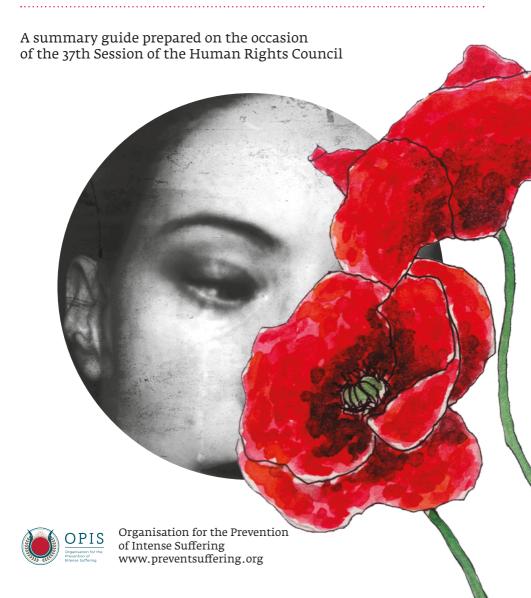
ENDING THE AGONY

ACCESS TO MORPHINE AS AN ETHICAL AND HUMAN RIGHTS IMPERATIVE



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Millions of children and adults around the world, afflicted with terminal or life-threatening illnesses, suffer from severe physical pain, screaming out and begging for help. There is an effective treatment available that is easy and cheap to produce. And yet, for various reasons, including government regulations based on disproportionate concerns about misuse, and a historical neglect of suffering even within medical systems, most people are unable to access this treatment.^{1,2}

The lack of access to morphine and similar opioids is a reality specific to most low- and middle-income countries, and it is a critical issue from an ethical, human rights, medical and humanitarian perspective. It is urgent to effect rapid change through effective, compassionate, evidence-based policies. Every delay means more people suffering needlessly.

While each country has its own specific issues and bottlenecks, policymakers can make real progress in solving the problem by implementing some basic principles and measures, based on successes achieved in other parts of the world.

There are remarkable individuals who have taken the initiative, overcoming bureaucracy and facilitating access to morphine and palliative care in specific regions and countries. So much more could be achieved, and more quickly, if central health authorities made this a top priority, loosened regulatory hurdles, ensured widespread training and education on palliative care, and facilitated the procurement, production, distribution and prescription of oral morphine. Dr. Faith Mwangi-Powell, founding Executive Director of the African Palliative

Care Association, has said that the success story of Uganda shows what's possible when different groups come together, but that the "most important thing is good political will."³

This short guide summarises some of the key issues and solutions, including an emphasis on the fundamental ethical principles from which all else flows. The many organisations working on the subject of pain relief have developed country-specific recommendations and solutions through painstaking work on the ground. This guide offers an additional voice in support of these efforts.

AN ETHICAL ISSUE

Intense suffering may be a private, internal phenomenon, often hidden from the gaze or awareness of others, but it is the most viscerally overwhelming experience there is, pleading desperately for relief. There is nothing else that has greater urgency than preventing or relieving intense suffering – of human beings and, indeed, of any sentient beings capable of suffering. It is the single most important goal of a compassionate society. Although OPIS's understanding of ethics explicitly places the greatest emphasis on intense suffering, coming to the assistance of the least well off – those suffering the most – can also be seen as the strongest imperative within many other traditional ethical frameworks.

It is a tragedy that millions of people are condemned to suffer every year because they cannot legally access the extract of an abundant plant. How governments respond to this tragedy is a test of their willingness to implement the most basic ethical principle common to diverse cultures over thousand of years, known as the Golden Rule: "Do unto others as you would have them do unto you." If it were one-

self, one's child or one's parent suffering from the extreme pain of a terminal or life-threatening illness, most people would do everything in their power to secure pain relief, and denounce any interference or needless bureaucracy. The suffering of others matters just as much and merits the same attention, with the most extreme suffering being of the greatest urgency.

There are many issues under international discussion competing for attention and resources, and the loudest, most powerful voices can distract from clear reflection. It is critical that we not lose sight of what matters, and remember that preventing intense suffering must be our highest ethical priority.

A HUMAN RIGHTS ISSUE

Among the rights guaranteed to all human beings under international treaties are:4

- The right to the highest attainable standard of health
- Freedom from torture and cruel, inhuman or degrading treatment or punishment

Freedom from preventable pain is a cornerstone of these fundamental human rights.

The UN Committee on Economic, Social and Cultural Rights has clearly stated that access to essential medicines is an element of the right to the highest attainable standard of physical and mental health under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁵

The UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,

Dainius Pūras, wrote in a 2015 open letter:6

"International human rights law places particular and explicit emphasis on the obligation of States to guarantee a number of relevant health and health-related services. This includes the provision of essential controlled medicines for the management of pain, including in palliative care, the treatment of drug dependence, and other conditions. Despite this obligation, approximately four fifths of the world population, overwhelmingly in the global south, lack adequate access to opiates for the treatment of pain."

The UN Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, wrote in a 2013 report:7

"Ensuring the availability and accessibility of medications included in the WHO Model List of Essential Medicines is not just a reasonable step but a legal obligation under the Single Convention on Narcotic Drugs, 1961. When the failure of states to take positive steps, or to refrain from interfering with health-care services, condemns patients to unnecessary suffering from pain, states not only fall foul of the right to health but may also violate an affirmative obligation under the prohibition of torture and ill-treatment. (...) Governments must guarantee essential medicines—which include, among others, opioid analgesics—as part of their minimum core obligations under the right to health, and take measures to protect people under their jurisdiction from inhuman and degrading treatment."

A MEDICAL ISSUE

The World Medical Association's "Declaration of Geneva" (Physician's Oath) states: "The health and well-being of my patient will be my first consideration." The 2014 World Health Assembly resolution on pallia-

tive care acknowledges more specifically "that it is the ethical duty of health care professionals to alleviate pain and suffering." Medical doctors and the medical establishment have the role and responsibility not only to ensure that people can live out their lives in as healthy a state as possible and prevent them from dying prematurely, but also to keep them free of pain and suffering, even when their lives are nearing an end. In fact, it is the prevention and alleviation of physical and emotional suffering due to illness or disability that is arguably the physician's most important role.

The World Health Organisation recognises morphine as an essential medicine. ¹⁰ Morphine and similar opioids are needed to treat moderate to severe pain in, among others:

- Terminal cancer patients
- End-stage AIDS patients
- Patients suffering from other non-oncological conditions
- (e.g. COPD, cardiopathy, ...)
- Women in labour suffering from uncontrolled pain
- Patients suffering from injuries caused by accidents or violence
- Post-surgical patients

DEPENDENCE AND DIVERSION: THE FACTS

The Global Commission on Drug Policy's (GCDP) 2015 report, citing a 2008 research article, states that "research, while limited, has shown that among patients with no history of substance misuse who were treated with opioid analgesics, only 0.43% misused their medication, while just 0.05% developed dependence."

The opioid epidemic in the United States, while a serious health problem, has little connection with palliative care or the treatment

of patients in moderate to severe pain. It is in large part the result of aggressive corporate marketing practices, in a context where physicians have not been properly educated to treat pain, leading to the widespread over-prescription of opioids in cases where they were not appropriate. Clear-headed policymakers should ensure that people in agony in lower-income countries are not left to suffer because of unfounded fears, based on a distinct issue specific to another country.

The fear that opioids will be diverted for illicit use is similarly unfounded. The International Narcotics Control Board (INCB) has itself stated: "Despite the ever-increasing scope of the international drug control system, diversions of narcotic drugs from the licit to the illicit market are virtually non-existent." ¹²

STATUS QUO BIAS AND IRRATIONALITY

It is a common human tendency to stick with the familiar and to favour decisions already made, even if the situation is unsatisfactory. The status quo bias is one of the many cognitive biases that affect human thinking and is an obstacle to rational decision-making. We can more clearly identify this bias by imagining the reverse situation and recognising that there would be less rationale to change things than in the present situation. If, for example, cancer and AIDS patients around the world were already receiving sufficient opioids to treat their severe pain, no reasonable policymaker would advocate taking away their medication, even if there were some associated issues – the issues would be addressed directly and specific solutions found.

The decades-long draconian approach of the international community to preventing drug dependence is now widely recognised to have been a human disaster, both in the failure to tackle the primary issue and for the additional human suffering caused, including the patients in moderate to severe pain who have been prevented from accessing essential medicines. We need politicians and policymakers to be courageous enough to admit that past policies were misguided, and to rebalance their priorities and approaches in ways that will reduce human suffering.

CONCRETE STEPS TO SOLVING THE PROBLEM

1. DEVELOP A CENTRALISED STRATEGY

Human Rights Watch's 2011 report "Global State of Pain Treatment: Access to Palliative Care as a Human Right", section IX, lists a series of specific recommendations. One of the most important recommendations to governments is: "Establish, where this has not yet been done, a working group on palliative care and pain management. This working group should include all relevant actors, including health officials, drug regulators, health care providers, nongovernmental palliative care providers, and academics, and develop a concrete plan of action for the progressive implementation of pain treatment and palliative care services."

GCDP's 2015 report mentions in point 7: "Governments should establish clear plans to remove the barriers to ensuring access to controlled medicines, [the barriers] including: national drug policies anchored in a criminal justice approach, rather than a public health and human rights approach; burdensome domestic regulatory frameworks; stigmatized societal attitudes driving a fear of prescribing opioids for pain relief and the treatment of opioid dependence; poor knowledge of these medicines by health professionals and regulators; and

overpricing." The GCDP argues that the national bodies appointed to oversee states' dual obligations under international drug treaties overwhelmingly adopt a criminal justice lens, and that ensuring access to controlled medicines should be the role of a separate body controlled by the Ministry of Health or other relevant ministry.

The implementation of palliative care programs and the provision of all the medicines and materials they require are essential for ensuring the wellbeing of those in end-of-life or "life-limiting" situations. Countries should introduce a comprehensive palliative care program that also incorporates the Essential Package of palliative care and pain relief interventions specified by the Lancet Commission's comprehensive 2017 report. ¹⁴ Making available oral morphine in sufficient quantities to relieve the suffering of those in moderate to severe physical pain, and providing adequate countrywide training in its use, are fundamental to the implementation of palliative care programs. ¹⁵

Governments should also implement the nine roles agreed upon and stated in the 2014 World Health Assembly resolution on palliative care, encompassing areas such as policy development and revision to ensure palliative care access, training of health workers at the various levels, ensuring availability of morphine, research and engaging all stakeholders in the public and civil society sectors.

2. ADAPT REGULATIONS TO ENSURE BETTER BALANCE BETWEEN ACCESS AND CONTROL

GCDP's 2015 report lists some of the diverse national regulatory barriers that directly influence the availability and accessibility of controlled medications, in particular opioid analgesics. All overly strict limits and regulations should be loosened. These include:

• Limits on the number of days' supply that can be provided

in a prescription;

- · Limits on doses;
- Limitations on who can prescribe, with some countries only allowing certain classes of doctors to issue a prescription;
- "Special" procedures for prescribing opioids making the process more onerous, including "specific" forms that are difficult to obtain, or a requirement that multiple forms be completed;
- Patients either needing to "register" or "receive special permission" to ensure eligibility;
- "Excessive penalties" for prescription errors or "mishandling of opioids";
- Limited number of pharmacies being able or willing to dispense opioids;
- Unreasonable storage requirements.

3. AIM FOR AN AMBITIOUS SCALE-UP OF TRAINING AND ORAL MORPHINE DISTRIBUTION

Hospice Africa Uganda adopted two key measures that can be replicated elsewhere:

- Train and empower nurses, and clinical officers/medical assistants where they exist, to give palliative care in communities and to prescribe oral morphine for severe pain, so that the number of doctors available is not a limiting factor.
- Centrally manufacture oral liquid morphine from morphine powder, allowing bulk purchasing, cost reduction and control of the countrywide distribution process, and minimising any risk of diversion. Morphine powder is cheap and affordable for all countries, and the reconstitution setup can be stepped up from basic kitchen sink technology to bulk reconstitution and packaging. The liquid form is of no interest to those wishing to divert morphine for misuse.

The Lancet Commission report, Panel 12, makes several recommendations for ensuring safe and adequate access to morphine, including:

- Oral morphine should be available at all hospitals and local health centres.
- Local health care staff should be trained in palliative care and opioid analgesia.
- Safe local storage facilities: locked, well-anchored boxes or cupboards.
- All doctors should be legally empowered to prescribe morphine in any dose needed to provide adequate pain relief, and specially trained nurses may also prescribe morphine when there are insufficient doctors.

4. DESTIGMATISE USE OF MORPHINE AND OTHER OPIOID ANALGESICS

An additional barrier to the administration of oral morphine is the stigma in many countries and communities among both doctors and patients, based on irrational fears of addiction¹⁶, or that administering morphine implies a death sentence, or the belief that those dying should be kept in as conscious a state as possible and endure their pain. Governments can destigmatise the use of morphine and other opioids through an information campaign in hospitals, clinics and pharmacies throughout their countries, informing patients and doctors that everyone has the right not to die in pain.

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ADDITIONAL RESOURCES

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