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Removing barriers to palliative care medicine

Rational medical use of essential controlled medicines in Africa

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Katherine Pettus holds a PhD in political theory from Columbia University, and a master's in health law and policy from the University of California San Diego. As senior advocacy director for the International Hospice and Palliative Care, Katherine leads delegations at meetings of UN entities to advocate for improved availability, and rational use of opioids for palliative care as a component of the right to health. She addresses issues of global palliative care development and policy as an essential element of primary health care and universal health coverage throughout the life course.

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Acronyms and abbreviations

AU	African Union
APCA	African Palliative Care Association
CND	Commission on Narcotic Drugs
ICEM	Internationally controlled essential medicine
INCB	International Narcotics Control Board
SHS	Serious health-related suffering
UNODC	United Nations Office of Drugs and Crime
WHO	World Health Organization

SUMMARY

In April 2021, the African Group of the UN Commission on Narcotic Drugs (CND), the central drug policymaking body within the UN, expressed 'grave concern about the access, availability and affordability of medicines, including pain-relieving drugs for millions of people who need them most on the African continent'. The Group was referring to a persistent public health crisis across Africa: lack of essential medicines for the relief of severe pain and suffering, including for anaesthesia, trauma, obstetrics, neurological disorders, and palliative care. Unlike many other essential medicines, those required for these applications – namely opioids – are subject to strict international control due to concerns that they contain substances believed to induce dependence under certain circumstances. Palliative care, the medical specialty that was developed to address health-related suffering, is available in most of North America, Australasia and Western Europe. All WHO member states, including the African Group, have pledged to integrate palliative care into primary health care. However, in eastern and southern Africa, shortages of opioids for palliative care present a persistent challenge to this integration. The underlying barriers to access are well known and some African governments are already taking steps in partnership with civil society to overcome them.

This policy brief reviews the common barriers to opioids for rational medical use in the region and proposes solutions that align with international law and multilateral commitments. It is recommended that African governments adopt a public health approach to palliative care and access to essential medicines, which rests on three pillars: enhancing education of patients and medical practitioners; strengthening supply chains for medicine availability; and developing consistent government policies and practices that balance opioid access and control.

ACCESSING PALLIATIVE CARE MEDICINES

Since international drug control bodies began instituting strict control of essential medicines[1] to combat the opioid crisis, the response has led to a different kind of global health crisis that particularly affects lower-income countries: severely limited access to medicines for palliative care. Opioids[2] such as morphine are cornerstone therapeutic agents of the internationally controlled essential medicines (ICEMs)[3] used for the treatment of moderate to severe pain, critical care, terminal breathlessness, neurological conditions, anaesthesia, obstetrics, mental health and palliative care.[4] Between 2010 and 2013, only 0.03% of the opioids distributed globally went to low-income countries.[5] The issue of inadequate access to essential medicines for palliative care around the world persists and presents a particular threat to low-income individuals in Eastern and Southern Africa.

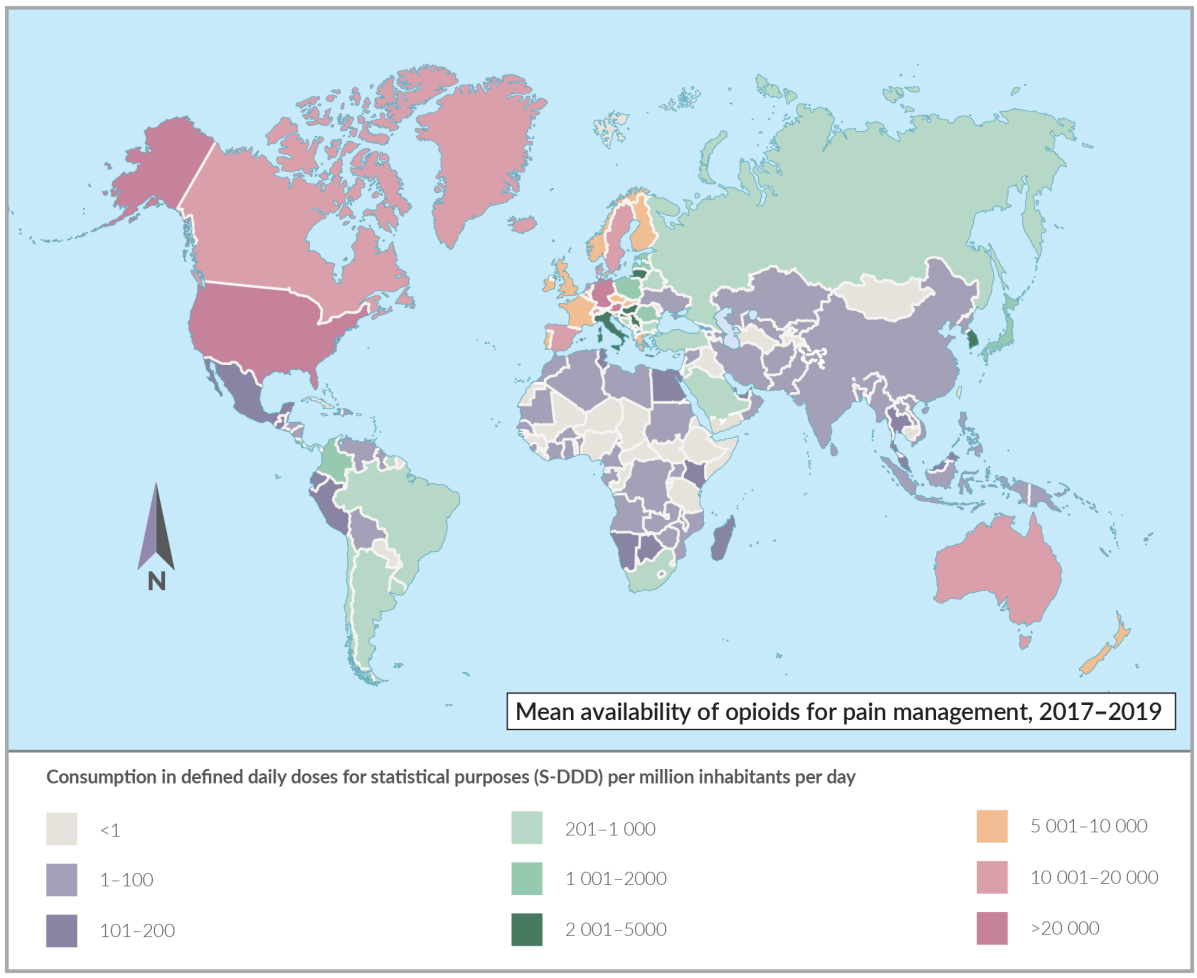

FIGURE 1: Availability of opioids for pain management.
Source: Adapted from International Narcotics Control Board

Palliative care and rational use of medicines

Palliative care is required to alleviate pain from serious health-related suffering (SHS) caused by a number of life-limiting and life-threatening conditions. The global burden of SHS is projected to escalate 78% by 2060. In other words, an estimated 48 million people will die while enduring significant avoidable health-related suffering.[6] As a result, all WHO member states have pledged to integrate palliative care into primary health care.[7] However, these services remain largely underdeveloped in low- to middle-income settings, where over 80% of patients with conditions that require palliative care live. Lack of access to opioids is a significant component of this issue, limiting effective integration of

palliative care into other essential health services, such as cancer treatment and control, and impairing health workers' ability to deliver effective palliative care.[8]

The laws and policies underlying the limited access to ICEMs in most lower-and middle-income countries, including on the African continent, are rooted in practices dating back to colonial era treaties designed to contain the commodification of opium, which was legally marketed and sold throughout the British empire.[9] Although the use of opioids as a therapeutic substance was historically overseen by traditional healers and the medical profession, non-medical use of opioids and other controlled substances has slowly grown into what is now known as the 'world drug problem'. Notwithstanding the illicit use of these substances, the therapeutic properties of opioids, in particular the opium derivative morphine, are officially recognized in the WHO Model List of Essential Medicines, which is a key guide for national-level drug policymaking and health agendas

In the 2000s, a dramatic rise in opioid dependence and deaths from overdoses in the United States – the largest global opioid consumer – led policymakers to broadly increase regulations on opioids and restrict their use.[10] The International Narcotics Control Board (INCB) and the UN Office on Drugs and Crime (UNODC) are the foremost international bodies that monitor and influence drug regulations within and between countries to ensure access to opioids for rational medical use,[11] while preventing their diversion for illicit purposes. The CND is the operational policymaking segment of the UNODC, tasked with deciding the scope of international drug control conventions.[12] A significant component of the CND mandate is to ensure that state governments understand and fulfil their obligations to create adequate access to ICEMs.

In recent years, concern has mounted that among these bodies, the mission to prevent opioid and other controlled substances diversion globally has taken precedence over the mission to ensure access to these essential medicines locally, despite lack of evidence that opioid diversion is, in fact, a widespread crisis. The subsequent policy decisions have had dire consequences for people with SHS in low- and middle-income countries, and particularly in Eastern and Southern Africa.

Impact of the crisis in Africa

In April 2021, at the annual meeting of the CND, the African Group expressed 'grave concern about the access, availability and affordability of medicines, including pain-relieving drugs for millions of people who need them most on the African continent'.13 In 2015, it was estimated that nearly 17 million people in sub-Saharan Africa had SHS – the second largest population by subregion, following East Asia – and were in need of essential medicines for palliative care.[14] Yet access to palliative care medicines in Africa is the lowest of all major subregions and has actually decreased since 1994, while access has vastly increased in other subregions.[15] On average, the African opioid consumption rate is 50 daily doses per million per day, compared with 14 320 in the US, which has the highest global consumption rate.[16] This is despite the fact that an aging population, the HIV epidemic and noncommunicable diseases have created a marked need for ICEMs in Africa.

The need for ICEMs

In Africa, HIV/AIDS is the largest source of SHS requiring palliative care, with 77% of the need stemming from HIV. In general, between 54% and 83% of HIV patients experience pain of moderate to severe intensity.[17] In spite of medical progress, reported pain rates have not diminished in the past 30 years and under-treatment of pain remains an issue. A survey of the availability of ICEMs for managing HIV-related pain and symptoms in East Africa showed a concerning lack of availability of opioid formulations for both children and adults.[18] This is particularly troubling, as Eastern and Southern Africa have the highest mortality rates due to advanced-stage AIDS (330 000 deaths recorded in 2018), meaning the need for ICEMs in this region is acute.[19]

In addition, 80% of cancer patients are likely to experience suffering at some point of the disease trajectory.[20] Malignant cancers represent the second-highest source of SHS requiring palliative care in Africa. Under-treatment for pain can have knock-on consequences. For instance, one longitudinal survey conducted in Sudan found that uncontrolled pain was associated with patients' frequent use of cancer care services.[21]

Although palliative care is a clinical approach appropriate for people of all ages who have preventable SHS, in sub-Saharan Africa it is particularly important for older persons. The elderly population in this region is expected to grow to 67 million by 2025, and to 163 million by 2050.[22] While the increased lifespan in Africa is a success story, the suffering produced by the diseases that inevitably accompany older age presents a great risk to a population that is unable to access the essential medicines to relieve it. At the same time, on the other end of the age spectrum, Africa also has the largest global share of children aged 0–19 years in need of palliative care, at 52%.[23]

The state of palliative care by country

The development and provision of palliative care within a country can be assessed in terms of the doses of ICEMs administered, the number and location of facilities, and the percentage of the population reached. A 2017 systematic review mapping levels of palliative care service development in Africa from 2005 to 2016 showed that the bulk of development comes from the East and Southern African regions, with Somalia and Comoros being the notable exceptions where nothing is known about the state of care in those countries.[24] The review revealed that palliative care services on the continent are concentrated in Uganda, Kenya and South Africa, with other countries in various stages of capacity building and integration.

South Africa reports the highest consumption of ICEMs for pain management, with a score of 201-2 000 daily doses for statistical purposes (S-DDD) per million inhabitants per day. The other countries in the region reported 1-100 S-DDD.[25] Given that the INCB considers doses below 200 S-DDD inadequate, countries such as Mozambique can be categorized as facing acute inadequacy, while countries like South Africa are making good progress.

Although some African countries have community-based models of palliative care, access to and availability of ICEMs remain a challenge.[26] For example, although Uganda has made great progress in developing palliative care services, the country's consumption of about 58 S-DDD only meets the needs of 11% of the population.[27]

Although some governments are working with the UN organizations and civil society on improving this situation in the region, much still needs to be done to ensure adequate access to all in need.

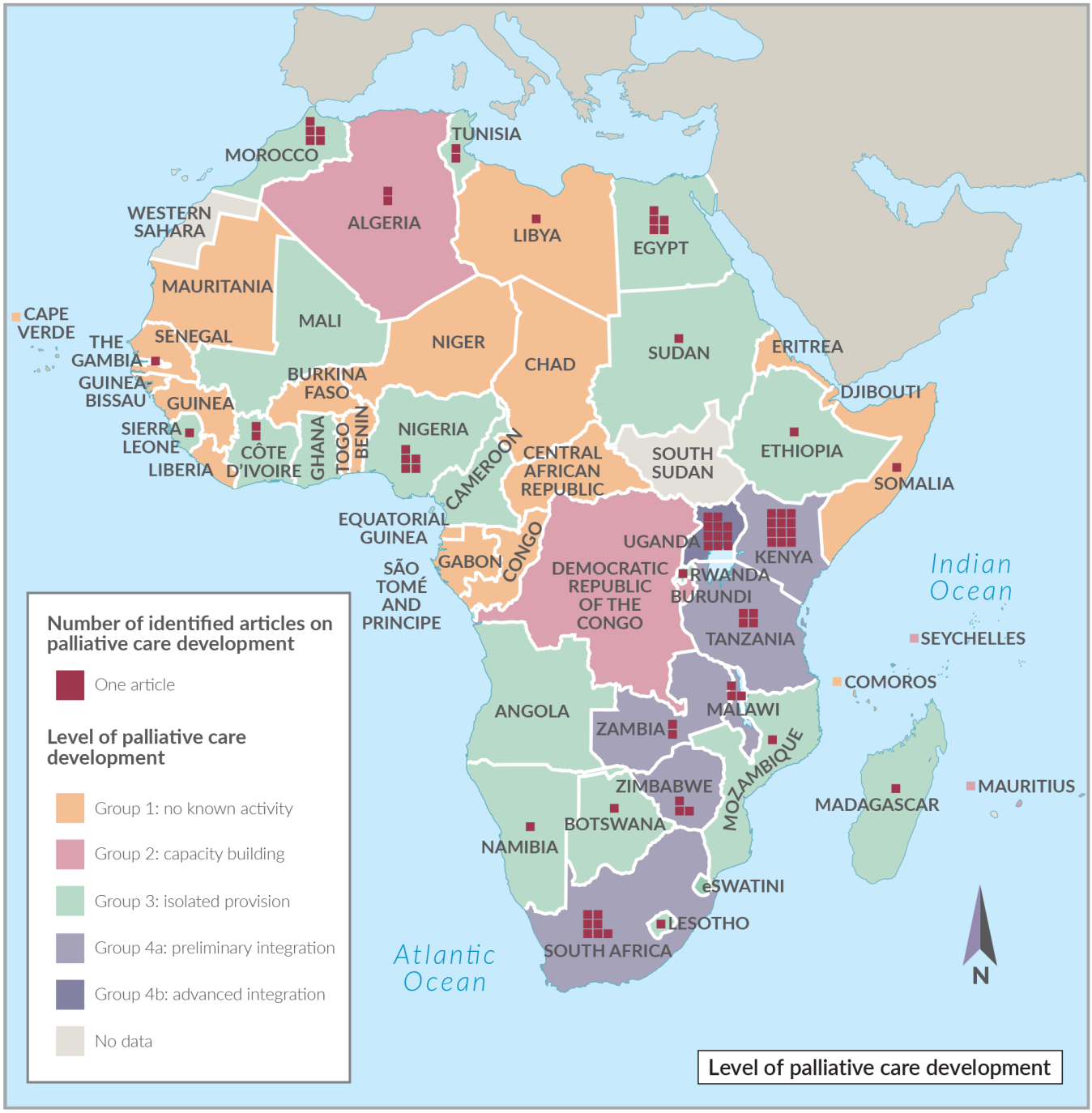

FIGURE 2: Level of palliative care development.

Source: John Y. Rhee, Eduardo Garralda, Carlos Torrado, et al., Palliative care in Africa: a scoping review from 2005–16, *The Lancet Oncology*, 18, 9, E522–E531

BARRIERS TO CARE

In order to propose policy options that can effectively address the unmet need for ICEMs in Eastern and Southern Africa, it is critical to understand the documented barriers to access and availability. The most significant barriers in the region are:

- unduly restrictive national policies and regulations that prioritise narcotics control over public health;
- lack of workforce capacity to safeguard and prescribe controlled essential medicines;
- fear of opioids based on ideological narratives and lack of appropriate medical training;
- unaffordability as a result of unregulated pharmaceutical markets; and
- highly localized access to palliative care services.

Most of these barriers have been exacerbated by the US opioid crisis, with implications for policy, health workers and medicine availability.

A misunderstood crisis

During the 1990s, the development of hospice and palliative care in Kenya, Swaziland, Botswana, Tanzania, Zambia, Uganda, the Democratic Republic of Congo and Malawi was often led by medical missionaries and charitable organizations.[28] By 2017, almost half of the health departments on the continent had appointed at least one staffer responsible for palliative care. Meanwhile, opioid consumption per capita remained low across all African countries, with South Africa and Tunisia among the countries with the lowest rates.[29]

Recently, the slow progress in implementing a public health approach to palliative care in the African region has faced a strong headwind from the international health community, which has been predicting a global 'opioid crisis' that will mimic the US phenomenon of misuse and overdose. The US public health crisis of opioid misuse originated from a highly deregulated, market-driven health policy space characterized by lack of appropriate clinical education in the treatment of pain, aggressive direct-to-consumer marketing on the part of pharmaceutical companies, and non-evidence-based prescribing on the part of physicians.

By contrast, the few WHO Regional Office for Africa health systems with adequate access to opioids have reported no significant problems of diversion or misuse of legitimately prescribed controlled medicines. Although concerns about a global, or even African, opioid crisis may well be overstated, they have had a chilling effect on professional efforts to improve rational medical use of ICEMs in African countries.

A 2013 study of access to opioids for cancer pain in Africa showed that the availability of most drugs was inconsistent overall.[30] Only three countries in the survey had morphine available at all times. These availability issues are attributed to stock-outs and regulatory restrictions to access. ICEM stock-outs due to supply chain failures can lead to avoidable patient deaths and exacerbate avoidable health-related suffering of patients living with uncontrolled symptoms. For example, lack of access to ICEMs is one factor that explains observed survival gaps of paediatric cancer patients.[31]

The restrictions limiting access to ICEMs are multiple: requirements for special authorization for physicians to prescribe opioids; patient permission to obtain a prescription; limits on prescription amounts; and limitations on authorized dispensing locations.[32] Despite legislative and regulatory changes, as well as other improvements reported by authorities, including authorized nurse prescribers in Uganda, Malawi and Rwanda, the number of medical professionals who have the necessary credentials to prescribe opioid analgesics remains limited and must be increased to strengthen provider confidence. Ongoing work to strengthen supply chains and educate prescribers of controlled essential medicines should be supported.[33]

For patients to access ICEMs, however, they and their clinicians must first desire and demand these opioids for rational medical use. At present, there is widespread distrust of opioids on the continent, with doctors reluctant to prescribe, and patients reluctant to take the treatment. The use of stigmatizing terminology in drug laws perpetuates negative associations with opioids in the public consciousness. Health workers and patients therefore require greater education about the importance of opioids in pain management.

A WAY FORWARD THROUGH INTERNATIONAL FRAMEWORKS

All of the barriers to essential medicines in Eastern and Southern Africa can be dismantled by appropriately trained healthcare providers, sensitized patients and families, and concerned policymakers who understand how the UN system authorizes availability at the national level, while regulating illicit supply to prevent diversion and non-medical use.

This first requires an appropriate regulatory environment such as that proposed by the UNODC Technical Guidance, which includes supply chain strengthening and workforce training, such as that carried out at Hospice Africa Uganda Institute and other educational facilities.[34] The outcome agenda of the 2016 UNGASS Special Session on the World Drug Problem began to undo the damage caused by decades of placing a primacy on anti-diversion measures in drug control.[35] UNGASS recommendations that are still relevant to governments include:

- reviewing domestic legislation and regulatory and administrative mechanisms to simplify and streamline processes;
- removing impediments to the availability of substances;
- addressing issues of affordability of substances and expanding coverage to rural areas;
- providing capacity building and training;
- developing national supply management systems for selection, quantification, procurement, storage, distribution and use; and
- updating national Essential Medicines Lists to align with the WHO Model List.

Following UNGASS recommendations, which were informed by African members, one of the main pillars of the 2019–2023 African Union Plan of Action on Drug Control and Crime Prevention is prioritizing the dual mission of ICEM access and control.[36] This pillar includes activities to address barriers to availability and accessibility by engaging with pharmaceutical associations, governments and civil society organizations, as well as by training healthcare staff. Another major area of activity is increasing the local production of controlled substances and plants for medical use, in line with the international drug conventions.

LOCAL PRODUCTION OF ORAL MORPHINE

One explanation for the low rate of diversion and misuse of opioids reported in African is the choice of a liquid oral formulation of morphine, which is less prone to diversion than more expensive formulations, such as oxycodone and fentanyl. As a result, African clinicians have begun working in collaboration with government to procure the raw ingredients in powder form, reconstitute them as liquid morphine and distribute to facilities.

In Uganda, the non-profit Hospice Africa Uganda began producing morphine locally in the 1990s using a simple, low-cost process. See the video from the BBC that documents the production process of pharmacy technicians to produce affordable morphine for the entire country (BBC News, How Ugandan hospice makes cheap liquid morphine, 2014, https://www.bbc.com/news/av/health-27664121). The process, which relies on powder from the UK, results in an ICEM that is one-sixth the price of commercially made equivalents.

The African Palliative Care Association and Hospice Africa Uganda are supporting the uptake of the formulation and training process to other African countries. Today, local oral morphine production systems have been established in Namibia, Rwanda, Malawi and Kenya, with Rwanda emerging as a leader.[37] Since starting in 2014, Rwandan pharmacists now produce the liquid morphine under strict regulations, directly controlled by the government to limit diversion. After production, access to the drug is tightly controlled during distribution to facilities and prescription.

This is achieved, in part, through training of medical practitioners to differentiate between SHS that can and cannot be treated with morphine.

Pathways to care are also highlighted in the broader framework of the Sustainable Development Goals (SDGs). Since medicine availability impacts outcomes of care, access to ICEMs is included in the Universal Health Care Coverage[38] component of SDG Target 3.8.[39] The African Health Strategy 2016-2030 is the regional framework designed to meet the health-related SDG targets.[40] The strategy envisions an integrated and prosperous Africa free of its heavy burden of disease, disability and premature death – and, we would add, free from SHS.

Civil society organizations and other advocates have pushed policymakers at all levels to adjust drug control mechanisms to allow rational medical use. However, this evolutionary process takes time and inter-departmental coordination, and will regrettably continue to leave patients with little to no access to the medicines they need. This comes as governments must increase access within their health systems by increasing the demand for, and supply of, narcotic drugs for medical and scientific purposes after decades of fighting to reduce both demand and supply.[41]

CONCLUSION AND RECOMMENDATIONS

The WHO public health approach should be adopted to address the unmet need for internationally controlled essential medicines in Eastern and Southern Africa. This requires policymakers, state governments and medical practitioners to see palliative care and access to ICEMs as essential to ensuring the general health of their countries. There is recent evidence that African stakeholders are recognizing this. In 2020, the World Health Assembly, led by the African Group in this respect, called on governments and, where applicable, regional economic integration organizations, to include palliative care in their pandemic response and preparedness plans.[42]

The public health approach consists of three synergistic pillars: education, medicine availability and policy development. A public health approach led by medical professionals and civil society organizations can support medicine regulators and ministries of health in all countries to take the following actions:

- Strengthen the regulatory and legislative environment by developing consistent policies and practices – in consultation with health system providers and patients – that ensure balanced access to internationally controlled essential medicines for public health needs while preventing non-medical use.
- Train the primary care health care workforce, including community health workers, in the safe handling and prescribing of controlled medicines to relieve pain and suffering, and prevent non-medical use along the lines of the Uganda model.[43]
- Strengthen regional and national supply chains, including through regional manufacturing and pooled procurement through multistakeholder consultations with civil society organizations, national competent authorities and relevant ministries, including health, transportation, industry and agriculture.[44]

Notes

[1] Essential medicines are those that satisfy the priority health care needs of the population. They are intended to be available in functioning health systems at all times, with assured quality and adequate information, and at a price the individual and the community can afford.
[2] Opioids are a category of substances that include organic (i.e., opiates derived from opium), semi-synthetic, and synthetic substances. They are typically used to treat moderate to severe pain. Due to their addictive nature, many opioids are classified as 'controlled substances', which require extensive regulation.
[3] Palliative care medicines (including opioids) that are regulated by international drug control conventions, which are primarily overseen by the UN and the WHO, are considered internationally controlled essential medicines (ICEMs).
[4] Palliative care involves the holistic treatment of individuals with serious health-related suffering (SHS) due to severe illness, and especially of those near the end of life. It aims to improve the quality of life of patients, their families and their caregivers.
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