23rd April, 2004

STATUTORY INSTRUMENTS SUPPLEMENT

to *The Uganda Gazette No. 18 Volume XCVII dated 23rdApril, 2004*

Printed by UPPC, Entebbe, by Order of the Government.

STATUTORY INSTRUMENTS 2004 No. 24.

PART II - PRESCRIPTION AND SUPPLY OF CERTAIN NARCOTIC ANALGESIC DRUGS

4. Subject to regulations 5,6 and 7 a Clinical Officer or a Nurse with a certificate in specialist palliative care shall be authorised to prescribe and supply the narcotic analgesic Drugs specified in the Schedule.

5. A Clinical Officer or a Nurse authorised to prescribe drugs under regulation 4 may only prescribe drugs for the management of pain and as part of the palliative care of patients suffering from severe pain and similar symptoms.

6. The narcotic analgesic drugs to be prescribed under regulation 4 shall be only those products and in the form described in the Schedule.

7. The requirements for prescribing narcotic analgesic drugs referred to in regulation 6 shall be those in paragraph 3 of the Ministry of Health Guidelines for Handling of Class A Drugs, March 2001 or any revisions to those guidelines.

SCHEDULE

NARCOTIC ANALGESICS WHICH MAY BE PRESCRIBED AND SUPPLIED BY CLINICAL OFFICERS AND NURSES

1. Morphine oral solution 1 mg/1mL (or 5 mg/5mL)
2. Morphine oral solution 50mg/5mL
3. Morphine tablets SR 10 mg
4. Morphine tablets SR 30 mg
5. Morphine tablets SR 60 mg

BRIG JIM MUHWEZI,
Minister of Health.

Guarding access oral liquid morphine

Guarding access to oral morphine is a continuous process at the following levels:

- Policy and Law
- Financing
- Supply Chain
- Education
- Service delivery and prescription

Palliative care stakeholders meeting the Parliamentary Committee on health to ensure access to morphine is afeguarded in the new Narcotic Medicines and substances Bill now Act

On awareness do not leave out the Police

APCA staff with a team of police officers in Uganda after an awareness session

Extending the model to other African countries

- The African Palliative Care Association facilitates experiential country-to-country learning to extend the model to other countries
- Recipient countries of this arrangement include:
- - Rwanda
- - Eswatini
- - Kenya
- - Tanzania
- - Malawi
- - Zimbabwe etc.

Increasing knowledge and awareness

APCA team with representation from Uganda, Rwanda, Tanzania associations presenting to the East African Legislative Assembly meeting in Zanzibar as part of the advocacy for improving access to medicines and palliative care.

APCA team presenting to the East African Legislative Assembly meeting in Zanzibar

Supporting our partner PCAU as they meet members of the Health Committee of the Ugandan Parliament

Engaging the policy makers: African Ministers of Health Palliative Care Sessions

Each ministers of Health Palliative Care Session has a focus and an eventual declaration

1. **Johannesburg 2013:** focused on unanimous support for the 2014 WHA Palliative Care Resolution
2. **Kampala 2016:** focused on implementation of the WHA Palliative Care Resolution and appropriate technologies including Radiotherapy and the mobile phone applications
3. **Kigali 2019**: focused on the Basic Palliative Care Package for inclusion in UHC
4. **Kampala 2022:** focused on integration of palliative care into epidemics and pandemics preparedness, staff training and service delivery to avoid a repeat of loneliness and suffering experienced by many patients during COVID19

Kigali 2019 African Ministers o Health Palliative Care Session

Extending the Model to other countries.

- Creating opportunities for others to learn from the Uganda model

The Minister of Health of Eswatini (Swaziland) at the Morphine production unit in Uganda before Eswatini on an APCA- facilitated trip

Expanding training to DRC

APCA works across Africa with and through

- Ministries of Health
- National and regional Parliaments
- National Palliative Care Associations
- Local governments
- Hospices and specialists and non specialist hospitals
- Homebased care and community organisations
- Patient and disease survivor organisations
- Health worker training institutions and universities
- Faith-based organisations etc.
- Individuals with palliative care passion and interest
- Other CSOs

APCA staff with DRC MoH, Pallia Famille and rep of Network of Hospitals in DRC in Kisantu at Kisantu in Equator Province OF Democratic Republic of Congo April 2021

Training and mentorship to expanding access to oral liquid morphine

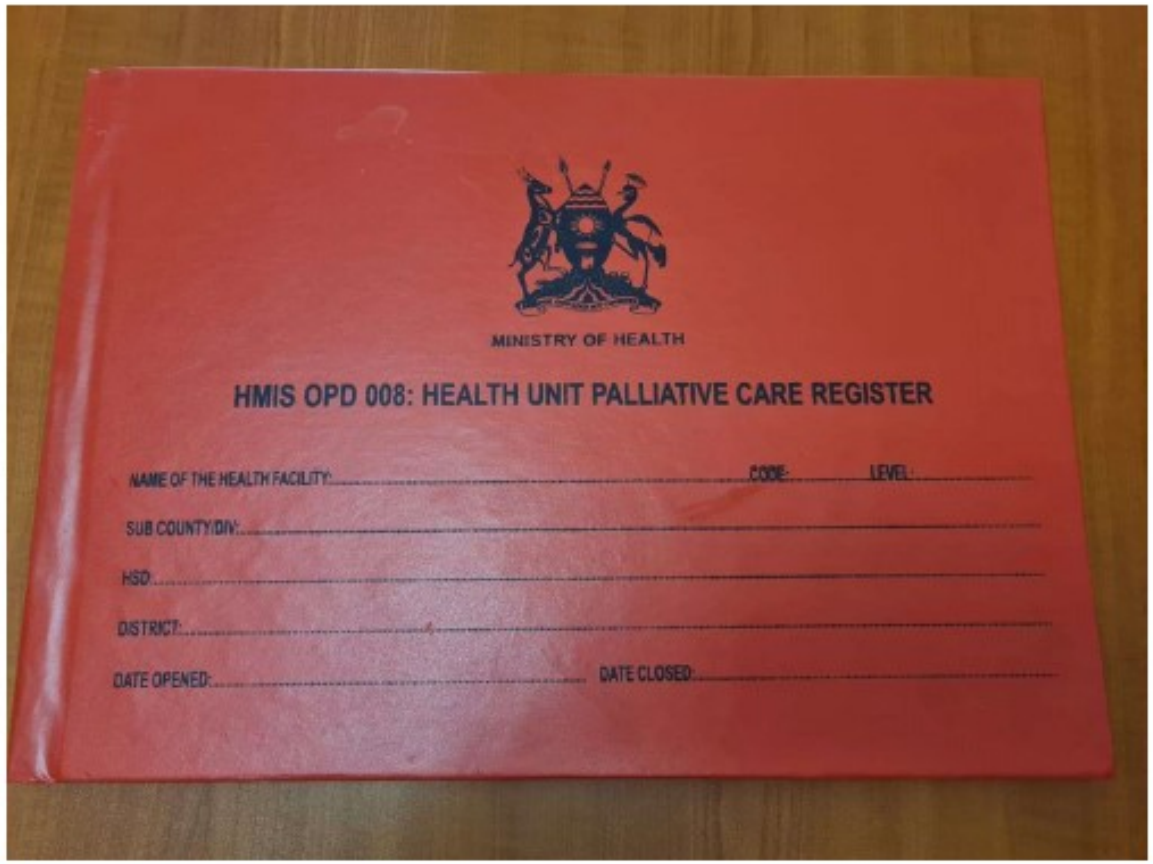
Methodology:

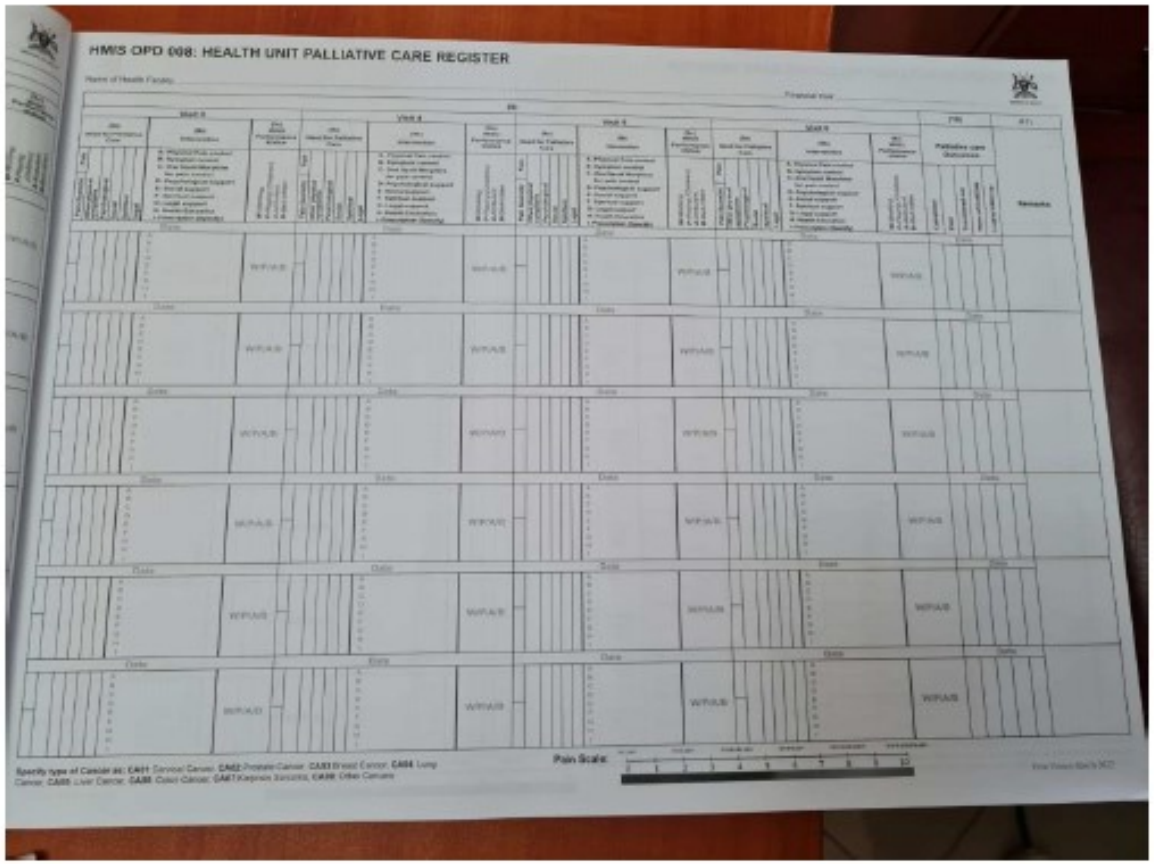
- Identified wider stakeholders at MoH, University of Kinshasa, Civil society
- Site visits and and Needs assessment
- Designed an appropriate training package
- Implemented at 10 hospital sites concurrently over a 6 months period using the ECHO platform
- Ran a mentorship programme monthly for the 10 sites over 12 months covering clinical care and management of sites and medicines
- Did an experiential visit for the 7 member team from DRC for a week in Uganda
- Developed integrated draft guidelines for use of controlled medicines in DRC covering palliative care, general practice, mental health, anaesthesia, harm reduction

Results: Trained 10 hospital teams concurrently over 18 months in two provinces of DRC

Meeting the multidisciplinary teams at Kisantu St Luc Hospital Kisantu, Equator Province one of the ten hospitals for the training

Documentation at the facility





DRC delegation studying the Uganda national morphine supply chain

Countries that APCA has provided technical assistance to start production

- Uganda
- Kenya
- Rwanda
- Eswatini
- Botswana
- Malawi
- Tanzania
- Zimbabwe
- DRC (still early phase)

APCA team meeting controlled medicines stakeholders at DRC MoH Kinshasa in April 2021

Acknowledgements of APCA Partners

- Hospice Africa Uganda and the Institute of Hospice and Palliative Care in Africa
- The Ministry of Health Uganda
- Uganda National Medical Stores
- Joint Medical Stores
- American Cancer Society
- The Bartlett Foundation
- Global Institute of Psychosocial, Palliative and End- of -Life Care (GIPPEC)
- Global Partners in Care
- King's College London
- Open Society Foundations- New York (OSF)
- Rand Corporation
- National Institutes of Health
- Makerere University School of Public Health
- The Open Society Initiative for Eastern Africa (OSIEA)
- The Open Society Initiative for Southern Africa (OSISA)
- Uganda Cancer Institute
- The True Colours Trust
- University of Leeds
- University of Navarra
- World Health Organization
- Worldwide Hospice Palliative Care Alliance (WHPCA)
- National Palliative Care Associations in Africa
- Walther Centre, University of Indiana
- IAHPC
- IHPCA/ HAU
- Ministries of Health of Uganda, Rwanda, DRC, South Africa, Kenya, Eswatini, Zimbabwe, Malawi, Ghana, Togo, The Gambia, Liberia, Mozambique, Namibia, Botswana, Tanzania,
- East African Legislative Assembly,
- Our partners in Research and Academia in Africa, Europe and North America

Safeguarding access to pain medicine in Lebanon

Presenter:
Janane Hanna, RN,MSN,AOCNS
Clinical Nurse Specialist-Pain & Palliative Care
American University of Beirut Medical Center
Balsam-The Lebanese Center for Palliative Care

Challenges

- Availability of opioids in Lebanon
  - Limited armamenturm of opioids
  - Financial crisis started end of 2019

- Accessibility to patients
  - Prescription limitations
  - Inadequate knowledge
  - Pricing
  - Social stigma

Availability of Opioids Lebanon

Narcotics	Composition	Key Routes	Form	Availability	Dosage
Morphine	Morphine Sulfate	Oral	Tablet SR	Pre-012	10, 30, 60, 100
			Tablet IR	X	
			Elixir	X	
		Rectal	Suppository	X	
	Morphine Chlorhydrate	Injectable	Vial	Pre-2012	10mg/ml 20mg/ml
Fentanyl	Fentanyl Citrate	Injectable	Vial	Pre-2012	0.5 mg/10ml
		Transdermal	Patch		25, 50,100
		Transmucosal	Nasal Spray	X	
			Sublingual Tablet	As of 2012	100, 200
			Oral Lollipop	X	

Availability in Lebanon

Narcotics	Composition	Key Routes	Form	Availability	Dosage
Sufentanil	sufentanil	Injectable	Vial	Pre-2012	10mcg/2ml 250mcg/5 ml
Remifentanil	Remifentanil HCL	Injectable	Vial		2mg 5mg
Buprenorphine	Buprenorphine HCL	Oral	Tablet		2/0.5,8/2,16/4
		Transdermal	Patch	X	
Pethidine	Pethidine HCL	Injectable	Vial	Pre-2012	50mg/ml
Oxycodone	Oxycodone HCL	Oral	Tablet SR	As of 2015	
			Tablet IR		
			Elixir	X	
		Injectable	Vial	As of 2015	

The WHO list of essential medicine and that of IAHPC

	WHO Essential Medicine	IAHPC
Codeine		✓
Morphine, PO Immediate Release (tablet or liquid)	✓	✓
Morphine, PO controlled release Granules formulation	✓	✓
Injectable Morphine	✓	✓
Oxycodone, PO Immediate Release	✓	✓
Fentanyl, TD		✓
Methadone, PO Immediate Release	✓	✓
Hydromorphone	✓	

Source: WHO 2015, International Association of Hospice & Palliative Care

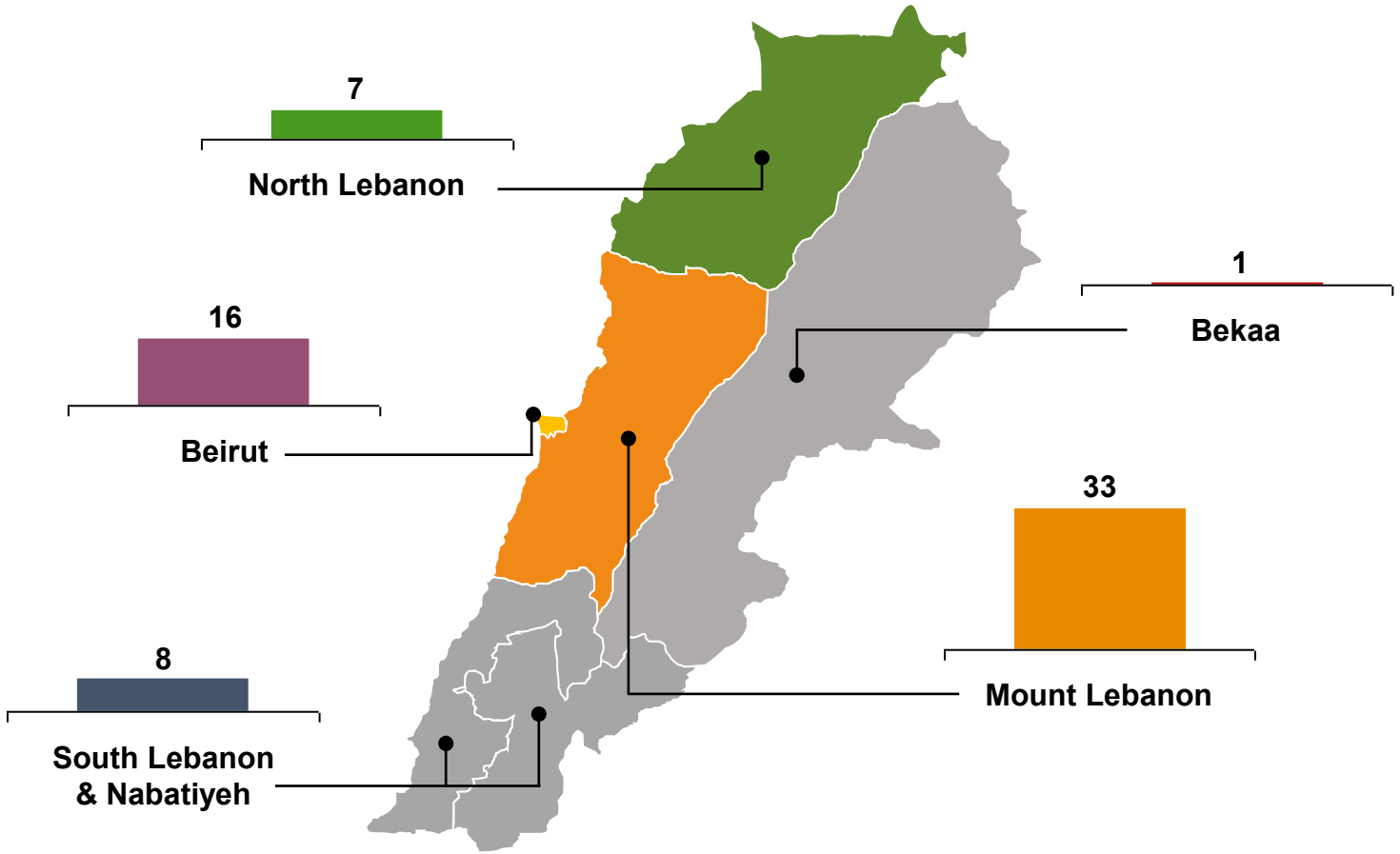
Over the years, Lebanon witnessed major improvements in the accessibility of opioid drugs

Major regulatory milestones

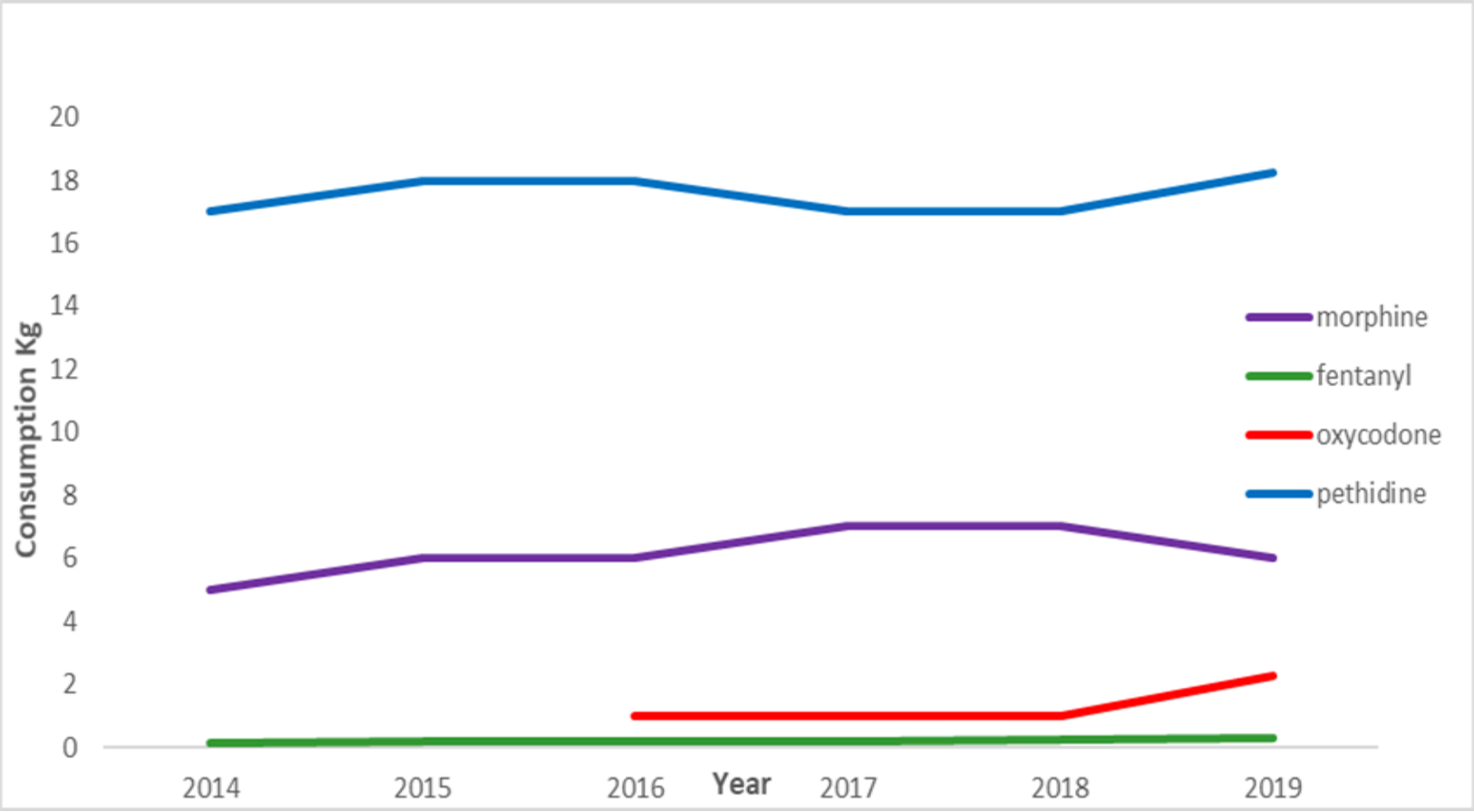
	Pre-2006	2006 - 2009	Post 2009
Patient 	Cancer	Cancer	Moderate to severe pain resistant to other analgesics
Prescribing Doctor 	Oncologists	Oncologists	Oncologists or Pain Management Or Palliative Care
Pathology Report	Required	Required	Not Required
Validity of single prescription 	15 days	1 month	1 month
Approvals required for every drug delivery 	Narcotics Department of MoH	ID Card issued by MoH valid for 10 deliveries	ID Card issued by MoH valid for 10 deliveries

Only select pharmacies are allowed to deliver opioid, the number of pharmacies varies widely among the Kazas

Number of Pharmacies Delivering Opioids by Kaza



Opioids consumption in Lebanon



Prices of Opioids in Lebanon by unit price

Drug	Price per Unit in US $
Morphine vials 10mg/ml	1.26
MST 10mg tablets	0.18
MST 30mg tablets	0.44
MST 60mg tablets	0.47
MST 100mg tablets	0.7
Durogesic 25mcg	3.45
Durogesic 50	6.9
Durogesic 100	8.8
Abstral 100, 200	4.7

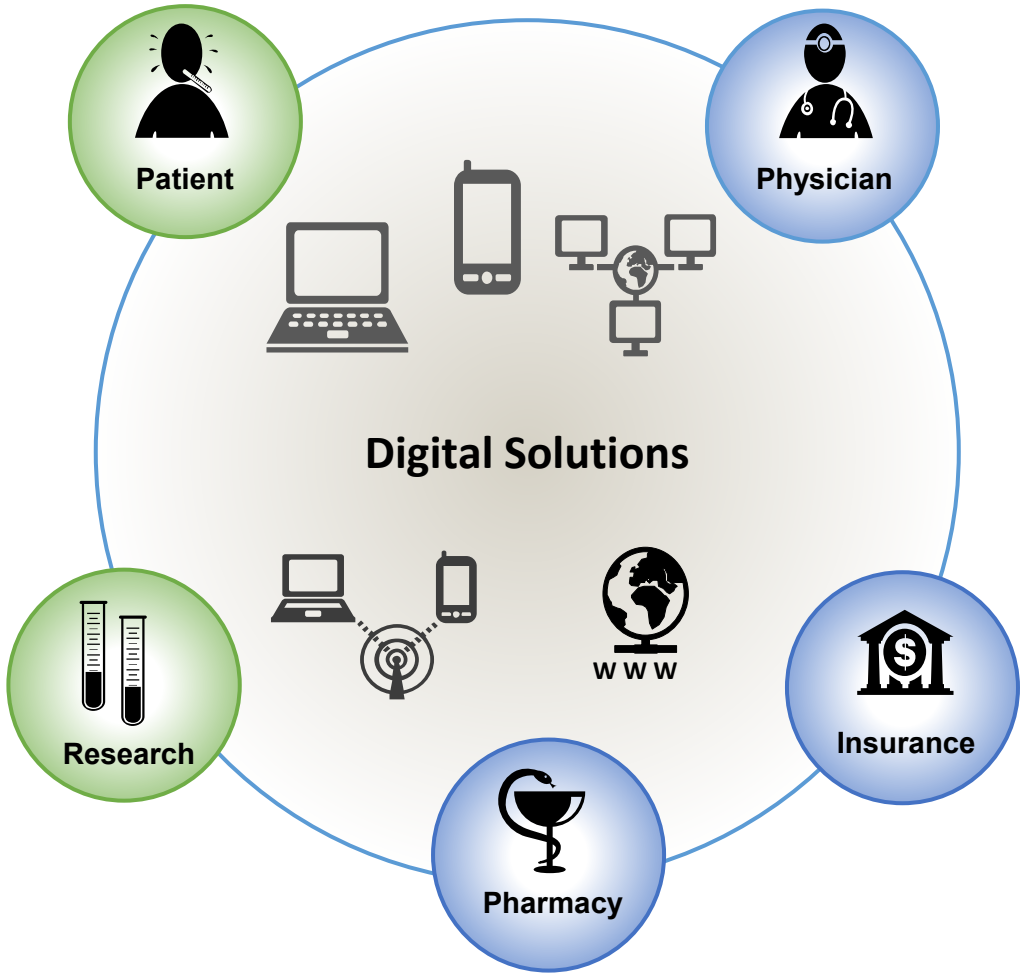
Drug	Price per Unit in US $
Targinact 10/5	0.7
Targinact 20/10	0.86
Oxynorm 5mg Tablets	0.26
Oxynorm 10mg tablets	0.26
Oxynorm 20 mg tablets	0.5
Oxynorm 10mg/ml vials	3.6

Opioid	Equianalgesic dose	Quantity (1 month)	Relative cost index
Fentanyl patch	25mcg every 72 hours	10 patches	34.5$ 1.06%
Morstel	10 mg po q 4hours	180 tablets	32.4$ 1
Oxycontin	Oxycontin 20 mg Q12hrs	60 tablets	51.6$ 1.6$

Solution

- Develop a national medication policy of essential pain medications that ensures supply chain demand .
- Manufacture opioids in Lebanon
- Develop and implement an opioid prescribing course.
- Amend opioid prescribing law to make opioid prescription based on competency (passing the opioid prescribing course) not specialty.
- Improve awareness through public education campaigns

Accessibility: Way Forward



Monitor

Misuse of opioids

Medication side effects

Opioid rotation

Enable

Research

Overall pain management plan

Etc.

MONASH University

Government approaches to prevent misuse and achieve a balanced policy:

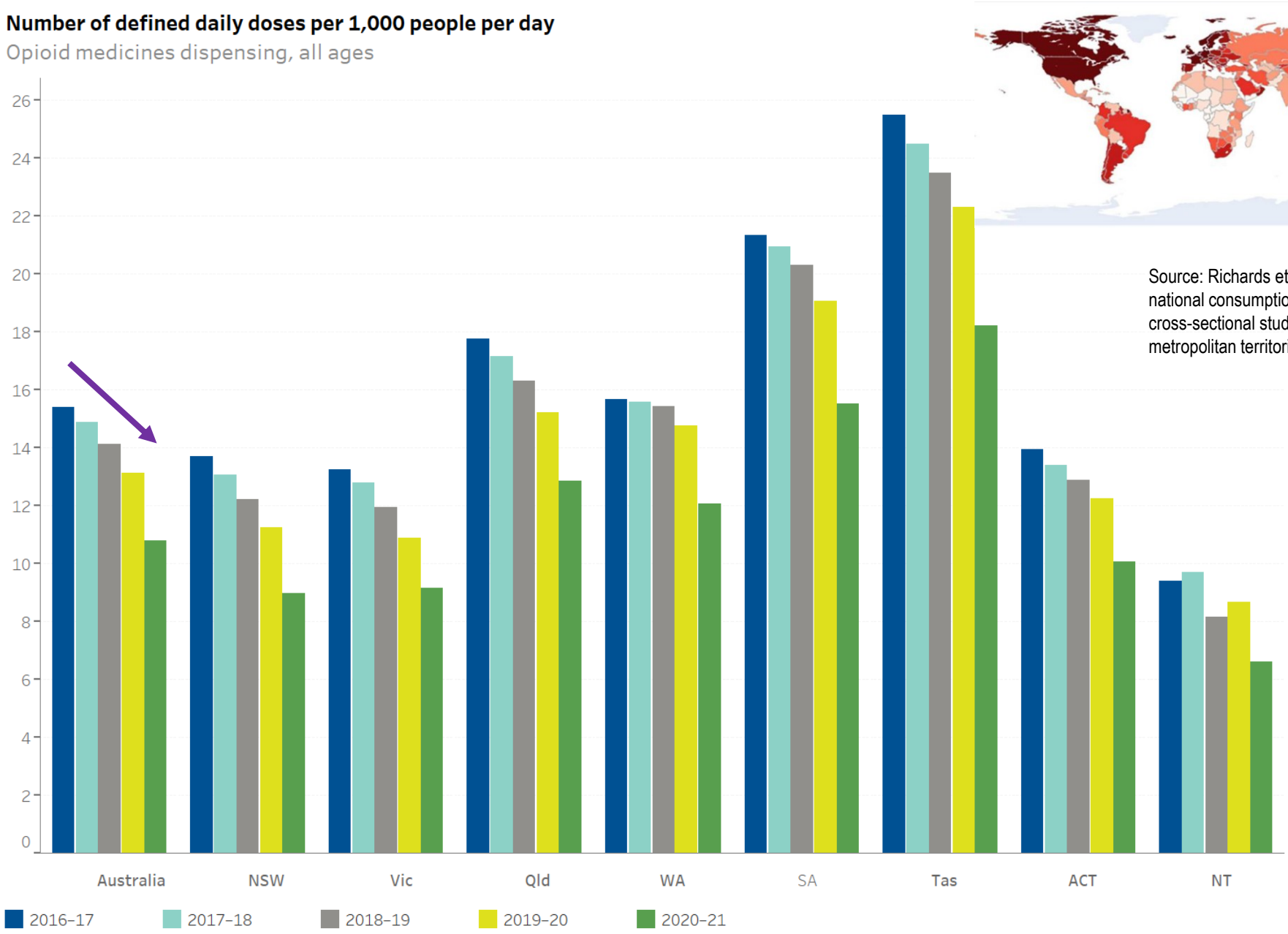
Australian evidence of outcomes

Suzanne Nielsen BPharm BPharmSc(Hons) PhD MPS
Professor and Deputy Director
Monash Addiction Research Centre

September 12, 2023

Opioid Use in Australia

Quantity decreasing each year



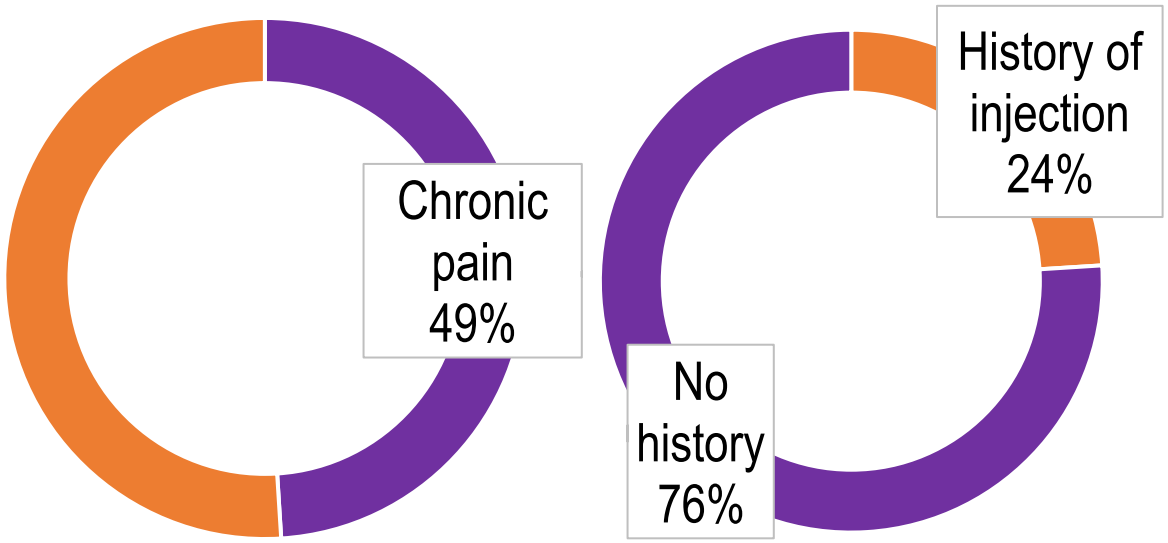
Source: Richards et al. Global, regional, and national consumption of controlled opioids: a cross-sectional study of 214 countries and non-metropolitan territories. Br J Pain. 2022

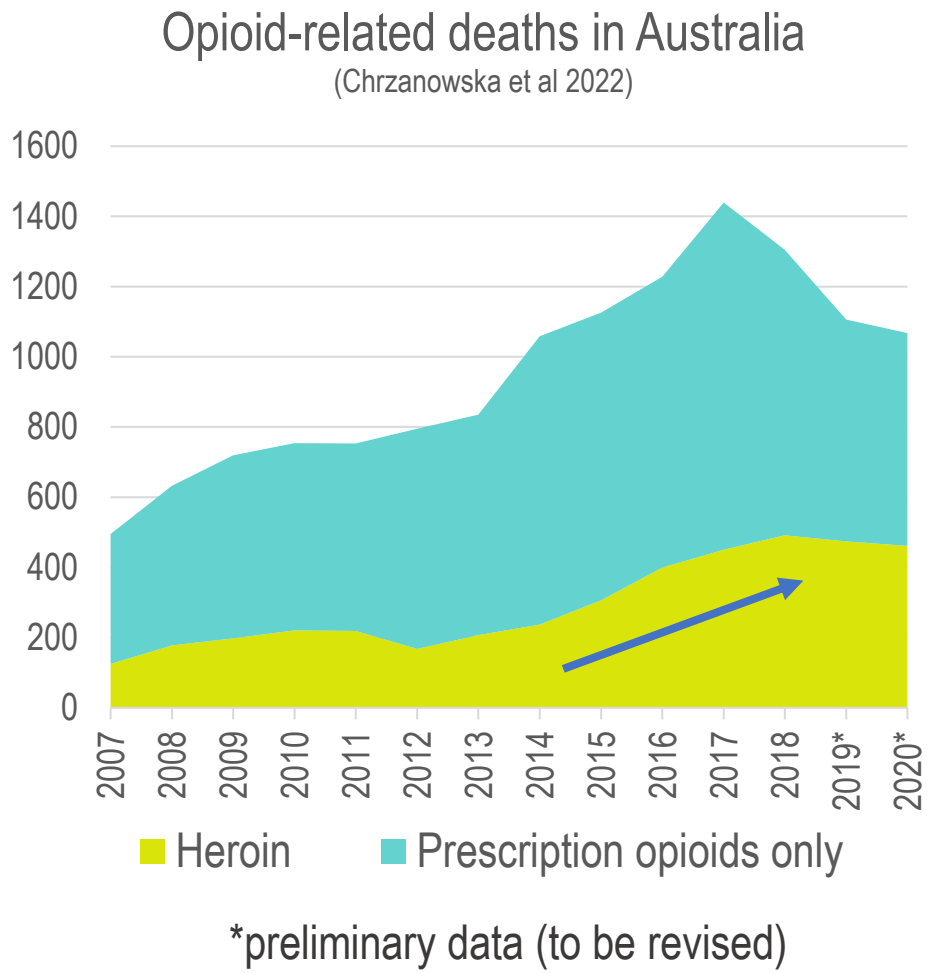
Sources: AIHW analysis of Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme (collectively termed PBS here) data 2016-17 to 2020-21 and ABS Estimated Resident Population 30 June 2016 to 30 June 2020.

Notes

Opioid harm in Australia

- Since 2014 >1000 deaths per year
- Rx opioid deaths now declining
- Steady increase in heroin deaths and nonfatal overdoses
- Deaths from *opioids used for pain:*





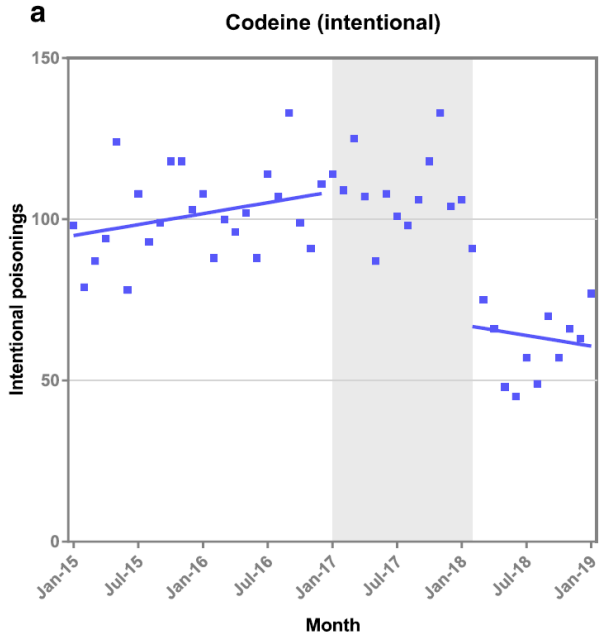
Interventions and evidence of effect

Year	Change	Impact
2014	Oxycodone reformulation	Mixed
2018*	Codeine rescheduling (all products prescription only)	Reduced harm, no evidence of unintended effects
2019*	National Prescription Drug Monitoring Program	Limited evidence /limited impact to date
2019	National Take Home Naloxone Program (pilot)	Increased supply, estimated 3 lives saved/day
2020	Changes access to subsidised opioids: Reduced quantities (acute pain) Ltd indications (severe chronic pain, 2-3rd line) Requirement for a second review	Reduced supply Limited evaluation of health outcomes
2023	Opioid Agonist Treatment funding	Not yet measured

* To discuss today

Codeine rescheduling to prescription only

- All codeine prescription only - February 2018 – note limited evidence for efficacy of low dose codeine for pain that were over-the-counter
- Consistent evidence of large decreases in poisoning, dependence
- Evidence of no impact on pain management or increased prescribing of other medicines
- Implementation context → considerable investment in patient and provider education about alternative pain management/reason for change



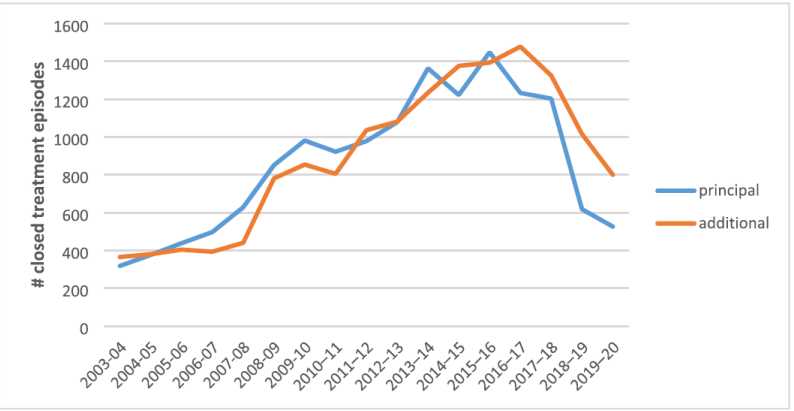


FIGURE 1 Closed drug treatment episodes involving codeine as a principal or additional drug of concern

Prescription Drug Monitoring Programs

- Provides information to doctors (prescribers) and pharmacists (dispensers) about patient's history of controlled medicine use when they are considering prescribing / dispensing

Goals :

- identify patients at risk of harm
- limit visiting multiple doctors for controlled medicines
- provide regulators with data

Controlled medicines include pain medications such as oxycodone, morphine and fentanyl and other high-risk medicines (determined within each State or Territory), e.g. benzodiazepines, prescription stimulants

Outcomes: real time prescription monitoring

- Limited research (most from Victoria, first state to make mandatory)
- Anecdotal feedback from clinicians supports clinical utility of information

- **Challenges** for patients centred on experiences of **stigma** and lack of **access**
- Impact of policies different when a large population already rely on strong opioids

ORIGINAL PAPER

Drug and Alcohol Review ADSAD WILEY

Opioid-related policy changes: Experiences and perspectives from people who use opioids to manage non-cancer chronic pain

Sarah Haines[1] | Michael Savic[2,3] | Suzanne Nielsen[3] | Adrian Carter[1]

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[2]Turning Point, Eastern Health, Melbourne, Australia
[3]Monash Addiction Research Centre, Monash University, Melbourne, Australia

Abstract

Introduction: People who use prescription opioids to manage non-cancer chronic pain are particularly vulnerable to opioid-related policy change. This study aims to better understand what prescription opioids provide this population, what concerns they have in the context of new and changing opioid policies, such as the recently implemented prescription drug monitoring program in Victoria.

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Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

ELSEVIER

DRUG POLICY

Research Paper

Self-reported challenges obtaining ongoing prescription opioids among Australians with chronic non-cancer pain

Ria E Hopkins[a,*], Gabrielle Campbell[b], Louisa Degenhardt[a], Nicholas Lintzeris[c,d], Briony Larance[a,e,f], Suzanne Nielsen[g], Natasa Gisev[a]

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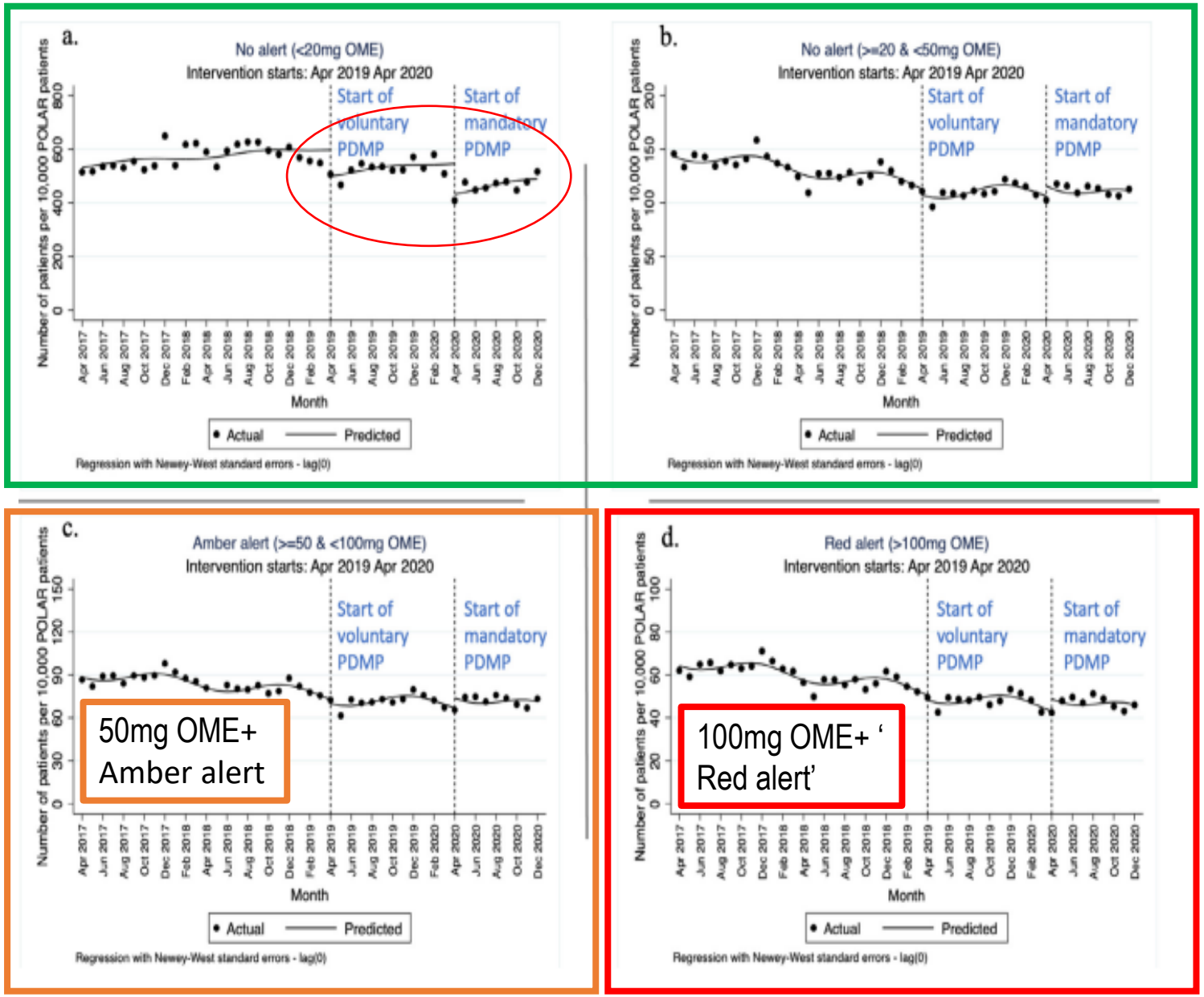
[g] Monash Addiction Research Centre, Monash University, Mooroodue Hwy, Frankston, VIC, 3199, Australia

No impact of PDMP on ‘high dose’ prescribing

- Background trend of reducing opioid supply
- Only significant impact on lowest dose group
- No immediate or longer term impact on higher dose prescribing
- Increased prescribing of non-monitored medicines (e.g. tricyclic antidepressants)



Nielsen, S., et al. (2023). Int J Drug Policy 117: 104053.

Summary

- Range of polices have evolved over time, not one policy or one setting
- Implementation context is key (Are alternatives available for pain management? How are needs of dependent populations addressed?)
- Harm reduction and treatment for opioid dependence also important in preventing mortality from opioids
- Get good clinical governance and information systems in place early to avoid unintended harms and support confidence in increasing evidence-based access
- Focus needs to be from a health rather than a law enforcement perspective

References: codeine rescheduling and prescription monitoring in Australia

1. Cairns, R., et al. (2020). Codeine use and harms in Australia: evaluating the effects of re-scheduling. Addiction 115(3): 451-459.
2. Harris, K., et al. (2020). Rescheduling codeine-containing analgesics reduced codeine-related hospital presentations." Med J Aust 212(7): 328.
3. Mathias, R., et al. (2023). Reduced gastrointestinal-related hospitalisation costs following rescheduling of over-the-counter codeine-containing compound analgesics in Australia: results of a single hospital audit in South Australia. Intern Med J.
4. McCoy, J., S. Nielsen and R. Bruno (2022). A prospective cohort study evaluating the impact of upscheduling codeine in Australia among frequent users of codeine. Addiction 117(3): 677-686.
5. Middleton, M. and S. Nielsen (2019). Changes in Australian prescription opioid use following codeine rescheduling: A retrospective study using pharmaceutical benefits data. Int J Drug Policy 74: 170-173.
6. Noghrehchi, F., R. Cairns and N. A. Buckley (2023). Hospital admissions for paracetamol poisoning declined following codeine re-scheduling in Australia. Int J Drug Policy 116: 104040.
7. Tscharke, B. J., et al. (2023). A wastewater-based evaluation of the effectiveness of codeine control measures in Australia. Addiction 118(3): 480-488.
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10. Picco, L., A. Ritter and S. Nielsen (2023). Prescription drug monitoring programs in Australia: A call for a comprehensive evaluation. Drug Alcohol Rev 42(4): 745-747.
11. Picco, L., et al. (2022). "How do patient, pharmacist and medication characteristics and prescription drug monitoring program alerts influence pharmacists' decisions to dispense opioids? A randomised controlled factorial experiment." Int J Drug Policy 109: 103856.

Panel discussion

A problem well-stated is a problem half-solved.

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?

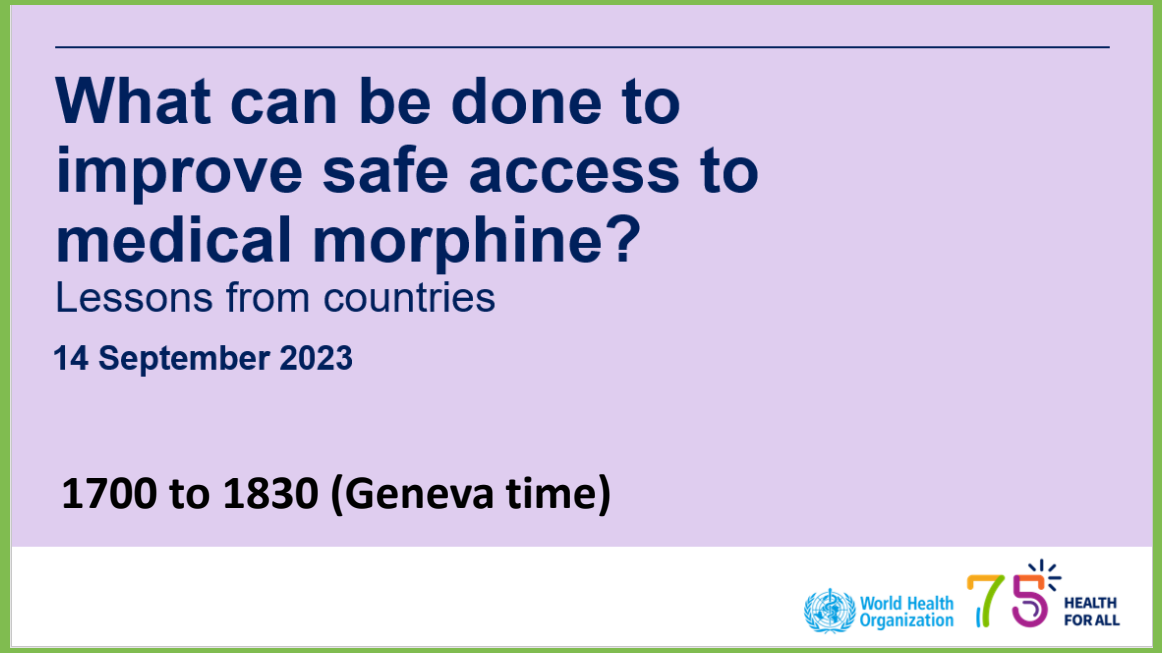
SUSTAINABLE DEVELOPMENT GOALS

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



World Health Organization 75 HEALTH FOR ALL