

Evaluating a Human Rights-Based Advocacy Approach to Expanding Access to Pain Medicines and Palliative Care: Global Advocacy and Case Studies from India, Kenya, and Ukraine

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Abstract

Palliative care has been defined as care that is person-centered and attentive to physical symptoms and psychological, social, and existential distress in patients with severe or life-threatening illness. The identification of access to palliative care and pain treatment as a human rights issue first emerged among palliative care advocates, physicians, and lawyers in the 1990s, with a basis in the right to health and the right to be free from cruel, inhuman, and degrading treatment. Using a case study approach, we evaluate the results of a human rights-based advocacy approach on access to pain medicine and palliative care in India, Kenya, and Ukraine. In each country, human rights advocacy helped raise awareness of the issue, identify structural barriers to care, define government obligations, and contribute to the reform of laws, policies, and practices impeding the availability of palliative care services. In addition, advocacy efforts stimulated civil society engagement and high-level political leadership that fostered the implementation of human rights-based palliative care programs. Globally, access to palliative care was increasingly recognized by human rights bodies and within global health and drug policy organizations as a government obligation central to the right to health.

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Introduction

Palliative care has been defined as care that is person-centered and attentive to physical symptoms and psychological, social, and existential distress in patients with severe or life-threatening illness.¹ The goal of palliative care is to optimize the quality of life of patients and to address the needs of their families or close friends.² Palliative care can be provided in parallel with curative treatment, but its main purpose is to ease or prevent suffering. The World Health Organization (WHO) has emphasized that palliative care is particularly important in developing countries, where many terminally ill patients first seek medical attention when their illness is so advanced that it is beyond cure, and has urged countries with limited resources to focus on developing home-based palliative care services.³

An important part of palliative care is addressing chronic and severe pain. Chronic pain is one of the most significant causes of suffering and disability worldwide, and is a common symptom of both communicable (for example, HIV and TB) and non-communicable (for example, cancer and diabetes) diseases, as well as accidents.⁴ Pain has a profound impact on quality of life and can have physical, psychological, and social consequences. It can lead to reduced mobility and a consequent loss of strength, compromise the immune system, and interfere with a person's ability to eat, concentrate, sleep, and interact with others.⁵ People who live with chronic pain have been found to be four times more likely to suffer from depression or anxiety than people who are not in pain.⁶ The physical and psychological effects of chronic pain can also negatively influence the course of disease and indirectly influence disease outcomes by reducing treatment adherence.⁷

Most pain in palliative care patients can be controlled well. WHO's "pain relief ladder" recommends the administration of different types of pain medications, depending on the severity of pain, and is the basis of modern pain management.⁸ For mild pain, WHO calls for basic pain relievers, usually widely available without prescription. For mild to moderate pain, it recommends a combination of basic pain relievers and a weak opioid, such as codeine. For moderate to severe pain, WHO has

recognized that strong opioids, such as morphine, are "absolutely necessary."⁹ Because oral morphine can be produced cheaply and is easily taken at home, it is commonly used for home-based palliative care.

The identification of access to palliative care and pain treatment as a human rights issue first emerged among palliative care advocates, physicians, and lawyers in the 1990s.¹⁰ This notion, especially with regard to pain treatment, has since gained wide recognition. For example, in 2008 the United Nations (UN) Special Rapporteur on the right to health and the Special Rapporteur on torture jointly recognized that a failure to address barriers to palliative care can be a violation of human rights:

Many countries do not recognize palliative care and pain treatment as priorities in health care, have no relevant policies, have never assessed the need for pain treatment or examined whether that need is met, and have not examined the obstacles to such treatment. ... The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines—which include, among others, opioid analgesics—as part of their minimum core obligations under the right to health.¹¹

Human Rights Watch began working on access to pain treatment and palliative care in 2007 and issued a report tied to the high level segment of the Commission on Narcotic Drugs in 2009. Like the Special Rapporteurs' report, our analysis focused on two main rights that may be violated by a lack of access to palliative care: the right to the highest attainable standard of health and the right to be free from cruel, inhuman, and degrading treatment.¹²

Given that palliative care is an essential part of health care, the right to health requires that countries use the maximum available resources to ensure that it is available.¹³ Indeed, the UN Committee on Economic, Social and Cultural Rights has called for "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity."¹⁴ Two

different state obligations flow from this: (1) a negative obligation to refrain from enacting policies or undertaking actions that arbitrarily interfere with the provision or development of palliative care; and (2) a positive obligation to take reasonable steps to ensure the integration of palliative care into existing health services, both public and private, through the use of regulatory and other powers, as well as funding streams. While the positive obligation is subject to progressive realization, countries must comply with core obligations, including the provision of essential medicines as determined by WHO, irrespective of financial constraints.¹⁵

In many countries, however, access to palliative care and to opioid analgesics for pain is very limited. Because strong pain medicines such as morphine (which are commonly used in palliative care and are included in WHO's Model List of Essential Medicines) are controlled substances, they are subject to strict regulation and control under the 1961 Single Convention on Narcotic Drugs.¹⁶ Under the system set up by the convention, states must estimate their need for such medicines and closely monitor and regulate their use, and pharmaceutical suppliers must obtain import and export licenses to transport these medicines across international borders.¹⁷

Although the 1961 convention specifically declares the medical use of narcotic drugs indispensable for the relief of pain and mandates their adequate availability, many states fail to properly ensure the availability of opioid pain medicines or severely restrict access through onerous regulations. The International Narcotics Control Board, charged with monitoring the implementation of the UN drug conventions, clarified in 1995 that the Single Convention on Narcotic Drugs "establishes a dual drug control obligation: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing illicit production of, trafficking in and use of such drugs."¹⁸

Yet despite a clear consensus among medical authorities and an obligation outlined in international human rights and drug control treaties, approximately 80% of the world's population lives in countries with either no or insufficient access to

treatment for moderate to severe pain.¹⁹ Millions of people suffer from such pain each year, especially in low- and middle-income countries, which consume only 6% of the morphine used worldwide.²⁰

In many countries, the lack of access to palliative care stands in stark contrast to the investment by health systems in more expensive curative care for the minority of individuals who can access it. Although governments must address the health needs of entire populations, their health policies, strategies, and indicators often revolve entirely around curative therapies. Similarly, curricula and other training programs for medical students and physicians routinely do not teach even basic knowledge of palliative care.

Between 2007 and 2015, Human Rights Watch worked with a number of human rights, palliative care, and public health groups, including the International Association of Hospice and Palliative Care, the Open Society Foundations, the Union for International Cancer Control, and the Worldwide Hospice Palliative Care Alliance, as well as numerous local partners, to conduct human rights research and advocacy in nine countries—Armenia, Guatemala, India, Kenya, Mexico, Morocco, Russia, Senegal, and Ukraine—on the lack of access to pain medicines and palliative care. This paper examines the impact of these efforts in India, Kenya, and Ukraine. In each setting, a human rights advocacy approach provided synergies to local programmatic efforts, helped foster a greater understanding of structural barriers and government obligations, focused attention on the issue, and led to concrete advances. The paper also presents the global advocacy efforts undertaken in parallel, which sought to strengthen recognition of the right of access to palliative care, increase support for palliative care through global health authorities, and remove barriers created by drug control efforts.

A rights-based advocacy approach to improving access to pain medicine and palliative care

Public health programs adopting human rights-based approaches have been shown to improve

service delivery, focus attention on marginalized populations, and enhance equality, equity, inclusiveness, and accountability.²¹ Critical to the success of rights-based programs, however, is the existence of a dynamic civil society, high-level political leadership, and an enabling policy and legal environment.²² This paper, by contrast, presents a rights-based *advocacy* approach to expanding access to pain medicines and palliative care, and, drawing on case studies, examines the unique challenges of evaluating the impact of seeking changes to legal and policy environments and fostering political will.

Traditionally, palliative care advocates have focused on improving the availability of palliative care through investment in expanding services, training care givers, and developing guidelines and other clinical or health programming tools, sometimes defining these efforts as a human rights-based programmatic approach. With a few exceptions—notably the work of the Pain and Policy Studies Group at the University of Wisconsin—little attention has been paid to public advocacy. Even when public advocacy is part of the work, its focus is generally technical in nature.

By contrast, a human rights-based advocacy approach to palliative care and access to pain medicines can be understood to emphasize four key strategies:

- *Elevate the voices of people affected by the rights violation.* In all our projects, we sought to include the testimonies of people with incurable illnesses, as well as those of their families. These testimonies provided powerful and specific evidence of the consequences of the lack of access to pain medicines and palliative care, and they humanized the issue and the need for change.
- *Analyze structural barriers.* In examining why individuals were unable to access pain medicines or palliative care, we focused on identifying structural barriers and the way that laws, policies, and their enforcement influenced such access.²³
- *Clarify government obligations.* Beyond simply asserting that governments have an obligation to progressively realize the right to health, we

examined specific absolute (or non-derogable) and core minimum obligations related to access to pain medicines and palliative care, including government obligations to develop national palliative care strategies, to refrain from arbitrary interference in the provision of medical care and access to essential medicines, to ensure non-discrimination, and to protect vulnerable populations.²⁴

- *Advocate for change.* Our advocacy emphasized holding governments accountable for their failure to address, or their explicit responsibility in creating, barriers to relieving needless suffering. Our advocacy approach involved both long-term direct engagement of government officials at the national and international levels and public pressure through media. Working with health care providers, families, and palliative care activists, we and our partners sought to engage governments to commit to change and to ensure that this commitment was enacted in law, policy, and practice.²⁵

The four elements of our strategy humanized the issue of palliative care, identified key barriers, clarified government obligations, and prioritized advocacy as a means to hold governments accountable.

Case Studies

India

I felt as if someone was pricking me with needles. I just kept crying [throughout the night]. With that pain, you think death is the only solution.

—Zaid Ahmed in Priya, Hyderabad²⁶

From March 2008 to February 2009, Human Rights Watch conducted research on access to pain medicine and palliative care in four states in India: Andhra Pradesh, Kerala, Rajasthan, and West Bengal. Over the course of five weeks in the field, we conducted 111 interviews with a variety of stakeholders, including patients, health care workers, and drug control and health officials. Most interviews with patients were conducted at health care institutions (such as hospitals and palliative

care providers) or in communities (including palliative care patients' own homes). Interviews were semi-structured and covered a range of topics related to palliative care and pain treatment.²⁷

Our 2009 report *Unbearable Pain: India's Obligation to Ensure Palliative Care* estimated that hundreds of thousands of people in need of pain management in India were unable to access strong pain medications. It found that India's central and state governments had essentially abdicated their responsibility to ensure the availability of palliative care, the provision of which was left largely to non-governmental organizations and individual health care workers. Many hospitals simply sent patients at the end of life home to die without any professional support. Our research found that 18 of India's 29 major public sector cancer centers did not have morphine or personnel trained in palliative care.

The report identified a number of barriers to the development of palliative care. India did not have a national palliative care program or policy, nor did any—save for one—of its states and territories. Needlessly complex drug regulations impeded access to morphine and other strong pain medicines in the majority of India's states, leading many hospitals and pharmacies to simply not stock the medications. Finally, the curricula of the vast majority of India's medical schools and postgraduate medical programs did not address the issue of palliative care.

These barriers had created a vicious circle. Since the government did not prioritize palliative care and pain treatment, health care workers did not receive adequate training on how to provide these services. Lack of training and complex regulatory barriers led to the widespread undertreatment of pain and, predictably, low morphine demand. This, in turn, reinforced the low priority given to pain management and palliative care.

Following the release of the report, we and our partners engaged in diverse advocacy strategies that included "naming and shaming" and constructive engagement. These efforts involved publicizing the findings, holding a series of meetings with government officials to present the results of the research and recommendations about how to address key

barriers, and supporting a case before India's Supreme Court that invoked a right to palliative care and challenged the lack of government policies to promote palliative care. We also mobilized international scrutiny on the issue of access to palliative care in India.

Simultaneously, we worked with local and international partners, such as the Indian Association of Palliative Care, Pallium India, and the US-based Pain and Policy Studies Group, to offer technical support on training curricula, policy development, and regulatory reform. We also sought to facilitate opportunities for the government to report on progress, including at the UN Commission on Narcotic Drugs and the World Health Assembly. Key partners from India traveled to Vienna and Geneva to attend these meetings, as well as side meetings with India's official delegation and other UN agencies, such as the International Narcotics Control Board, the UN Office on Drugs and Crime, and WHO.

Since the start of this effort, India's government has undertaken a number of important steps to improve access to palliative care. For example, in 2011, the Medical Council of India recognized palliative care as a specialization of medicine, and the Tata Memorial Hospital in Mumbai established a palliative care specialization program. In 2012, India's federal health ministry launched the National Program in Palliative Care, which seeks to increase palliative care capacity throughout the country and develop a supportive policy and regulatory environment. In 2014, India's Parliament amended the Narcotic Drugs and Psychotropic Substances Act to eliminate many of the regulatory barriers that had resulted in the near disappearance of morphine from the country's hospitals and pharmacies.

The change to the drug law and the adoption of the National Program in Palliative Care are critical positive steps. However, a number of limitations remain. Funds to support the implementation of the National Program in Palliative Care have been limited, and instructions for states on the implementation of the 2014 changes to the drug act have yet to be issued. Moreover, progress in training health care workers in palliative care has been slow.

To date, palliative care is not a standard topic in curricula for medical and nursing students or part of exams for medical and nursing licenses.

Kenya

The body and his wounds were very painful, and eating was very difficult. He would refuse food and cry. ... [I]t would hurt him to bathe. He would cry because of wounds and peeling off of skin.

—Community health worker in Kisumu, describing the case of Douglas O., who died of HIV-related consequences at age five²⁸

In February and March 2010, Human Rights Watch conducted research on access to pain medicine and palliative care in two locations in Nairobi and Nyanza Provinces in Kenya. As a part of this research, we interviewed the parents or guardians of 30 children (17 girls and 13 boys). Eleven of the children had a confirmed diagnosis of cancer, and ten were reported to be HIV positive. Other children had burns, TB, malaria, and sickle-cell anemia. We also conducted 50 interviews with health care workers, including 15 doctors, 18 nurses, 14 community health workers, a clinical officer, a nutritionist, and a hospice administrator. Within the Kenyan government, we interviewed representatives of the Ministry of Public Health and Sanitation, the Ministry of Medical Services, the Ministry for Gender, Children and Social Development, the Pharmacy and Poisons Board, the Medical Practitioners and Dentists Board, the Kenyan Medical Research Institute, and district health authorities. We also interviewed staff members of several church-run orphanages, community health projects, and Kenyan and international nongovernmental organizations working on health and child rights.²⁹

Our 2010 report *Needless Pain: Government Failure to Provide Palliative Care for Children in Kenya* found that many children with pain in Kenya suffered severe, and avoidable, pain because of a lack of government investment in palliative care services, government policies that restricted access to inexpensive pain medicines, and inadequate training for health workers. The report found that Kenya did not have a national palliative care plan,

that only 7 of its 250 public hospitals had palliative care services, and that none of those services catered specifically to children. Furthermore, health care workers were not adequately trained in palliative care, and they rarely assessed—let alone treated—patients for pain. Our research found that pediatricians were often misinformed about the goals of palliative care, confusing it with “giving up” on a child.

The report found that although Kenya recognized oral morphine as an essential medicine, the Kenya Medical Supplies Agency, which procures essential medicines for public hospitals, did not purchase or stock oral morphine—meaning that hospitals had to negotiate individually with pharmaceutical companies to obtain the medication. Moreover, the government levied an import tax on morphine powder, pushing up the price. Since Kenya’s drug law prescribed heavy prison sentences for the illicit possession of morphine and provided no detailed guidelines on lawful possession for health care workers and patients, many health care providers viewed morphine as a dangerous drug rather than an essential medicine for pain. Finally, we found that health care workers frequently failed to communicate effectively to children and their families about the child’s illness, leaving children and their parents uninformed of their diagnosis and prognosis.

Following the release of our report, we and our partners again engaged in a diverse set of advocacy efforts, publicizing the findings and holding a series of meetings with government officials to present the findings and recommendations. Simultaneously, the Kenya Hospices and Palliative Care Association, the Pain and Policy Studies Group, and the American Cancer Society’s Treat the Pain project offered technical support on training curricula, medicines availability, policy development, and regulatory reform. Jointly with the Kenyan government and the Kenya Hospices and Palliative Care Association, we organized the first-ever side event on palliative care at the World Health Assembly, where Kenyan officials presented progress on national palliative care policies and practices. Partners from Kenya traveled to Geneva to attend the

assembly, during which meetings were held with Kenya's official delegation and WHO.

Since the report's release, Kenya has taken numerous steps to improve palliative care for adults and children, increasingly integrating it into the public health care system. As a result, as of late 2014, palliative care was being offered by forty-three public hospitals, of which two had inaugurated specific programs for children. Further, by late 2014, morphine consumption had jumped more than threefold. In 2011, the government incorporated palliative care into its national cancer control plan and developed national palliative care guidelines, which address the needs of adults and children alike. It also published the National Patients' Rights Charter, which includes the right to palliative care; included palliative care in its national strategic framework for noncommunicable diseases; and introduced a specialty course in palliative care at the Medical Training College. Moreover, the Kenya Medical Practitioners and Dentists Board developed mandatory courses in palliative care for medical students; the Nursing Council of Kenya included 35 hours of palliative care instruction in the core nursing curriculum and 12 hours in the nursing diploma course; and the Pharmacy and Poison Board added instruction on pain management to the pharmacy curriculum. In 2013, the Kenya Medical Supplies Authority began to procure morphine centrally for public hospitals, and the government removed its tax on morphine powder. Nevertheless, a number of challenges remain, including the need to strengthen community-based palliative care and the need to integrate palliative care into the national HIV/AIDS strategy and programs.

Ukraine

I wanted to fall head down and be dead right away so it wouldn't hurt anymore.

—Vlad Zhukovsky, a cancer patient with severe pain, describing a failed suicide attempt³⁰

From March 2010 to March 2011, Human Rights Watch and local partners conducted research on access to pain medicine and palliative care in two provinces (Kharkiv and Rivne) and three cities

(Kyiv, Lviv, and Cherkassy) in Ukraine. Our local partners were the Institute of Legal Research and Strategies in Kharkiv and with the All-Ukrainian Network of People Living with HIV in Rivne and Kiev. Overall, we interviewed 67 individuals, including 20 people with cancer, HIV, and other life-limiting health conditions, or their relatives; 35 health care workers, including oncologists, HIV specialists, anesthesiologists, palliative care doctors, and administrators of hospitals, hospices, and palliative care programs; and 12 drug control and health officials.³¹

Our 2011 report *Uncontrolled Pain: Ukraine's Obligation to Ensure Evidence-Based Palliative Care* found that although hundreds of thousands of Ukrainians need palliative care every year, few can access it. It identified a lack of cohesion, urgency, and coordination on the part of the government in its efforts to develop palliative care; unnecessarily onerous drug regulations; and inadequate academic and clinical training for Ukrainian health care providers.

Our research found that access to opioid pain relievers was particularly problematic. Ukraine did not have any oral morphine, and injectable morphine could be administered only by a health care provider. This meant that patients who needed morphine required multiple visits by nurses each day. Since hospitals did not have the nursing staff to conduct more than one or two visits a day—or at all in most rural settings—a majority of patients were left without adequate pain medications for most or all of the day.

The report also found that most medical students received no instruction in palliative care and that most Ukrainian physicians did not know or apply basic principles of pain management or palliative care. Furthermore, Ukraine lacked a national palliative care policy. Although the country's cancer strategy aimed to establish nine hospices over a five-year period, it assigned no budget for doing so.

In Ukraine, our advocacy strategy prioritized early outreach to the government to seek commitments for change prior to the report's release. We shared advanced copies of the report and, together with the International Renaissance Foun-

TABLE 1. Statements in support of the right to palliative care from human rights authorities

Organization	Document/Report/Declaration	Relevant Text
Council of Europe (2014) ³³	Recommendation of the Committee of Minister to Member States on the Promotion of Human Rights of Older Persons	<i>Member States should offer palliative care for older persons who suffer from a life-threatening or life-limiting illness to ensure their well-being and allow them to live and die with dignity. [para. 44]</i> <i>Trained specialists in the field of palliative care should be available to lead education and research in the field. Programmes of palliative-care education should be incorporated into the training of all health and social-care workers concerned and co-operation of professionals in palliative care should be encouraged. [para. 48]</i> <i>Member States should ensure the adequate availability and accessibility of palliative-care medicines. [para. 49]</i>
Committee on the Rights of the Child (2013) ³⁴	General Comment No. 15 on the Right of the Child to the Enjoyment of the Highest Attainable Standard of Health	<i>Children are entitled to quality health services, including prevention, promotion, treatment, rehabilitation and palliative care services. [para. 25]</i>
Special Rapporteur on Torture (2013) ³⁵	Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment	<i>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. [para. 56]</i> <i>[N]ot every case where a person suffers from severe pain but has no access to appropriate treatment will constitute cruel, inhuman, or degrading treatment or punishment. This will only be the case when the suffering is severe and meets the minimum threshold under the prohibition against torture and ill-treatment; when the State is, or should be, aware of the suffering, including when no appropriate treatment was offered; and when the Government failed to take all reasonable steps to protect individuals' physical and mental integrity. [para. 54]</i>
Special Rapporteur on the Right to Health (2012) ³⁶	Submission to the Committee against Torture regarding Drug Control Law	<i>Access to controlled medicines is essential in the management of moderate to severe pain, including as part of palliative care for people with life-limiting illnesses; certain emergency obstetric situations; and management of epilepsy. The right to health requires States to provide essential drugs mentioned in the WHO list of essential medicines. [para. 22]</i>
Committee on the Rights of the Child (2011) ³⁷	Consideration of Reports Submitted by States Parties Under Article 44 of the Convention, Concluding Observations: Belarus	<i>[T]he Committee recommends that the State party establish a funding mechanism for the provision of palliative care for children and support the palliative care services provided by non-governmental organizations. [para. 56]</i>
Special Rapporteur on the Right to Health (2011) ³⁸	Thematic Report on the Realization of the Right to Health of Older Persons	<i>Palliative care requires important funding and mobilisation of numerous actors and stakeholders within the medical sector, and it is absolutely crucial in order to prolong the lives of older persons affected by life-threatening diseases and to ensure their death in dignity. [para. 60]</i>
UN High Commissioner on Human Rights (2011) ³⁹	Opening Statement at the Human Rights Council 18th Session, Panel on the Right to Health of Older Persons	<i>Adequate access to palliative care is essential to ensure that these people can live and—ultimately—die with dignity. [para. 15]</i>
Committee on the Elimination of All Forms of Discrimination against Women (2010) ⁴⁰	General Recommendation No. 27 on Older Women and Protection of Their Human Rights	<i>States parties should adopt a comprehensive health-care policy aimed at protecting the health needs of older women. ... Such policy should ensure affordable and accessible health care to all older women through ... long-term health and social care, including care that allows for independent living and palliative care. [para. 45]</i>
Special Rapporteur on Torture (2009) ⁴¹	Promotion and Protection of All Human Rights, Civil Political, Economic, Social and Cultural Rights, including the Right to Development	<i>Similarly, the Special Rapporteur is of the opinion that the de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment. [para. 72]</i> <i>Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care. [para 74(e)]</i>

Special Rapporteurs on Torture and the Right to Health (2008) ⁴²	Letter to Chairperson of the Commission on Narcotic Drugs	<i>Many countries do not recognize palliative care and pain treatment as priorities in health care, have no relevant policies, have never assessed the need for pain treatment or examined whether that need is met, and have not examined the obstacles to such treatment. ... The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines—which include, among others, opioid analgesics—as part of their minimum core obligations under the right to health. [p. 4]</i>
Committee on Economic, Social and Cultural Rights (2001) ⁴³	General Comment No. 14 on the Right to the Highest Attainable Standard of Health	<i>In particular, States are under the obligation to respect the right to health by, inter alia, refraining from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and palliative health services. [para. 34]</i>

dation, held various briefings for the drug control agency and the health ministry. The report was released at a press conference at which the deputy head of Ukraine's drug control agency embraced the report's findings and committed to implementing reforms to expand access to morphine. Immediately following this press conference, the International Renaissance Foundation organized a seminar on the report with leading government officials, palliative care providers, and cancer specialists, and a working group was formed to draft new drug control regulations. Subsequently, foundation staff attended the UN Commission on Narcotic Drugs on various occasions, which served as an opportunity for follow-up meetings on the progress on the working group. Simultaneously, the foundation launched a public campaign around the right to pain treatment, including a powerful video telling the story of a young man suffering from incurable brain cancer who was unable to get access to adequate pain relief while dying at home under his mother's care.³² The young man's mother spoke at the press conference where our report was presented.

Since 2011, Ukraine has made substantial progress in improving access to morphine. In 2013, it registered oral morphine as an approved medicine, and two pharmaceutical companies began local production by late 2014. The government also introduced major changes to its drug regulations, making them the most progressive of all former Soviet states. Palliative care patients are now allowed to take a 15-day supply of morphine home, which means that they no longer need nurses to visit them at home to administer dos-

es. The new regulations also reduced the number of people required to sign off on a prescription for strong pain medicines from four to two: the treating physician and the hospital or clinic manager. These prescriptions can now be filled at any licensed pharmacy; previously, they could be dispensed only at one specific pharmacy.

Ukraine also integrated palliative care into its national HIV, TB, and cancer control programs and developed and disseminated a national pain treatment protocol. These changes removed a number of major barriers to expanded access to palliative care. However, significant challenges remain, as greater investment is needed in developing a home-based palliative care system and in training future and current health care workers. In addition, the Russian occupation of Crimea and the ongoing armed conflict in the Donbass region of Ukraine have drawn resources away from palliative care and seriously interfere with its provision in Crimea and Donbass.

Global Advocacy

In addition to our work to address palliative care in these three countries, we prioritized global advocacy. This advocacy focused on three distinct areas where we and our partners felt there were strategic opportunities to advance palliative care: (1) strengthening recognition of access to palliative care and pain treatment as a human rights issue among human rights bodies; (2) ensuring greater focus on access to controlled medicines in global drug policy debates; and (3) advocating for attention to palliative care in global health policy debates.

In 2007, before we and our partners began implementing the human rights-based advocacy approach to palliative care, no UN human rights bodies or Special Procedures had recognized or articulated a right to palliative care or access to pain medicine. Seeing such recognition as critical to our ability to advance global commitment to the issue, we prioritized working with the Special Rapporteurs on torture and health, treaty bodies, and the Human Rights Council to address this gap.

As a part of this work, our coalition briefed the Special Rapporteurs and the UN Committee against Torture, in addition to organizing a side event at the Human Rights Council where we provided relevant information on research findings. Starting with the joint statement of the Special Rapporteurs on health and torture in 2008, there has been an increasing body of statements supporting a right of access to palliative care (see Table 1).

As the UN and regional human rights bodies began to address the lack of effective protection against human rights abuses for older people, we also tried to ensure that new standards explicitly recognize the right to access palliative care. The recently adopted Inter-American Convention on Protecting the Human Rights of Older Persons of the Organization of American States contains extensive provisions on palliative care, as does the Council of Europe's recommendation on the rights of older people.⁴⁴

Our second objective—to increase attention to access to controlled medicines in global drug policy debates—stemmed from the recognition that drug control regulations were frequently responsible for the lack of availability of pain medicines. Yet access to opioid analgesics such as morphine was barely part of global drug policy discussions. For example, in 1998, UN member states negotiated a political declaration on the world drug problem that proclaims drugs “a grave threat to the health and well-being of all mankind” without a single word on the medical uses of controlled substances or the treaty obligation to ensure their adequate availability for medical use.⁴⁵

Access to opioid medicines was not on the agenda of the Commission on Narcotic Drugs,

the annual UN gathering at which global drug policy issues are discussed, or on the radar of the UN Office on Drugs and Crime, which works with states on controlling the supply of illicit drugs and expanding access to drug dependency treatment and other health issues related to drug use.⁴⁶ Only the International Narcotics Control Board made periodic statements expressing its concern about the limited availability of controlled medicines in many countries.⁴⁷

In pursuing our advocacy, we and our partners believed that changing the discussion at the international level to include access to controlled medicines—and the role of drug control regulations in making them inaccessible—would be critical for influencing such regulations at the national level. Through briefings at the Commission on Narcotic Drugs, as well as coalition-building with drug policy nongovernmental organizations and a number of UN member states, we consistently pressed for attention to opioid medicines at the Commission on Narcotic Drugs, the UN Office on Drugs and Crime, and the International Narcotics Control Board.

Progress toward this objective has been significant. In 2009, UN member states negotiated a new political declaration at the Commission on Narcotic Drugs, along with a 10-year action plan “on international cooperation toward an integrated and balanced strategy to counter the world drug problem,” which contained references to access to controlled substances for medical purposes.⁴⁸ The commission adopted resolutions on the issue in 2010 and 2011 and added controlled medicines as a standing item to its agenda in 2010.⁴⁹ In 2011, the International Narcotics Control Board issued a detailed report on the topic.⁵⁰ That same year, the UN Office on Drugs and Crime published a discussion paper and initiated a review of its model drug law.⁵¹ The 2014 Joint Ministerial Statement of the Commission on Narcotic Drugs contained several paragraphs on the issue.⁵² The topic of controlled medicines is now firmly on the agenda for the planned 2016 UN General Assembly Special Session on Drugs, which will consider the successes and shortfalls of the 2009 global drug strategy and represents an opportunity for the international

community to commit to greater action to address the limited availability of medicines like morphine in much of the world.

To address our third advocacy objective—an increased focus on palliative care and access to pain medicine by global health policy agencies—we first conducted a review of resolutions adopted by the World Health Assembly between 2000 and 2010, which confirmed that the assembly had not once addressed palliative care in that period. World Health Assembly resolutions provide direction to the work of WHO and UN member states. The assembly's failure to discuss palliative care as a stand-alone topic during the past decade, despite the fact that tens of millions of people from around the world require it every year, provided us with a strong argument for the topic's inclusion during future meetings. At the same time, we reviewed WHO technical guidance on palliative care and found major gaps in this guidance regarding diseases other than cancer and HIV, as well as a lack of guidance on symptoms other than pain.

To encourage the World Health Assembly to address the issue of pain medicine and palliative care, we organized a number of briefings during assembly meetings, built coalitions of civil society groups and UN member states supportive of palliative care, and held meetings with WHO staff to encourage greater action on the topic. As a result of this work, in May 2014 the World Health Assembly adopted a detailed resolution on palliative care with 37 cosponsoring countries.⁵³ The resolution contained specific recommendations for action by member states, WHO, and several other UN agencies. Following the passage of the resolution, WHO hired staff to develop an implementation strategy for the resolution, as well as to undertake the implementation itself. The strategy is currently under development.

Considerations about impact

Human rights advocacy is often thought of, simplistically, as “naming and shaming”—that is, identifying human rights violators and using public pressure and confrontation to denounce their

actions. As described above, our approach, while including the identification of rights violations (naming) and putting public pressure on states to implement reform (shaming), is more varied and nuanced. Our work in specific countries often advanced most quickly through collaboration with key champions—frequently physicians experienced with, and frustrated by, their inability to address the pain suffered by their patients. These champions often had technical knowledge, professional credibility, and pre-existing ties with government officials. They had previously been engaged in promoting and developing palliative care, although not necessarily using a human rights framework or a public advocacy approach.

The combination of their technical knowledge, credibility, and contacts, along with our rights-based approach and advocacy expertise, generated synergies that helped develop the political will needed to address many (if not all) structural barriers to palliative care. We were able to shine a public light on government failures and neglect (naming and shaming) while at the same time offering the necessary expertise to develop solutions (constructive engagement) and, importantly, international opportunities for government officials to get credit for progress made.

Both in our country-focused research and in our global advocacy, we participated in formal and informal advisory groups, direct one-on-one advocacy, and roundtable discussions seeking to raise attention to the issue of access to pain medicine and palliative care and to share the experiences we have seen of countries implementing reform. In all of these settings, emphasizing the public, political, and legal acceptance of the legitimacy of human rights norms has been a core strategy for our advocacy.⁵⁴

This acceptance marks a shift from the early use of rights terminology to discuss palliative care, which was often primarily rhetorical. While a variety of declarations on access to palliative care as a human right were signed, little was done initially to explore the legal content of the right or to address accountability. Instead, the rights argument was used as an additional way to plead for greater attention to and action on palliative care: not only

was palliative care good medical and public health practice, the argument went, but it was also a human right.

By undertaking an in-depth analysis of barriers to pain medicines and the inadequacy of palliative care in several countries, as well as broader global advocacy, we tried to define what the right to access palliative care meant, and what obligations stemmed from this right. For example, the concept of the minimum core content of the right to health helped develop a set of steps that governments should take to realize the right. The concept that governments must respect, protect, and fulfill rights helped identify negative and positive obligations of governments. We furthermore explored the applicability of the right to be free from torture, cruel, inhuman, and degrading treatment to the denial of pain medicine in order to underscore the absolute obligation of governments and the severity of suffering experienced by patients.

Policy change is often unpredictable, and the processes by which policies, laws, and practices change can be extremely diverse, reflecting shifting norm internalization in public opinion, political considerations, and judicial engagement. Traditional advocacy frameworks based on predefined indicators can be difficult to construct or can lack nuance and specificity.⁵⁵

By contrast, flexible advocacy goals, described at each step or dimension of the advocacy framework, can shift as opportunities change and advocacy targets become more (or less) receptive to specific actions. Human Rights Watch often defines advocacy goals as our research advances and as we discover a more nuanced understanding of what change is possible and what specific barriers to change we must target. At the same time, our research and advocacy can create new possibilities for impact, and we are opportunistic in redesigning our advocacy plans as our work advances.

Reflecting this approach, we often use a retrospective case study analysis to evaluate our impact, rather than the approach described in WHO's monograph for human rights-based health programming.⁵⁶ This approach allows us to document

unanticipated impacts and tentative policy changes that can become the focus of follow-up advocacy. Of course, case study evaluation approaches have methodological shortcomings, and the absence of predefined goals can lack rigor. Because the definition of a "realistic" goal—and the assessment of the success in achieving it—are contemporaneously defined, hindsight can generously fill in or obscure any shortcomings. In our case study evaluation approach, we seek to be objective in our assessment while recognizing that we are not neutral in our goal, or content to ever consider our work finished: even after achieving sought-after changes, monitoring implementation and ensuring that there is not regression is key.

As noted, all three countries highlighted in this article have made significant progress, and global institutions and norms have increasingly recognized and supported expanded access to palliative care as a human right. As with evaluating other human rights advocacy work, attributing impact is often difficult because of complex policy environments and the wide range of influences on government policies and practices.⁵⁷ Similarly, it is difficult to assert that specific strategies or interventions are generalizable, geographically or temporally. Even when a specific change can be linked to a specific intervention, the success of the intervention may be dependent on a wide range of other circumstances that influence public awareness of the issue and its place on the political agenda. Nonetheless, a few key impacts from our work can be reasonably attributed to specific interventions:

- *Approval of India's palliative care medical specialization program.* As part of the release of our report in India, we and our local partners had a meeting with a leading member of the Medical Council of India, who asked our local partner to prepare a curriculum for a palliative care specialization course and promised to advocate for it with his colleagues. In 2011, the council approved the curriculum that our partner had prepared.
- *Regulatory change in Ukraine.* In 2010, we released our report at a press conference followed

by a roundtable, both organized by our local partners. At the roundtable, the deputy head of Ukraine's drug agency created a working group to develop new drug regulations. Over the course of the next two years, the working group, which included our local partners, wrote the new regulations. These regulations were adopted in 2013.

- *Organization of American States convention.* We and our partners proposed specific language on palliative care to negotiators. Much of this language was included verbatim or with small changes in the text of the convention that was adopted in June 2015.

Attributing the impact of our efforts is more complex in the case of India's legal changes and adoption of the National Program on Palliative Care, as well as the numerous reforms in Kenya. With regard to the legal changes in India, for example, our partners had been advocating, without explicit reference to human rights, for changes to the drug regulations for more than a decade, and the government had already undertaken some steps to address these regulations' negative impact on patients. However, a human rights advocacy approach that engaged with high-level government officials at international meetings helped generate greater awareness and political will. For example, during a visit to India, the International Narcotics Control Board used findings of Human Rights Watch's investigation to question the government on access to opioid analgesics. In another example, the Indian Supreme Court case on the right to palliative care resulted in repeated and critical questions of the government that clearly generated a sense of urgency for officials.

Even in the cases where we believe attribution is fairly straightforward, it was not always possible to identify which component of the human rights-based advocacy approach or which specific interventions were decisive. In Ukraine, for example, we know that the testimony of patients and their families struck a chord with key government officials and likely played a role in the decision to develop new regulations. But without continuous

advocacy over the following two years, these regulations might never have come to fruition because the urgency caused by the press attention around the report release had long subsided by 2013.

In Kenya, research into barriers to accessing pain medicines identified the government's exclusion of morphine from the centralized purchasing of essential medicines. That discovery, and the advocacy that led to the medicine's inclusion, was an essential step toward ensuring better access to morphine in the public health care system. Yet without long-term engagement with the government by the Kenya Hospices and Palliative Care Association and Treat the Pain, central procurement might never have happened. In other words, we believe that the four elements of the human rights-based advocacy approach to palliative care are essential to creating impact, although their relative influence may vary.

There are certain common elements to the areas where most progress has been made and where most challenges remain. In our analysis of government obligations related to palliative care, we differentiate between negative obligations (refraining from interfering with medical care) and positive obligations (ensuring that medical care is available). In all three countries, the most significant progress has been made in ending arbitrary government interference with proper medical practice. Progress on positive obligations has generally been much slower, although Kenya's rollout of palliative care services in the public health care system has been impressive.

Not all of our advocacy efforts were successful. As part of our effort to engage governments, we made a number of submissions to the Universal Periodic Review process and to treaty body country reviews. In general, these had little impact, either because the review process in the end did not consider the issue of palliative care, the resulting recommendation was too vague to be meaningful, or the government did not follow up on the recommendation. An inherent limitation of the Universal Periodic Review and treaty body review process is the fact that the Human Rights Council and treaty

bodies must consider a broad range of rights violations. This generally leaves little opportunity for attention to an issue like palliative care. Moreover, while it can be advantageous to engage a wider range of government officials, the officials involved in these review processes were not decision-makers in the areas of health or drug policy and often did not even know the relevant decision-makers in their countries. To advance our advocacy, we found that direct advocacy with health and drug policy makers, whether in specific countries or at UN forums, was more effective.

Conclusion

Attributing policy change to one specific organization, intervention, or strategy is often impossible and can be counterproductive.⁵⁸ Moreover, the long-term nature of policy or legal change makes it difficult to track the specific antecedents and contributions of actions that set the stage for later potentially more visible work.

Efforts by coalitions, which bring diverse expertise, authority, and perspectives, can provide critical momentum to the development of new norms and can increase pressure on international organizations to change priorities and practices. In this case, the involvement of mainstream human rights organizations in advocacy around access to palliative care lent credibility and specificity to the concept and helped generate a broad acceptance that palliative care is indeed a right.

Our efforts to advance an understanding and acceptance of access to palliative care as an element of the right to health were aided by recognition of the relationship between this right and two fundamental principles long recognized within human rights movements. First, the right to be free of unnecessary suffering is consistent with the principle of dignity, on which human rights are based.⁵⁹ Secondly, the de facto denial of access to pain relief, where it causes severe pain and suffering, can be considered cruel, inhuman, and degrading treatment. Using testimony from individuals and their families in our research provided vivid support of both the loss of dignity among people suffering

chronic pain and the inhuman and degrading consequences of the lack of access to pain relief. Frequently, the testimony provided provocative parallels with the testimony of victims of torture.⁶⁰

A human rights-based advocacy approach provided new tools and tactics to complement the traditional skill-building provided by palliative care advocates. The result was increased political will to address structural barriers, increased understanding of the technical solutions required, and the protection of the rights of millions of people suffering unnecessary pain worldwide.

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