

GLOBAL ACCESS TO PAIN RELIEF: EVIDENCE FOR ACTION

THE FIRST EVER GLOBAL SURVEY ON AVAILABILITY AND BARRIERS TO ACCESS OF OPIOID ANALGESICS FOR PATIENTS IN PAIN

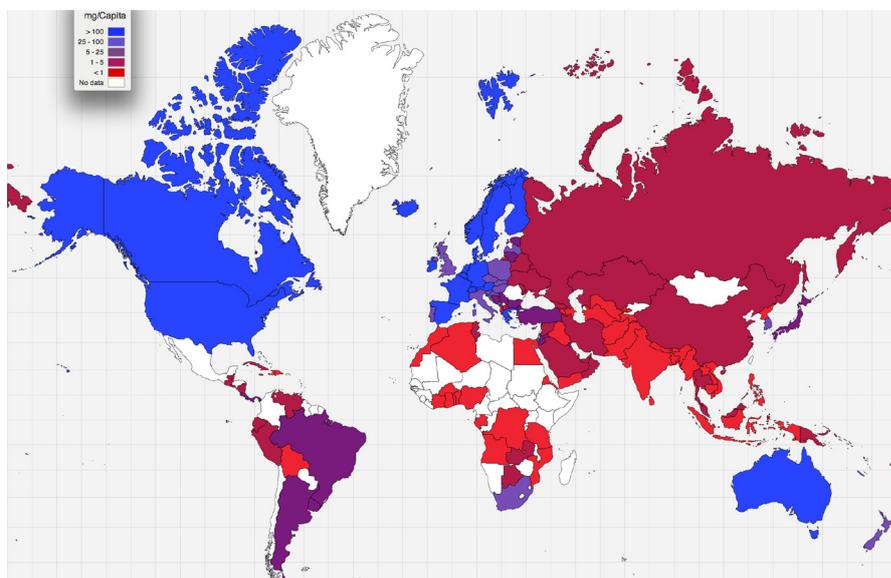
Conducted in 79 countries and 25 Indian states, representing 87% of the global population, this Global Opioid Policy Initiative (GOPI) survey provides a comprehensive view of access to pain relief for cancer patients in need. The survey reveals multiple barriers to routine use of low cost, efficacious pain management in the form of morphine and other opioid analgesics in most countries worldwide.

GLOBAL DISPARITIES IN ACCESS TO PAIN RELIEF

Vast and unacceptable disparities in access to pain relief exist between developed and developing countries. Across the developing world, internationally recommended medicines, indispensable to treat moderate to severe pain, are scarce and unnecessarily difficult for patients to access. The World Health Organization (WHO) estimates there are 5 billion people living in countries with little or no access to pain medicines, including 5.5 million terminal cancer patients and millions of others suffering from acute illness and end-of-life sufferingⁱ. Among patients with terminal cancer, 80% are estimated to experience moderate to severe pain due to inequitable access to medicine.ⁱⁱ

PALLIATIVE CARE aims to improve the quality of life of patients suffering life-threatening illness, and their families through the prevention and relief of suffering through the treatment of pain and other problems, physical, psychosocial and spiritual.

OPIOID CONSUMPTION MAP - MORPHINE EQUIVALENCE (WITHOUT METHADONE), MG/CAPITA, 2011



Source: Opioid consumption data – International Narcotics Control Board. Narcotic drugs: Estimated world requirements for 2013 - Statistics for 2011. New York, NY: United Nations, 2013.

↘ GLOBAL MOMENTUM FOR CHANGE

Today, pain relief is widely understood as a patient right and a human right. The WHO and International Narcotics Control Board (INCB) are increasing their efforts to encourage national governments to align their policies with international standards.

Although important precautions must be taken to prevent misuse of opioids, well-established global standards call for all countries to have balanced policies that ensure opioid analgesics are both available (i.e. present in hospital dispensaries and pharmacies) and accessible (i.e. affordable for patients with a prescription for the length of time and in the quantity required) to those in need. For more than 50 years, the international community has strongly backed the rational and responsible use of opioids to treat pain. Since the signing of the Single Convention on Narcotic Drugs (1961), narcotics control and international public health agencies, led by the INCB, Commission on Narcotic Drugs and UN Office on Drugs and Crime and the WHO, have established policies and programmes to encourage the responsible use of these medicines.



The Global Access to Pain Relief Initiative (GAPRI) is a programme of the Union for International Cancer Control (UICC) to address Target 8 of the World Cancer Declaration calling for effective pain control to be universally available by 2025. GAPRI aims to: empower governments to take the lead in expanding access to pain relief and palliative care; mainstream the issue in the global health and drug regulation agenda; call for the integration of pain management and palliative care into national cancer control plans, and support strengthening of the health systems response. For more information: <http://www.uicc.org/programmes/gapri/>

“medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and adequate provision must be made to ensure the availability of narcotic drugs for such purposes.”

The United Nations Single Convention on Narcotic Drugs, signed in 1961.

Challenged to develop reasonable systems to regulate these medicines, many developing country governments have limited the availability or supply for medical use and put strict policies in place that govern their prescription, dispensation and consumption. These policies have essentially cut off access to the majority of people in need, patients in severe pain. In order to better align drug management policies and systems with global need, vital work is underway within the drug control and public health communities to help partner countries implement new and responsible approaches to control that allow for greater access to those in need. The INCB and WHO have expanded their engagement with developing country governments and re-articulated their calls for countries to better balance efforts to ensure access accompanied by regulatory and legal frameworks that prevent misuse.

The global public health community is further expanding these calls for national policy reform. Increasingly, emerging chronic disease management strategies, plans and policies all call for the integration of **palliative care and pain relief as a patient right and human right**. This consensus is particularly evident in the new WHO Global Monitoring Framework and WHO Global Action Plan 2013-2020 for the Prevention and Control of Non-communicable Diseases (NCDs) adopted at the May 2013 World Health Assembly. These documents call for greater government commitment to pain relief and call for pain management and palliative care to be integrated within the continuum of care for cancer and other chronic diseases. These are among the many indications of strong global consensus and an urgent call for greater leadership and policy change at the national level.^{vii}

In developed countries, a growing commitment to palliative care and recognition of the vital role of legitimate medical use of opioid-based analgesics for moderate to severe pain relief has created a rise in opioid consumption over the past several decades.ⁱⁱⁱ

The disparities in worldwide use are still shocking, with just four countries - United States, Canada, United Kingdom and Australia - using 69% of opioids, while low and middle-income countries together only account for 7% of global use.^{iv} The good news is that opioids are not expensive, in short supply or difficult or dangerous to administer when used correctly. Unlike other medicines, opioid analgesics used to treat moderate to severe pain - such as morphine - are largely not under patent protection and can be produced inexpensively at sufficient quantities to meet global need.

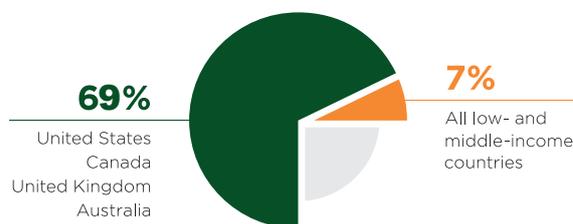
A clear understanding of the barriers restricting availability and access is critical for pain relief advocates and their partners in national governments, civil society and the private sector to work together for national change. A new international collaborative survey led by the European Society for Medical Oncology (ESMO) provides this vital information.

NEW DATA: THE GLOBAL OPIOID POLICY INITIATIVE (GOPI)

This landmark survey provides the most comprehensive overview of the availability of seven essential opioid formulations (as listed by the International Association for Hospice and Palliative Care (IAHPC), as well as policy and regulatory obstacles to their use, throughout the developing world. These important findings can help policy makers, clinicians and advocates pressure for change and effectively reform policies and practices in their countries to align with international standards and make pain relief available to those in need.

The survey revealed that with few notable exceptions, most governments in Africa, Asia, Latin America & the Caribbean, and the Middle East are failing to consistently or adequately alleviate the pain and suffering of cancer patients in their countries. Even where the essential opioids for management of moderate and severe pain are available, cost to the patient and pervasive overregulation make them virtually inaccessible to millions in need.

GLOBAL MEDICAL OPIOID CONSUMPTION



Source: www.treatthepain.org

The Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for cancer pain management was coordinated by the European Society for Medical Oncology (ESMO), the European Association for Palliative Care (EAPC), the International Program at the Pain and Policy Studies Group, University of Wisconsin Carbone Cancer Center (PPSG), the Union for International Cancer Control (UICC), and the World Health Organization (WHO), in collaboration with 17 leading cancer and palliative care organizations worldwide: <http://www.esmo.org/content/download/86371175558/file/ESMO-Opioid-Survey-Data-International-Collaborative-Partnership-List.pdf>

The new survey is a global expansion of the ESMO-EAPC survey of European countries in 2010. Led by ESMO's Palliative Care Working Group and Emerging Countries Committee, the survey gathered data on the legal, regulatory and social barriers determining the availability and access to seven essential opioids for cancer pain management in Africa, Asia, Latin America & the Caribbean, and the Middle East. The opioids included in the survey were selected based on the WHO Model List of Essential Medicines and the International Association for Hospice and Palliative Care list of essential medicines for palliative care. Between December 2010 and July 2012, researchers had clinicians in 79 countries and 25 Indian states complete in-depth questionnaires on formulary availability, cost and barriers to accessing essential opioids, to measure current national standards against the international standards established by the International Narcotics Control Board (INCB) and the WHO. Final data are officially published as a Supplement of Annals of Oncology (http://annonc.oxfordjournals.org/content/24/suppl_11.toc) and supported by an international advocacy campaign to promote the implementation of the changes recommended.

THE BARRIERS TO AVAILABILITY AND ACCESS TO PAIN RELIEF

1. Essential opioids not available

Essential opioids were included on national essential medicines lists in all regions of the world, but were not consistently made available anywhere.

In all regions, many of the 7 essential opioids were on national essential medicines lists (EML). With few exceptions, codeine and at least one, often more, morphine formulations were on national lists. Oxycodone, methadone and fentanyl were less consistently included on formularies, but also common. Yet, data revealed that in many of the countries and all of the Indian states surveyed, fewer than 3 of the 7 medicines were routinely available in hospital dispensaries and pharmacies.^v

In the Indian states, despite codeine, three morphine formulations and fentanyl commonly being on state-level essential medicine lists, only codeine is always or usually available. The 6 other medicines considered essential for pain management are either occasionally or never available.

All regions of the world show similar inconsistencies between adherence to global standards at the national policy level and the actual range and availability of essential opioids to patients.

2. Outdated policies discourage access

The survey found with few exceptions, outdated and unnecessarily stringent legal and regulatory restrictions impede clinicians' ability to prescribe and dispense pain medicines.

Nearly all of the 79 countries surveyed have a range of strict policies and regulations, which prevent pain relief from being integrated into patient care and create roadblocks to access. Across all regions, limitations were found on the types of hospitals or wards where opioids can be administered, the dose and length of time allowed by a single prescription and which clinician can prescribe opioids. These restrictions disincentivize clinicians from prescribing and create insurmountable barriers for pharmacists and families seeking access to pain medicines.

SURVEY SPURS REFORM IN INDIA

The Indian Association of Palliative Care (IAPC) mounted a successful advocacy campaign in the national media. As a result, the Supreme Court of India issued directives to all Indian States to ensure availability and ease of access to morphine to treat pain in terminally ill cancer patients. It is anticipated that a new bill amending the existing complex rules will be sent to Parliament for approval shortly.

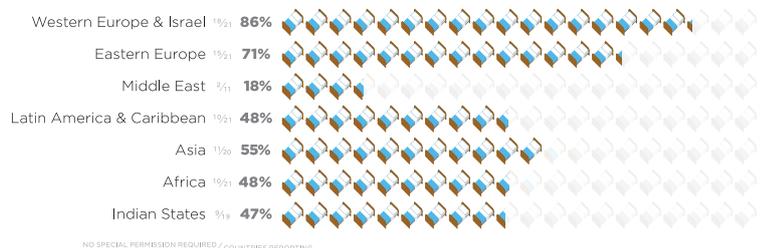
In Africa, **91%** of the countries include **opioids** in their **essential medicines lists**,

yet only **13%** report **immediate release morphine** is **always available**.

Source: N.I. Cherny, The Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for the management of cancer pain in Africa, Asia, Latin America & the Caribbean, and the Middle East. ESMO Palliative Care Working Group and ESMO Emerging Countries Committee. Available at: <http://www.esmo.org/Policy/Global-Opioid-Policy-Initiative>

OPIOID ACCESS FOR HOSPICE PATIENTS

Percentage of countries where patient in hospice are eligible for opioid prescription without special permit or registration.



Sources: N.I. Cherny, J. Baselga, F. de Conno and L. Radbruch, "Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative. N.I. Cherny, The Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for the management of cancer pain in Africa, Asia, Latin America & the Caribbean, and the Middle East. ESMO Palliative Care Working Group and ESMO Emerging Countries Committee. Available at: <http://www.esmo.org/Policy/Global-Opioid-Policy-Initiative>

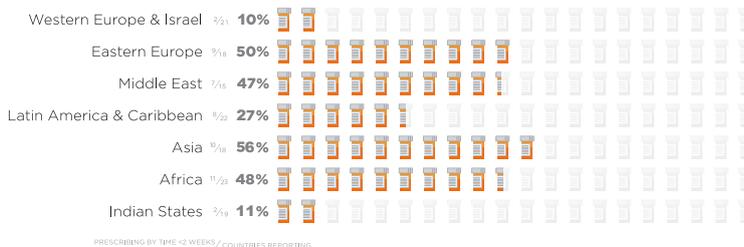
3. Limited awareness and unnecessary administrative obstacles

Patient demand and access to pain medicines is severely limited by unnecessary administrative obstacles and costs.

Public misconceptions about safety, such as concerns about addiction to opioids or the misconception that they should only be used for dying patients, and lack of awareness about their effectiveness for pain relief, has resulted in reduced demand for these medicines from patients and their families. For those who are aware of the value and do seek access, the survey documented significant barriers limiting patient access. Complicated prescription forms, limited government subsidization, inflated costs for medicines at the point of sale, and strict limits on the dosage of medicine provided—regardless of patient pain levels—are among the many discouraging challenges faced by millions seeking adequate access to affordable pain relief for themselves or their loved ones.

NEED FOR FREQUENT REFILLS

Percentage of countries reporting where number of days covered with each prescription is less than two weeks.



GOVERNMENT SUBSIDIES TO REDUCE PATIENT COST

Percentage of countries reporting where immediate release oral morphine (MOR) is available to patients at less than 50% its cost, by region.



4. Inadequate clinician education and empowerment

Inadequate clinician education and recurring misconceptions are persistent barriers to increased opioid use throughout the developing world.

Clinicians must be educated, informed and legally empowered to prescribe as they see fit based on individual patients needs. As noted in the ESMO-led collaborative survey, there is broad consensus among the international community that inadequate education and training of health care providers is one of the most pervasive and urgent obstacles to address. A recent Human Rights Watch survey on palliative care barriers in 40 countries found that most countries had inadequate medical education in palliative care and pain management and four of the countries surveyed had no relevant curriculum in these areas at all.^{vi}

Sources: N.I. Cherny, J. Baselga, F. de Conno and L. Radbruch, "Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative. N.I. Cherny, The Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for the management of cancer pain in Africa, Asia, Latin America & Caribbean and the Middle East. ESMO Palliative Care Working Group and ESMO Emerging Countries Committee. Available at: <http://www.esmo.org/Policy/Global-Opioid-Policy-Initiative>



↘ NEXT STEPS

Backed by the call for a Palliative Care Resolution at the 67th World Health Assembly in 2014, the time has come for governments, civil society and international agencies to come together to put new models, policies and approaches for pain management into place.

No single approach will work across regions - as the historical, legal and social influences that shape the use of these medications are country-specific. However, as evidenced in the survey, there are more commonalities than differences in the obstacles and misinformation that is shaping use across regions. Fortunately, there are countries in each region - including Uganda, Vietnam, Nepal, Jamaica, Ukraine - where recent government leadership, civil society engagement and education and mobilization of clinicians have resulted in important and replicable policy change and increased access to pain medications.

In each of these countries, the reform of national drug control and public health policies that impede medical access was an essential early step. Recent international commitments such as the 2011 UN Political Declaration on NCDs can serve as an important rallying call for other countries to take this first step. As a key development, the Executive Board of the WHO will be discussing palliative care needs and barriers at its January 2014 meeting, and is expected to propose a Palliative Care Resolution for adoption by governments at the World Health Assembly (WHA) in May 2014.

CALL TO ACTION

The ESMO-led collaborative survey provides clear evidence of the policy barriers that national governments should address to align their countries with current global standards of care for cancer, other NCDs and life-threatening and limiting illnesses.

For the 79 countries covered in the survey, advocates and their government partners now have specific and relevant information with which to seek more rational and appropriate policies to improve access to pain medicines.

Once policies are updated, the inclusion of pain relief within a continuum of care strategy for cancer in National Cancer Control Plans and other disease-specific and multisectoral plans will allow new services to be put into practice at scale. As called for in the WHO Global Monitoring Framework for the Prevention and Control of NCDs, active national monitoring and reporting on efforts will be essential to continually improve on our ability to deliver pain relief to everyone in need.

However, governments cannot do this alone. To take advantage of the current momentum, cancer advocates must work swiftly to mobilize other civil society groups and health advocates, and work together to engage the general public and the media to create change. In this effort, the ESMO-led collaborative survey provides essential detail on key advocacy and policy priorities that if addressed could rapidly improve access to pain medicines throughout the world.

Acknowledgements

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ⁱⁱ Global Alliance to Pain Relief Initiative (GAPRI). Access to Essential Pain Medicines Brief (2010). Available from: <http://www.gapri.org/understand-problem>

ⁱⁱⁱ The World Health Organization. Ensuring balance in national policies on controlled substances: Guidance for Availability and Accessibility of Controlled Medicines. Available from: <http://apps.who.int/medicinedocs/documents/s18050en/s18050en.pdf>

^{iv} Treat the Pain. Access to Essential Pain Medicines Brief (2011). Available from: <http://treatthepain.org/data.html>

^v Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for the management of cancer pain in Africa, Asia, Latin America & Caribbean and the Middle East. Data available by region from: <http://www.esmo.org/Policy/Global-Opioid-Policy-Initiative>

^{vi} Human Rights Watch. Global State of Pain Treatment: Access to Palliative Care as a Human Right. May 2011. Available from: <http://www.hrw.org/sites/default/files/reports/hhr0511W.pdf>

^{vii} The World Health Organization. Report on the Formal meeting of Member States to conclude the work on the comprehensive global monitoring framework, including indicators, and a set of voluntary global targets for the prevention and control of non communicable diseases. November 2012. Available from: http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_6-en.pdf