

Written statements public hearing on guideline scoping document: WHO Guideline on ensuring balanced national policies for access and safe use of controlled medicines

02 March 2020

Introduction

This document contains all written statements submitted to the World Health Organization regarding the scope of WHO guideline on ensuring balanced national policies for access and safe use of controlled medicines. The guideline is intended to assist Member States in developing and implementing balanced national policies for access and safe use of controlled medicines. The controlled medicines included will be those containing substances listed in Schedules I, II, III and IV of the 1961 Single Convention and Schedules I, II, III and IV of the 1971 Convention which have identified or emergent medical applications. The scope will also consider the role of national control measures and the placement of medicines therein.

Four key research questions are proposed under the scope:

1. What are the main barriers to access to, and appropriate use of controlled medicines?
2. What are the main factors that have been demonstrated to contribute to medical overuse and misuse of controlled medicines?
3. What are the policies or interventions that have been successfully implemented for improving access to controlled medicines?
4. What are the policies or interventions that have been successfully implemented for improving the safe use of controlled medicines?

Stakeholders were asked to present their views in maximum 200 words. Written statements could be submitted to WHO until February 23, 2020. In addition to making a written statement, stakeholders had an opportunity to present their views orally during the public hearing which took place on February 19, 2020.

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#1

Title, surname, name Dr. Harrop, Emily**Institutional affiliation** Association for Paediatric Palliative Medicine (APPM)**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

I am responding on behalf of the Association for Paediatric Palliative Medicine (APPM) UK, of which I am the Secretary.

We are pleased with the scope overall, but would like to raise the following issues:

1. Supply chain issue for accessing controlled drugs for palliative care exist in the UK (as well as LMICs)
2. There is frequently a lack of safe preparations to allow accurate doses of controlled medicines for infants and children
3. In the UK NICE produced guidance for End of Life Care in Infants, Children and Young People (NG61, 2016) which t'Em commends access to a number of controlled drugs, with access to specialist consultant support
4. Our organisation (APPM) produce and regularly review a Masterformulary of medicines for Paediatric Palliative Care. This contains the best evidence available for prescribing numerous controlled drugs for children. Despite this, we are aware of a lack of high quality evidence about the use of some of these drugs in children. This will act to restrict safe access.

Dr Emily Harrop MBBS BSc DCH FRCPCH PhD Dip Pal Med (Paeds)

#2

Title, surname, name Radbruch, Lukas**Institutional affiliation** University Hospital Bonn**The views expressed here pertain to**

- Key research question 3

Written statement**The German best practice model**

I am Lukas Radbruch, Chair of Palliative Medicine of the University Hospital Bonn, Germany representing myself.

The views I am presenting pertain to key research question 3 of the scope.

My views are that the upcoming revision of the Ensuring Balance guideline is based on concerns with overuse of controlled medicines in some parts of the world. The scoping document mentions that increasing opioid use in some countries including Germany has not been associated with negative health outcomes. Indeed, Germany could be described as a best practice model for the appropriate use of opioids.

Good clinical guidance, widespread education, for example with inclusion of pain management and palliative care in the undergraduate curriculum, and balanced regulations ensure adequate access to opioids for those who need them as well as prevention of abuse. Detailed data by the Federal Statistical office provides a total number of 312 opioid-related deaths for 2017.

Germany has a well established social security network, including full health insurance coverage, and thus economic reasons (opioid therapy offering a cheaper alternative to complex multimodal interventions) may have a lesser role in Germany compared to other countries. Many chronic pain patients would not consider expensive and time consuming nonmedical interventions if they would have to pay for it themselves.

I recommend consideration of the German experiences, for example detailed in Hauser et al. (Pain Management 6 (2016): 249-263).

#3

Title, surname, name Ghoshal, Arunangshu**Institutional affiliation -****The views expressed here pertain to**

- Key research question 1

Written statement

What are the main barriers to access to, and appropriate use of controlled medicines:

a. at international, national, and local levels

In India, opioids are supplied from manufacturers within the country, but due to age-old prohibitions, the medicine does not reach the end-user (patients). Some authorities have tried to ease the situation by amending the legislation, raising awareness among stakeholders (like physicians, government officials, etc.), but it's infinitesimally small in such a huge country with varied socio-cultural and infrastructure amenities.

b. what are the consequences of these barriers?

only 2-3% of patients in need get a regular supply of opioid analgesics. The shortage of such an inexpensive medicine forces the market to sell it at a higher price.

#4

Title, surname, name Rev. Díaz Velásquez, Martin Ignacio

Institutional affiliations The Knowmad Institut and Nierika AC

The views expressed here pertain to

- Key research question 1
- Key research question 2
- Key research question 4

Written statement

See next page



Joint Statement of
Knowmad Institut & Nierika AC



**Joint Statement of Knowmad Institut & Nierika AC for public consultation:
WHO Guideline on ensuring balanced national policies for access and safe use of medicines**

The European Institute for Multidisciplinary Studies on Human Rights and Science - **Knowmad Institut** - and the Multidisciplinary Association for the Preservation of Indigenous Traditions of Sacred Plants - **Nierika AC** - bring to this public hearing the concerns of **vulnerable groups and multidisciplinary experts** in relation to **access to controlled medicines**.

The WHO has repeatedly shown its commitment to "ensuring balance in national policies on controlled medicines", however, it is necessary to recognize that the current model of medicalization emerges from a social construction that has taught us to prioritize physical pain. The availability and accessibility of controlled medicines related to mental health have been left in the background. The pain produced by chronic depression, post-traumatic stress disorder (among other pathologies) represents a non-physical pain that in some cases pushes the sufferer to suicide.

By prioritizing access to medication to reduce physical pain and palliative treatments for chronic pain, psycho-emotional pain has been left in second place. As a result, the therapeutic outcomes of so-called psychedelic substances that have demonstrated therapeutic qualities for different mental health conditions have been ignored. The psycho-emotional needs of the patients and their affected family members are ignored.

It must be recognized that contemporary psychopharmacological treatments are not having the expected therapeutic effects in the treatment of several conditions such as depression, post-traumatic stress, alcoholism, complicated grief among others. Existing scientific data support the potential of psychedelics in the treatment of these conditions, however, the policies that regulate this class of substances have not allowed the necessary openness to access psychedelic treatments for mental health conditions.

We consider it fundamental that beyond controlled medicines, access to medicines must be safe, regulated and with quality controls. **The control model needs to be pragmatic in order to avoid the redirection of people to the clandestine market, as this represents a greater risk than the controlled medicines themselves.**

Access to controlled medicines in central or industrialized countries in a sensible, responsible and pragmatic way can contribute to lowering the costs of public health services while reducing adverse effects for people in controlled settings with standardized medicines and adequate doses.

Therefore, we call upon the World Health Organization (WHO) to:

- Member countries should be recommended that any controlled substance, insofar as it has a medical use, be included in the pharmacopoeia and in the lists of medicines to be subsidized and made accessible through public and private health systems, otherwise a system of social injustice is established for access to medicines.



Joint Statement of
Knowmad Institut & Nierika AC



- Considering the scientific evidence that psychedelic science has provided in the last decade, we believe that it is an opportune time for the WHO, in conformity with its guidelines aimed at not restricting, interrupting or denying access to controlled opioids, to facilitate and promote research, access and based on the "principle of compassion" to allow expanded access to medical and psychological treatments with psychedelics for populations suffering from emotional pain.
- Promote academic dialogue between WHO and different scientific research institutions on the re-evaluation of the therapeutic potential of so-called psychedelic substances.
- To balance its actions and recognize the contribution of traditional medicine, herbal medicines and the therapeutic activity of native peoples in mental health services, to facilitate access and promote a regulatory model for plants and mushrooms containing illegalized substances linked to the relief of psychological pain. It is important to note that scientific evidence indicates that the risks associated with the use of these medicines are minimal.
- That the list of controlled medications is devoid of prejudice and includes psychotomimetic products and those that alter perception, state of consciousness or generate significant dependence, but not other psychotropics, such as antidepressants that do not generate such alterations.
- That increased attention be given to the rates of "suicidal intentionality" and "suicidal thoughts", which, compared to the rates of consummated suicides, that are mostly reflected as results of mental conditions such as depression or anxiety, this rates can taking into account social conditions such as frustrations, difficulties in facing what reality proposes and which have their basis in symbolic and structural violence that allows the circle to continue over and over again.

It is time to become aware of the contexts and elements involved in order to find alternative ways to the current model of control of certain controlled medicines and to deepen through public policies the standards and public services of mental health.

Finally, in accordance with the Sustainable Development Goals, we are committed to working with the WHO and governmental entities to contribute to the development of policies, regulations, and best practices based on fact and science, in order to promote access to safe, effective, and affordable medicines for the treatment of pain and to prevent their misuse and the harm they may cause.

Science & Human Dignity



17/2/2020

#5

Title, surname, name Dr. Luyirika, Emmanuel**Institutional affiliation** African Palliative Care Association**The views expressed here pertain to**

- Key research question 1
- Key research question 3

Written statement

International barriers:

- Countries not having adequate information on sources of controlled medicines especially morphine powder.

National barriers:

- poor procurement systems for controlled medicines and a poor supply chain for essential controlled meds such as oral morphine,
- inadequate training of health workers in use of controlled medicines,
- lack of national treatment guidelines,
- restriction of prescription of controlled medicines to doctors only when majority of patients in need are seen by nurses, medical/ mental health assistants

The consequences of barriers:

- untold suffering for patients who need pain and symptom control
- encouraging illegal peddling of controlled medicines
- exploitation of suffering patients and their families through futile replacement remedies

Question THREE: Policies and interventions that have improved access:

- National level funded policies recommending access (Rwanda and Uganda)
- Increasing cadres for prescribers (nurses and clinical officers/medical assistants – Uganda)
- Formulations such as oral liquid morphine not useful for diversion but useful for patients (Rwanda, Uganda)
- Extending access to refills at home and integration of palliative care training in health worker training

- Using the public-private partnership to mentor sites (Uganda MoH & PCAU)

#6

Title, surname, name Sánchez-Bustos, Sergio**Institutional affiliation** Fundación latinoamérica Reforma**The views expressed here pertain to**

- Key research question 1
- Key research question 3

Written statement

The most important problem to access to medicines is compliance of regulatory frameworks of controlled substances, which acts like a barrier for access because the implicit logic within is to prevent illicit markets.

The regulatory system has no enough capacity of incorporate the scientific advances at a satisfactory speed, because Drug Conventions (1961, 1971) are located in a hide space between Health Policy and Internal Security Policy, used to control populations so the emphasis has been put into eliminate misuse and illicit traffic, and, as a secondary effect, has built a massive barrier to get this substances, much of them made by the governments in order to accomplish the international regulatory frameworks. Furthermore, the scientific evidence is also putted apart, most of the time encouraged by medical aggrupations that defended commercial interests of pharmaceutical industry or simply lack of proper knowledge mechanisms.

Controlled substances lists must be updated allowing integration of pharmaceutical derivates from cannabis sativa. Evidence shows they are good enough for chronic pain, spasticity associated to MS and nausea and vomit as AES (1)

1. National Academies of Sciences, Engineering, and Medicine. 2017. The health effects of cannabis and cannabinoids: Current state of evidence and recommendations for research

#7

Title, surname, name Dr Simon, Olivier

Institutional affiliation Collège romand de médecine de l'addiction (CoRoMA)

The views expressed here pertain to

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

See next page



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Le CoRoMA est partenaire avec
FOSUMOS et FOSUMIS de la
plateforme nationale:
www.praticiens-addictions.ch

WHO controlled medicine

Lausanne, February 12th, 2020

Public consultation: WHO guideline on ensuring balanced national policies for access and safe use of controlled medicines

Dear Sir or Madam,

The Collège romand de médecine de l'addiction (CoRoMA), literally translated as "French-speaking Swiss College for Addiction Medicine", was created at the end of the 90s' and was constituted as an association on 1st December 2011.

The CoRoMA brings together doctors, pharmacists and every professional within French-speaking Switzerland concerned, directly or indirectly, by the promotion of addiction medicine.

The purposes and objectives of the association are:

- To promote, support and develop addiction medicine;
- To support the professional skills of doctors in the field of addictions;
- To raise new doctors' awareness of receiving and looking after people presenting with addictive behaviors (illegal drugs, alcohol, tobacco, gambling);
- To connect the different French-speaking Swiss actors involved in the field of addictions (cantonal health authorities, primary care doctors, psychiatrists, specialized, academic and non-academic centers, pharmacies, professional and interprofessional associations);
- To facilitate collaboration between doctors and other concerned professionals from a bio-psychosocial perspective

Since its creation, the CoRoMA has been financially supported by the Federal Office of Public Health (FOPH) and it received logistical support from the Geneva University Hospitals (French acronym: HUG) and the Lausanne University Hospital (French: Centre hospitalier universitaire vaudois, CHUV). It does not receive any support from the alcohol, tobacco or gambling industries

Contact: Dr Olivier Simon
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Best regards

Dr Olivier SIMON
Président

Dr Gérard CALZADA
Vice-président

#8

Title, surname, name Merriman, Anne**Institutional affiliation** Hospice Africa in Uganda**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

I am Professor Dr Anne Merriman, representing the views of Hospice Africa Uganda, based in Uganda. The views I am presenting pertain to all key research question [1 / 2 / 3 / 4] of the scope. Our views are ...

As we train and visit the Francophone countries to support initiators of palliative care services, we find an embedded resistance to importation of morphine powder to make affordable and culturally acceptable liquid morphine, to relieve the severest of pains in untreated cancers. This suffering, akin to torture, are found in millions of cancer patients and others, all over Africa, most are unknown to the hospitals and not in their statistics.

The most recent Minister of Health I spoke with, in December 2019, wanted to allow the importation but she was bound by outdated regulations regarding opioids. Can we encourage their change with new WHO documents?

Can a statement come from this meeting reassuring Governments that the knowledge has moved on?

We in Uganda have treated 33,000+++ patients with oral morphine without addiction or diversion, while keeping all the regulations for safe prescribing of class A medications in place.

Nurses have been trained and legally approved, to supplement the few doctors, to write prescriptions for opioids. This is a success in Uganda since 2004 without problems. Can we persuade other LMICs to follow suit?

Professor Dr Anne Merriman, FRCPI, FRCPEd, MComm H., Founder and Director of Policy, Hospice Africa Uganda

#9

Title, surname, name Obumneme, Ezeanosike**Institutional affiliation -****The views expressed here pertain to**

- Key research question 1

Written statement

Main barriers to access and appropriate use of controlled medicines (CM) at the national and local levels.

1. Shortage of CMs
2. Poorly focused regulatory policies and strategies favouring prevention of diversion to illicit use without corresponding efforts to promote availability for medical use
3. Unavailability of a specific policy on CMs to promote equitable access and rational use
4. Outdated laws and regulations on CMs some of which used stigmatizing words like “dangerous drugs” etc that confuse prescribers
5. Lack of quantification of needs, poor funding for procurement, the irregular release of available funds, comparatively high cost of procurement due to low demand
6. Poor geographical coverage due to centralization of storage/stocking and distribution of CMs. Bureaucratic bottlenecks in distribution mechanisms
7. Limitation of outlet services/sale by private pharmacies and primary healthcare facilities
8. Restriction of prescription to senior medical officers rather than all qualified, trained officer

Consequences of these barriers include

1. Active diversion of the limited stock to higher-paying illicit users
2. Poor control of acute/chronic pain among patients in real need
3. Poor prescribing practices due to stigmatization in outdated regulations
4. Expiration of stocked drugs due to poor record-keeping and poor distribution.

#10

Title, surname, name Pettus, Katherine

Institutional affiliation International Association for Hospice and Palliative Care

The views expressed represent the views, decisions or policies of the institution Yes

The views expressed here pertain to k

- Key research question 1
- Key research question 2
- Key research question 3

Written statement

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INTERNATIONAL ASSOCIATION FOR HOSPICE & PALLIATIVE CARE
Advancing Hospice & Palliative Care Worldwide

IAHPC Statement for WHO 2/19/20 Public Hearing on Guidelines Scoping Document

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

I am Katherine Pettus representing the International Association for Hospice and Palliative Care. I address research Questions 1, 2 and 3.

International barriers include the current narcotics control framework that prioritizes restriction of illicit supply while neglecting member state obligations to ensure appropriate access and rational use of controlled medicines.

National and local level barriers are unduly restrictive regulations, weak supply chains, untrained health workforces, cultural fears of illicit drug use and addiction, and high cost of medications.

The consequences of both are unacceptably inequitable distribution of affordable, appropriate essential palliative care medicines on the WHO Model List.

Factors that contribute to medical over prescription and misuse are *also* rooted in lack of appropriate education, limited social and mental health networks of care and support, and fragmented health systems rather than health systems based on primary care grounded in a human rights perspective.

Policies or interventions that have successfully improved access to controlled medicines include education to train health workforces in appropriate use of opioids, government procurement and manufacture of opioids to ensure safe access such as the procurement and distribution models in Colombia and Uganda, and health system strengthening to include palliative care as an essential primary care service.

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#11

Title, surname, name Jayasekar Zurn, Shalini**Institutional affiliation** Union for International Cancer Control**The views expressed here pertain to**

- Key research question 1

Written statement

I am Shalini Jayasekar Zurn representing the views of the Union of International Cancer Control based in Geneva, Switzerland.

The views I am presenting pertain to impact of the lack of access to controlled medicines on health.

Cancers are among the leading causes of morbidity and mortality worldwide, responsible for 18.1 million new cases and 9.6 million deaths in 2018. These figures are set to rise, and most of these patients will need access to quality assured pain relief medicines. Unfortunately, often due to strict national regulation on controlled substances, even the authorized quota for these medicines is underused.

As mentioned in target 8 of the World Cancer Declaration, effective pain control and distress management services should be universally available. Furthermore, all medicines used for these purposes, listed on the WHO Model list of Essential Medicines should be available and affordable.

UICC therefore welcomes WHO's efforts to provide global guidance to national policy makers on how to create appropriately balanced policies on opioids and other controlled substances and prescribing regulations for effective and safe cancer pain management.

#12

Title, surname, name Ooms, Gaby

Institutional affiliation Health Action International

The views expressed here pertain to

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

See next page



Health Action International written statement on WHO Guideline on ensuring balanced national policies for access and safe use of controlled medicines

We commend the secretariat for including the full range of controlled essential medicines in the guideline revisions. However, the primary focus on opioids for pain relief and palliative care in the 'review of the latest evidence' in the WHO Guideline scoping document, as well as the lack of experts on surgical care, anaesthesia and epilepsy in the Guideline Development Group, give rise to concern that other controlled medicines and their rational use will become marginalised in the guideline development process.

In 2019, Health Action International held a high level meeting in which experts from across the fields of pain relief, palliative care, epilepsy, anaesthesia, mental health and management of substance use disorders stressed the common access barriers faced, and that efforts to address this issue must encompass the entire range of controlled essential medicines. This not only includes narcotics, such as opioids, but also psychotropic substances, such as benzodiazepines, barbiturates and amphetamines.

Can WHO please reassure us that the use of controlled medicines for surgical care, anaesthesia and epilepsy receive similar expert attention and inclusion in the guidelines as opioids for pain management, palliative care and management of substance use disorders?

(191 words)

#13

Title, surname, name Daniels, Alex**Institutional affiliation** International Children's Palliative Care Network**The views expressed here pertain to**

- **Key research question 1**

Written statement

I am Alex Daniels representing the views of the International Children's Palliative Care Network based in South Africa.

The views I am presenting pertain to key research question 1 of the scope.

Our views are that there is a need for access to controlled medicines such as opioids, in order to achieve pain/symptom control for babies, children and adolescents. Children's Palliative Care (CPC) aims to minimise needless suffering and optimise quality of life for children and their families. >21million children globally need PC, yet <5% have access to these interventions. 98% of children needing PC and pain management live in LMIC and yet they are the least likely to have their pain/symptoms controlled due to a lack of access to medications, such as those being addressed in these guidelines.

Whilst recognising in some parts of the world access to opioids is compromised and in others concerns have arisen around the misuse of controlled medicines, it is essential to address these inequities and ensure balance across settings. Strategies to help include: 1) National PC policies; 2) Appropriate local, national and regional policies that support access to and safe use of controlled medicines; 3) Training of health care professionals on pain and symptom management, including the prescription of controlled medicines; 4) Clinical guidelines including the use of controlled medicines, and 5) Ongoing research to develop/refine the evidence base for controlled medicines use in CPC.

#14

Title, surname, name Ling, Julie

Institutional affiliation European Association for Palliative Care

The views expressed here pertain to

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

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**European Association for Palliative Care**
One Voice, One Vision in Palliative Care**EAPC Written statement for the public hearing on guideline scoping document: WHO
Guideline on ensuring balanced national policies for access and safe use of controlled
medicines**

I am Julie Ling representing the views of the European Association for Palliative Care based in Belgium. The views I am presenting pertain to all of the key research questions of the scope. Our views are....

We recognise the essential need for appropriate regulation of controlled medicine's and stress the need for balance between restricting access to strong opioids to prevent misuse, whilst ensuring availability for adults and children with palliative care needs.

Barriers to controlled medicines in palliative care include:

- 1) Access and availability
Regulations restricting availability result in less access and lower consumption in LMIC (e.g. Central/Eastern Europe¹)
- 2) Affordability
Cost of drugs (system and the patient)
- 3) Prescribing
Regulation of who & how opioids can be prescribed, stored and dispensed and formulations available
- 4) Lack of knowledge on pain, symptom management and prescribing

This complex issue requires a systemic approach where access to opioids for symptom control in palliative care, and for people with opioid-use-disorders are available as part of Universal Health Coverage through:

- 1) Utilise evidence-based guidelines²;
- 2) Broad education on the safe use of controlled medicines (patients, families, society and policymakers)
- 3) Avoidance of generic terms such as 'chronic pain'
- 4) Research to develop a strong evidence-base

¹ EAPC Atlas of Palliative Care in Europe (2019)

² Caraceni A, Hanks G, Kaasa S, et al. Use of opioid analgesics in the treatment of cancer pain: evidence-based recommendations from the EAPC. *Lancet Oncol* 2012; 13: e58–e68.

#15

Title, surname, name Connor, Stephen R**Institutional affiliation(s)** The Worldwide Hospice Palliative Care Alliance**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

We recognise the essential need for appropriate regulation of controlled medicine's and stress the need for balance between restricting access to strong opioids to prevent misuse, with ensuring availability for adults and children with palliative care needs.

Barriers to controlled medicines in palliative care include:

- 1) Overly strict regulations restricting availability result in less access and lower consumption in Low & Middle Income countries
- 2) Affordability - cost of medicines (system and the patient)
- 3) Prescribing (regulations – who, how opioids can be prescribed, stored and dispensed and formulations available)
- 4) Lack of knowledge on pain, symptom management, and prescribing

Palliative care (PC) providers should not be restricted in providing opioids to patients, particularly in residential settings.

Standard PC practice includes regular monitoring of opioid usage in the home setting and prevention of misuse. This complex issue requires a systemic approach where access to opioids for symptom control in palliative care, and for people with opioid-use-disorders are available as part of Universal Health

Coverage through:

- 1) Avoidance of generic terms such as 'chronic pain';
- 2) Utilisation of evidence-based guidelines;
- 3) Broad education on the safe use of controlled medicines (patients, families, society and policymakers)
- 4) Research to develop a stronger evidence-base

#16

Title, surname, name Dr. Weseka, Esther Nafula**Institutional affiliation(s)** HCGCCK Cancer Center**The views expressed here pertain to**

- Key research question 1

Written statement

I am Dr. Esther Nafula Wekesa representing the views of HCGCCK Cancer morning Center based in Kenya.

The views I am presenting pertain to key research question [1] of the scope.

Our views are :

Barriers to access and use of controlled medicines can be divided into two categories

1) Health care providers

- Lack of knowledge on proper use of opioids. This includes knowledge on the choice of opioids for different patient groups as well as the appropriate dosage. For example we have adult patients being started on low doses of morphine for cancer pain such as 10mg sustained release tablet every twelve hours. Sometimes fentanyl patches have been prescribed for patients with acute pain. Opioids have also been prescribed for chronic noncancer pain.

- Opioid phobia. Many patients are denied opioids for pain due to fear that they may develop addiction. Opioids are prescribed for patients when they get to the end of life phase.

- Inadequate skills for proper pain assessment. Many healthcare providers are not aware of tools used to assess pain. Some of them also underrate the patients' pain.

-

2) Healthcare systems

- Restriction on opioid prescriptions. Only qualified medical doctors are allowed to prescribe opioids yet many basic healthcare facilities do not have access to doctors.

- Restriction on amount of opioids that can be imported to the country.

- Lack of pain management policies

- Prices of some medications are high and some patients are not able to afford them.

Consequences of these Barriers:

- 1) Opioid shortages due to restrictions on importation and distribution.
- 2) Many patients end up with poorly managed pain and therefore visit acute care settings frequently.

#17

Title, surname, name Dioka, Ruth

Institutional affiliation British Pharmaceutical Student Association

The views expressed here pertain to

- Key research question 4

Written statement

As an association we passed a policy during our annual conference in 2019 which states "better safeguarding should be put in place with regards to over-the-counter opioids". It was discussed that the risk of abuse with over the counter opioids and the regular purchase of these should have stricter controls, with sales mainly overseen by a pharmacy professional.

#18

Title, surname, name Dr. Jumanne, Shakilu**Institutional affiliation -****The views expressed here pertain to**

- Key research question 1
- Key research question 4

Written statement**PERSONAL STATEMENT ON THE BARRIERS TO ACCESS AND SAFE USE OF CONTROLLED MEDICINES IN TANZANIA**

1. Most training curriculum for health education do not include management of pain to equip health care providers with the necessary knowledge and skills on pain management including effectiveness of opioid medicines, safe use, side effects strategies to reduce and manage side effects and prevention of dependence and national regulations for controlled medicines importation procedures, prevention of diversion

- As a consequence of inadequate knowledge and skills most health care providers have undue concerns over opioid side effects and risk of dependence such that patients likely to benefit from opioids are denied access

2. Not including opioid medicines as essential drugs for management of pain in children due to fear of misuse and diversion, Morphine is not available in primary health care settings making it difficult to access for patients with moderate to severe pain especially on palliative care.

3. Prohibitive legislation on procurement, prescription and dispensing of opioids need to be reviewed to balance access for patients in need without increasing risk for misuse and diversion, WHO should provide template guidelines for access and safe use of controlled medicines which should be adopted by member countries when formulating legislations to safeguard access to these medicines and periodic monitoring and evaluation to be conducted to analyze country specific laws on access to controlled medicines and how these laws affect access to these medicines by patients

By Dr. Shakilu Jumanne

Paediatric Hematology/Oncologist

University of Dodoma & Benjamin Mkapa Hospital

Dodoma Tanzania

#19

Title, surname, name Dr. Oyebola, Folaju Olusegun**Institutional affiliation** Pain and Palliative Medicine Department, Federal Medical Centre Abeokuta, Ogun-State. Nigeria**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 4

Written statement**WHO Guideline on ensuring balanced national policies for access and safe use of controlled medicines****Access and safe use:**

Controlled medicine **ACCESS** in developing countries is variable depending on rural or urban settings. This is a far cry from the scenarios in developed world where the access could be non-discriminatory.

Access challenges in developing countries could be:

1. STOCK ACCESS – maybe optimal, inadequate or out of stock (Cf; Nigeria – 1year)! Availability of options usually may be rare! The cost implications in those environment that lack NHIS makes it impossible to access the best of controlled medicines with fewer side effects and better compliance.

2. PRESCRIPTION ACCESS – could be normal in urban facilities and impossible in rural settings.

2. Knowledge and skills of pain management and skills to prescriptions and dispensing controlled medicines by hospital staff.

Safe use is mostly affected by lack of prescription personnel to monitor access and availabilities. This is germane in rural areas whereby the controlled medicines become illicit and procure on the counters, made possible by crooked marketers and sold at exorbitant prices.

National policies should therefore put into cognizance the existing scenarios in developing countries sub-urban and rural communities in terms of good stocking and prescriptions to control safe use of controlled medicines. Regulated prescription of controlled medicines work effectively in developed worlds unlike in developing countries.

#20

Title, surname, name Dr. Dam, Abhijit**Institutional affiliation** Kosish - the Hospice**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

Drug manufacturers stand to benefit directly. Buprenorphine transdermal patches, which are very expensive, are difficult to obtain from most pharmacies, while cheap drugs such as morphine IR is not available. Pharmacists prefer to stock the costly patches as their profit margin is higher. Patients, those who can afford, also stand to benefit from the ready availability of the patches. It is a win-win situation.

#21

Title, surname, name Marston, Joan**Institutional affiliation** PalCHASE Palliative Care in Humanitarian Aid situations and Emergencies**The views expressed here pertain to**

- Key research question 1

Written statement

Those caught up in humanitarian crises, both acute and longer-term such as Refugee Camps ,experience very limited access to controlled substances. Apart from the need for opioids for traumatic injuries,those with existing life-limiting conditions requiring palliative care should have access to opioids to relieve pain, breathlessness and enable them to live and die with dignity and without pain. The Barriers are caused by the humanitarian situations , the limited inclusion of opioids in humanitarian response packs , countries who refuse to allow opioids to cross borders, and a lack of knowledge on how to store, prescribe and use these substances by health professionals. We believe controlled substances for pain and symptom management should always be included in emergency humanitarian aid packages and all relevant health responders should be trained in pain management and use of opioids.

#22

Title, surname, name Williamson, Samantha**Institutional affiliation** Mayo Clinic Arizona**The views expressed here pertain to**

- Key research question 1

Written statement

Multiple restrictions along the continuum of both the production and procurement of controlled medicines which include but not excluded to; lack of financial resources to develop and build a framework for the countries that need these medications, lack of governmental support and/or funding and oversight, lack of governmental appreciation for human suffering and pain especially in the palliative medicine population, restricted guidelines regarding moving controlled medicines across the globe such as moving from the U.S. to other countries that are in dire need, patient education on the risks and benefits of using controlled medicines in palliative care settings, possible lack of creative thinking in developing solutions that don't already exist, insufficient training of medical staff on the risks and benefits of using these medications and insufficient training on how to dose and administer, and too many checks and balances from production to procurement. The main consequence is unnecessary human suffering.

#23

Title, surname, name Bikosa, Mwesiga Mark Donald

Institutional affiliation Palliative Care Association of Uganda (PCAU)

The views expressed here pertain to

- Key research question 1
- Key research question 4

Written statement

See next page



I am Mwesiga Mark Donald Bikosa submitting a statement on behalf of the Palliative Care Association of Uganda (PCAU).

Response to question 1;

The main barriers to access to, and appropriate use of controlled medicines at the national and local level in Uganda have been the following:

- a) The limited number of prescribers for these medicines. Whereas Uganda's legislation allows Nurses who are palliative care trained to prescribe certain opioids including oral liquid morphine, the numbers of doctors and palliative care trained nurses is still very low.
- b) The limited knowledge leading to some myths and misconceptions among sections of health workers including pharmacists.
- c) Some issues concerning the medicines supply chain such as poor forecasting by pharmacists, delays in ordering and supplies are barriers to access.
- d) Low funding leading to low quantities of the controlled medicines is also a barrier.

Key research question 4

The policies or interventions that have been successfully implemented for improving the safe use of controlled medicines in Uganda are:

- a) The local manufacture/reconstitution of the oral liquid solution
- b) The statutory instrument allowing specially trained nurses to prescribe oral liquid morphine
- c) The partnership between government and civil society in strengthening the medicines supply

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#24

Title, surname, name Dr. Clark, Joseph**Institutional affiliation(s)** Palliative Care Research Centre, University of Hull**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

The International Narcotics Control Board operates the 'Estimates of Annual Requirements for controlled substances' system. Under this system, countries estimate population level 'need' for opioids and also their 'requirements', that is, the total opioids the health system can safely administer.

There is no evidence-based method of estimating population level need or requirements for controlled substances.

Urgent evidence-based methods of estimating population level needs and requirements for therapeutic opioids are required.

Only with accurate estimates of need, can we understand the gap between 'needs' and 'requirements' and identify the level of need need for health system reform to ensure that needs and requirements become equivalent.

#25

Title, surname, name Marroquin, Maria Mercedes

Institutional affiliation(s) Asociación Latinoamericana de Cuidados Paliativos, ALCP

The views expressed here pertain to

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

See next page

Bogotá, February 19, 2020

ALCP Statement WHO Public Hearing on Guidelines Scoping Document *WHO guideline on ensuring balanced national policies for access and safe use of controlled medicines*

The views expressed here pertain to research questions 1 through 4:

The Latin American Association for Palliative Care (ALCP) welcomes the Scoping Document's balanced approach to opioids.

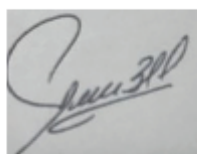
The main barriers at the international level is the existence of a regulatory framework heavily focused on control with limited scope on availability and rational use of opioids.

At the national barriers the main factors that have been demonstrated to contribute to medical overuse and misuse of controlled medicines include inappropriate influence by the pharmaceutical industry on prescribers and the lack of education of health workers, mainly doctors, pharmacists and nurses on the appropriate use, prescription, titration and dispensation of opioids.

Some successful strategies and policies have been implemented in the Region and include the procurement and monitoring system such as the one adopted by Colombia for generic opioids. A successful example of government intervention to ensure safe access is Argentina.

To balance regional diversity, we respectfully request the inclusion of more members from Latin America in the Guidelines Group.

The ALCP will continue to provide technical support to member states aspiring to meet the goals and targets of the 2030 Agenda, and the Astana and UHC Declarations. These commitments that all entail adequate access to internationally controlled essential medicines.



Patricia Bonilla
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#26

Title, surname, name Issimouha, Dille**Institutional affiliation** SOS Cancer Niger**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement

Key research question 1

The main barriers to access to controlled drugs and appropriate use include:

at the international, national and local levels:

- lack of training,
- lack of enforcement of laws and recommendations in force at the central level.

Lack of training leads to a low medical prescription.

The consequences of these obstacles are the low control of patients' pain in different medical specialties

Key research question 2

The main factors that have been demonstrated to contribute to medical overuse and misuse of controlled medicines

The best way in my opinion to avoid misuse and drug abuse is intensive training in palliative care and pain management

Key research question 3

The policies or interventions that have been successfully implemented for improving access to controlled medicines, including: are

The international regulations must be adopted for all countries

National regulations must be applied

Countries must focus in educational interventions

Clinical practice guidelines; and prescription monitoring systems must be developed in all countries by specialist of palliative care and other specialist...

Key research question 4

The policies or interventions that have been successfully implemented for improving the safe use of controlled medicines, including:

- a. To minimize diversion; A rigorous training of pharmacists and health service administrators is essential. They have to control all prescription and release procedures for drugs
 - Prescription books must be adapted and available
 - The unused drugs must be returned and justified
- b. To improve appropriate use of controlled medicines, limiting overuse and misuse; and to prevent such abuses, emphasis should be given to the procedures for distributing medicines and on the control of stocks
- c. To minimize the risk of harm, Health care workers must be rigorously trained in the use and prescription of these drugs. They also need continuing training.

#27

Title, surname, name Dzotsenidze, Pati**Institutional affiliation** Georgian National Association for Palliative Care**The views expressed here pertain to**

- Key research question 1

Written statement

a. The main barrier to access to pain medications in Georgia is that opioids aren't considered as medications and the legislation regulating opioids use is overly restrictive. Opioids can be prescribed only in terminal stage of the disease, when there are no more treatment options. Outpatients can only obtain morphine through the state program "Palliative Care for Incurable Patients". Like regulations, the program covers only patients in the terminal stages (outpatients can benefit for a maximum of six months). Opioids are not sold in pharmacies. Only several authorized pharmacies, located in police stations, dispense opioids prescribed on special forms once or twice in a week. Prescription forms are available only in the framework of the same state program for family doctors, who prescribe under the supervision of the special commission. The commission meets once or twice in a week to decide on initiating or escalating the morphine dose.

b. consequences

16-18% of terminally ill patients benefit from Georgia's palliative care program. The need for opioid analgesics only for the cancer patients (about 16% of total deaths) was 31.75 kg in 2018; actual total consumption around 10 kg. Hence, most terminally ill patients are in pain or are dying in pain.

#28

Title, surname, name Fernández Dávila, Alexandra Tatiana**Institutional affiliation** Asociación Ecuatoriana de Cuidados Paliativos (Ecuadorian Association of Palliative Care)**The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3

Written statement

1)

- a. At international level a barrier is the prioritization of restriction before ensuring access to controlled medicines. The calculations that the member states have to do, giving that at least in Latin America no country is currently reaching the optimum quantity of controlled medicines per capita, makes that every year countries ask for suboptimum quantities. The ways countries control the prescription and distribution of controlled medication, is not fast enough to supply the needs of the population, and is imbedded with cultural fears of illicit drug use and addictions. Also lack of training is a serious barrier.
- b. Patients that stay with pain, a form of torture that could be preventable. In palliative care patients, sometimes they die before they can have an appropriate relief of pain.

2) Lack of training among clinicians, lack of social and mental health networks, fragmented health systems.

3) Educational interventions have been useful in Latin America, but they should be more widespread and begin from undergraduate phases. Clinical practice guidelines have also been useful but when associated with awareness campaigns. In El Salvador the electronic prescription monitoring system is an example of way to reach the further places.

#29

Title, surname, name Rana, Smriti**Institutional affiliation** Pallium India**The views expressed here pertain to**

- Key research question 1
- Key research question 3

Written statement**Key Research Question 1**

Local and National level

1. Regulatory issues: In 1985, in an attempt to curb misuse of opioids, the Govt of India created the Narcotic Drugs and Psychotropic Substances (NDPS) Act. This act and the state NDPS rules posed the following problems:
 - a. Rules varied from state to state and required cumbersome licensing procedures. As many as three or four licenses were typically needed to procure every consignment of morphine. Several agencies, including the Excise, Drug Control, and Health Departments, were involved in the process of licensing to obtain morphine. Frequently the validity of one license (e.g., the possession license) expired by the time another license (e.g., transport license) was obtained. It was very difficult (or sometimes impossible) for doctors and hospitals to obtain all the licenses necessary to procure morphine.
 - b. Harsh punishment prescribed in the NDPS Act (e.g., 10 years of rigorous imprisonment even for minor offenses) has had the effect of alienating pharmacists. Most pharmacies in the country fear punishment in the event of small discrepancies in stock and have stopped ordering opioids.
2. Interruptions in opioid availability - even hospitals that had obtained the licenses in time were unable to procure morphine for dispensing to patients.
3. Problems related to attitude and knowledge:
 - a. Through decades of strict regulation, medical professionals developed a fear of morphine; they would not use it and taught students to avoid it. This attitude came out of exaggerated fears of addiction and respiratory depression, and was reinforced by an unbalanced regulatory environment governing opioids.
 - b. The general public and government officials associates morphine with inevitable addiction and are reluctant to accept the drug for medical needs.
 - c. Over decades, scientific advances in medicine have resulted in an overemphasis on “cure” and a downturn in the practice of symptom control, including pain relief.
 - d. Medical education (till. 2019) did not include pain management.

- e. The amended NDPS Act of 2014 was followed by NDPS Rules of 2015 for their implementation which are far from perfect and the proposed revision of the same is pending for long. The existing rules have not been implemented by the majority of state governments.

International level:

- The US opioid epidemic has caused a general environment that is not conducive to pain management. People study the US situation too superficially and the obvious solution for many appears to be avoiding opioids altogether. If you look deep enough you find that when the US started promoting pain management at the turn of the century and did wide advocacy for it, and it was encouraged by the industry in favour of an expensive opioid. This encouragement of prescription was done without any proper protocol or training of physicians so much so that even though the routine practice for a dentist was to prescribe 3 weeks supply of continuous release of oxycontin after a tooth extraction. While most people quote this, adequate attention has not been given to the successful practice in the UK and western European countries, or even Kerala and Uganda, that with minimal controls, widespread balanced use of opioids can be quite possible. This is not a casual finding. We have decades of experience in all these countries.
- Rather than applying the Principle of Balance, international agencies often favours rigid control. Currently there is an effort initiated by China and supported by other countries to bring in international scheduling of Tramadol. If this scheduling is balanced, it might be acceptable, but unbalanced scheduling prevents access to step two opioids, and that would be a calamity.
- The insistence on evidence base in terms of randomised control studies is another barrier. While we are convinced that in matters as subjective as pain, and its relief, randomised control studies are often ineffective, particularly on children, and insisting on them is irrational. What we should go by should be lower levels of evidence because if randomised control studies cannot be done, how can we not rely on cohort studies?

Key Research Question 3

What are the policies that have been successfully implemented for improving access to controlled medicines?

- Some of the international interventions that have been successfully implemented include the WHO guidelines of 2012 which have now been withdrawn, we believe rather unwisely and without adequate thought.
- In Uganda and Kerala, India, the successful strategy has been to educate people and limit the use of opioids only by institutions where a trained person is available. In Uganda, it is specialist nurses with proper training. In Kerala, it's any doctor with 10 days training in pain management. This has meant that more than 117 institutions in the tiny state of Kerala, now stock and dispense opioids including oral morphine. This has been published in the Lancet.

- In India, advocacy spanning over 20 years has resulted in inclusion of pain management in the curriculum for medical students, starting in 2019. Concurrent education in terms of short courses like 10-day foundation courses have been successful too.
- Clinical practice guidelines by the WHO and by other organisations have been successful.
- As far as prescription monitoring systems have been concerned, the most important thing has been to avoid bringing in pointless and needless monitoring processes like triple prescriptions which actually discourage doctors from writing prescriptions. In India we now have a double prescription system and that seems to be working reasonably well. On the other hand, we also fear that the lack of any monitoring system, like today's system that involves the institution and the state Drug Controller, would result in abuses like in the USA.

#30

Title, surname, name León, Marta Ximena

Institutional affiliation Universidad de La Sabana

The views expressed here pertain to

- Key research question 3

Written statement

See next page



Dr. Marta Ximena León – Colombia

I am Marta Ximena León, Chair of Palliative Medicine at the Universidad de La Sabana, Bogotá -Colombia, representing my self

The views I am presenting pertain to question 3 of the scope.

In Colombia South America in 2018, we did a quanti-quality research with representatives of 33 regions, to identify the perception about availability and accesibility of opioids and the impacts of the lack of access to controlled medication. We interview physicians, patients, insurance companies, representatives of the Ministry of Health, National competent authority, regional competent authorities

The results of the research show that the lack of access to control medicines has an impact in the quality of life of patients and families, increases the consultation to emergency rooms, increases health spending, increases the inequity between regions, forces the patients to move to other regiones generating uprooting of family and culture and is a factor of burnout for caregivers.

The research sought to have objective data related to access to control medications and give a voice to people from different regions, who are importante actores for opioid access in a middle income country of Latin America. In Colombia the lack of access to opioids impairs the lives of peoples and families.

#31

Title, surname, name Cernesì, Simone**Institutional affiliation** Movimento Giotto**The views expressed here pertain to**

- Key research question 1
- Key research question 3

Written statement

I am Simone Cernesì (Movimento Giotto, palliative care interest group).

There are many barriers in Italy, both cultural and organizational.

The training of health personnel is insufficient, both during the degree and in post-graduate studies: a school of specialization in Palliative Care is lacking. People fear the use of certain drugs, such as opioids, both because of the theoretical risk of addiction and because they link the use of these drugs to imminent death.

The major organizational problem is the complexity of prescribing and storing some forms of drugs (injectable morphine, fentanyl and buprenorphine, phenobarbital, methadone, ketamine, propofol).

Access to palliative care for vulnerable groups is a weakness.

The consequence is the incorrect treatment of the symptoms; this generates more suffering and additional expenses: more medical visits, more prescriptions, more hospitalizations, more work permits for family carers.

In Italy, a new law has been issued, in 2010, regarding palliative care and pain. It made it compulsory to record the pain level and treatment in every patient's medical history; it simplified the prescription of some opioid, as compared with the previous situation: in some areas, the opioid prescription has increased tenfold.

This improvement notwithstanding, clinical practice guidelines from different scientific societies can be significantly divergent, thus making it difficult to build common strategies.

#32

Title, surname, name Gueye, Coumba**Institutional affiliation** Joliot Curie Institute**The views expressed here pertain to**

- Key research question 1

Written statement

Selecting an analgesic is based on pain classification. However, making severe pain treatment more available, adequate, and safe in all settings is challenging due to different obstacles including inaccurate of needs' assessment, lack of training limited access.

First, the Health system remains pyramidal and specialists are mostly appointed in hospitals and main medical centers. In rural or suburban areas, access to standard care is limited.

Legally, only physicians has the authority to prescribe morphine. However, pain management is not well specified in medical trainings. Consequently, there is a lack of competency in pain assessment, classification and the fear of morphine side effects is still up to date. In addition, tools available for pain assessment are not always understood when translated.

Secondly, the National Pharmacy is responsible for the importation, stock, and distribution of morphine. Annually, the amount needed is mainly evaluated based on hospitals' statistics. The accuracy of needs assessment is decisive for morphine availability.

Finally, morphine has been added to the list of essential medicines. However, the lack of training has limited effective pain management .Moreover, the absence of defined quality improvement about pain management not helping for the evaluation of programs effectiveness.

#33

Title, surname, name Atout, Maha**Institutional affiliation -****The views expressed here pertain to**

- Key research question 1
- Key research question 2
- Key research question 3
- Key research question 4

Written statement**Key Question 1:**

The main barriers:

1. The fear of using opinion among health professionals.
2. The overprotection done by the policy maker
3. The public fear of using these medications.

The consequences:

The under-usage of these medications. Therefore, patients' quality of life is significantly decreasing.
Inefficiency of decreasing pain management.

Key question 2:

Factors contributing to overuse or misuse of these medications:

- Decrease the public awareness (especially the young age group) toward the consequences of overusing of these medications
- Factors associated with the tendency of some people to abuse these drugs such as poverty, unemployment and family problems
- The inefficient laws and legislations to reduce the misuse of such medications.

Key Question 3:**The policies or interventions that have been successfully implemented for improving access to controlled medicines, include**

- international regulations; this might be a guidance for the national regulations.
- national regulations; should be reevaluated, reassessed and renewed
- Educational interventions; this should be more effective. Right now, it is now less than it should be. Effective education should be given for HCPs, patients and for the public as well.

- Clinical practice guidelines: increasing the HCPs. awareness toward these guidelines and renewing these guidelines continually
- prescription monitoring systems. This should be more effective than it is now. Additionally, increasing awareness toward this system among HCPs.

Key Question 4:

- Increasing the public awareness toward the risk of these medications
- Using different media channels to increasing the public awareness.
- Increasing the medication administration safety system to decrease the medication errors. To decrease the misuse of these medications in the hospitals.

#34

Title, surname, name Ruiz Ospina, Paola Marcela**Institutional affiliation** Asociación Cuidados Paliativos de Colombia**The views expressed here pertain to**

- Key research question 1
- Key research question 3

Written statement

En Colombia existe legislación y regulación respecto a la dispensación y uso de opioides, sin embargo no hay lineamientos prácticos que permitan garantizar cobertura y disponibilidad suficiente de los mismos en zonas diferentes a las capitales o grandes centros urbanos. En la práctica la ruta que deben seguir nuestros pacientes para acceder a la medicación opioide se ve truncada por interpretaciones equivocadas de la norma y consideraciones que se hacen alrededor del uso de este tipo de medicamentos basadas en un miedo profundo al desvío. Las normas del país tienen un fin regulatorio y de limitación del abuso pero aun carecen de claros conceptos que permitan ejemplo definir una ruta clara de control y retorno de los opioides a los dispensadores, cuando ya no estén en uso o cuando el paciente fallece. Tampoco existe la formación suficiente y sistemática al personal médico respecto a indicaciones y formulación segura de opioides lo que se convierte en una barrera de acceso. La educación al personal asistencial no médico y a la población general respecto al beneficio de uso de opioides cuando están indicados, es insuficiente por lo que predominan mitos y creencias culturales equivocadas que se convierten en otra barrera de acceso.