

**Special Article**

# Toward Safe Accessibility of Opioid Pain Medicines in Vietnam and Other Developing Countries: A Balanced Policy Method

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**Abstract**

Moderate or severe pain is common among people with advanced cancer and other life-threatening illnesses. Yet despite agreement that pain relief is a human right, the poorest 80% of the world's population rarely have access to strong opioid analgesics. Excessively restrictive opioid policies, especially in developing countries, both stem from and propagate misguided fears about opioids, so-called *opiophobia*. Because *opiophobia*, like any norm, is historically, socially, and culturally situated, efforts to change *opiophobic* policies will be most effective if guided by awareness of their historical, social, and cultural determinants. We describe some of these determinants in Vietnam and report on results of an ongoing project there to allay *opiophobia* and improve safe access to opioids for medical uses. We used a method that entails working with committed local partners, including a high-level official from the Ministry of Health, to review all Vietnamese policies governing opioid accessibility to identify the barriers; devising an action plan to safely reduce or circumnavigate the barriers; obtaining buy-in for the plan from all stakeholders, including drug regulators and the police; and assisting the Ministry of Health to implement the plan. Since the start of the project, morphine consumption has increased each year and as of 2010 was ninefold greater than in 2003, and the number of hospitals offering palliative care has increased from three to 15. We conclude that this balanced policy method appears to be helping to reduce barriers to opioid access in Vietnam and should be used in other developing countries. *J Pain Symptom Manage* 2015;49:916–922. © 2015 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

**Key Words**

*Pain, palliative care, opioid, morphine, global health, policy, cancer, AIDS*

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**Introduction**

Moderate or severe pain is common among people with advanced cancer, AIDS, and other chronic life-threatening illnesses.<sup>1–3</sup> Yet despite wide agreement that pain relief is a human right,<sup>4</sup> more than 5.5 billion people—around 80% of the world's population—have insufficient access to treatment for moderate or severe pain.<sup>5,6</sup> Pain is usually undertreated or not treated at all in low- and middle-income countries (LMICs). In such countries, strong opioids such as morphine are rarely available to treat pain. In 2011, high-income

countries, where 17% of the world's population live, consumed 94% of the world's opioids (Table 1). In general, the rich have access to opioid pain medicines, while the poor do not and suffer unnecessarily and unspeakably as a result. In recognition of the crucial importance of strong opioids to human health and well-being, the World Health Organization (WHO) lists oral immediate-release morphine and injectable morphine on its essential medicines list.<sup>9</sup> In addition, availability of morphine and other essential palliative medicines is one of the four pillars of the WHO public

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Table 1  
The Global Pain Divide<sup>a</sup>

Country Income Level	Percentage of World's Population (2011) <sup>b</sup>	Percentage of Global Opioid Consumption in Morphine Equivalence (2011) <sup>c</sup>
High-income countries	17	94
Low- and middle-income countries	83	6

<sup>a</sup>An enormous disparity exists between high-income countries and other countries in consumption of opioids for medical purposes, primarily pain relief.

<sup>b</sup>Data from World Bank.<sup>7</sup>

<sup>c</sup>Data from the International Narcotics Control Board Report for 2011.<sup>8</sup>

health strategy for national palliative care programs.<sup>10,11</sup> The WHO guidelines on ensuring balance in national policies on controlled substances state that efforts to minimize diversion of opioids for illicit purposes must be balanced with efforts to maximize availability of opioids for pain relief and other medical purposes, such as methadone substitution therapy.<sup>12</sup> The 1961 Single Convention on Narcotic Drugs, to which almost all countries are signatories, requires that the International Narcotics Control Board (INCB), an agency of the United Nations based in Vienna, works to assure this balance.<sup>13</sup> Why, then, are morphine and other strong opioids so rarely accessible in LMICs?

Despite the Single Convention and WHO guidelines, most countries have policies that severely restrict opioid prescribing.<sup>8</sup> These overly restrictive laws and regulations both stem from and propagate misconceptions and misguided fears about opioids—so-called *opiophobia*. Because of *opiophobia*, a vicious circle exists particularly in LMICs of low rates of morphine prescribing, leading to low estimates of morphine requirements submitted by governments to the INCB, in turn leading to correspondingly small amounts of morphine approved by the INCB for import or production by these countries, resulting in low morphine availability that—in combination with *opiophobia*—keeps the rate of morphine prescribing low. Although *opiophobia* also exists in high-income countries,<sup>14</sup> the much greater regulatory restrictions on opioid prescribing in LMICs,<sup>15,16</sup> combined with the massive disparity in opioid access and consumption,<sup>17</sup> suggests that *opiophobias* in LMICs are a bigger public health problem. *Opiophobias*, like any norms, have historical, social, and cultural determinants. For example, in East Asian countries where the colonial powers actively encouraged opium dependence as a means of social control, or where an epidemic of heroin addiction now is driving the epidemic of HIV/AIDS, *opiophobia* may be stronger and more complex than in countries without negative

historical and social experiences with opioids, and there may be more resistance to achieving balance in national opioid control policy. To dispel *opiophobic* beliefs, it is crucial to understand their origins.

We report progress toward eliminating barriers to opioid accessibility in one such country, Vietnam, using a balanced policy method, developed by the Pain & Policy Studies Group (PPSG) at the University of Wisconsin-Madison. This method is designed to help LMICs achieve more balanced national opioid control policies and thereby to safely improve access to opioids for medical purposes.<sup>18–21</sup>

### *Opioids in Vietnam*

In the late 19th and early 20th century, the French financed their colonial regime in Vietnam to a large extent through a monopoly on opium importation, refining, taxation, and sales.<sup>22</sup> From 1897 to 1901, opium “accounted for over one-third of all colonial revenues” in French Indochina and consistently provided 15% or more through World War II.<sup>22,23</sup>(p111) Under the French, habitual opium use and addiction became common among the educated elite and especially among village officials—frequently corrupt and hated—who both collected taxes for the French and enforced village opium quotas.<sup>24</sup> During the First Indochina War, which became increasingly unpopular in France, the French military began financing covert counterinsurgency warfare by airlifting opium from Laos to Saigon and collaborating with local Chinese and Vietnamese organized crime syndicates to sell it.<sup>22</sup>(pp.131–161) Thus, the Vietnamese came to associate opium with foreign brutality and hypocrisy.<sup>25</sup>

Beginning in 1958 and throughout the “American War” in Vietnam from 1964 to 1975, corrupt South Vietnamese military and political officials assumed control of lucrative opium trafficking from Laos for personal profit. When production of cheap and high-grade heroin began in the “Golden Triangle” region in 1970, large numbers of U.S. soldiers serving in South Vietnam quickly became regular users, as many as 20% in some units.<sup>22</sup>(pp193–261) Since Vietnam began to open to the world in 1986, and especially since the U.S. ended its economic blockade of Vietnam in 1994, a black market for heroin from the Golden Triangle resumed, this time throughout the country. With an estimated 200,000 heroin addicts, Vietnam now has the highest prevalence of injection drug use in Southeast Asia,<sup>26</sup> and injection drug use with heroin has been the main catalyst for the epidemic of HIV/AIDS. Approximately 60% of HIV infections in Vietnam are the result of unsafe practices when injecting heroin.<sup>27</sup> These events have contributed to a perception within Vietnam of opioids as a “social evil” associated with foreign

aggression and corruption and at odds both with traditional Confucian morality and with moral standards promulgated by the late President Ho Chi Minh.<sup>22,24(pp193–261),28,29(p68)</sup>

We have found opiophobia to be prevalent among both clinicians and government health care officials.<sup>30</sup> Specifically, we have found exaggerated fears that morphine and other opioid pain medicines will harm patients by causing respiratory depression or addiction, negative language about opioids in Vietnamese laws and Prime Ministerial decrees, and highly restrictive opioid prescribing regulations issued by the Ministry of Health (MoH). As a result, Vietnam's consumption of morphine for medical use in 2004 was minimal and ranked 122 of 155 countries for which data were available.<sup>31</sup>

### *Vietnam's Palliative Care Initiative*

A concerted effort to make pain relief and palliative care more accessible in Vietnam began in 2004 when Vietnam was chosen to receive support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The U.S. Congress had determined that 15% of the \$15 billion allocated for PEPFAR should be used for palliative care. This made Ministries of Health in recipient countries more cognizant of the concept of palliative care. In 2005, the Vietnam MoH convened a Palliative Care Working Group that included a foreign palliative medicine specialist physician with experience working as a clinician-educator in developing countries and who was prepared to provide training and technical assistance to the MoH and Vietnamese colleagues over a period of years. The working group adopted the WHO public health strategy for national palliative care programs.<sup>11</sup> This entails a rapid situation analysis of palliative care services and needs (supply and demand) followed by attention to the four pillars of the public health strategy: policy, essential drug availability (especially oral immediate-release morphine), education, and implementation of pain relief and palliative care services. The situation analysis was done in 2005 in five provinces with a high prevalence of HIV infection chosen to include both northern and southern and both urban and rural populations. The study revealed that severe chronic pain is common among people with cancer and HIV/AIDS, oral morphine was virtually unavailable, injectable opioids including morphine were available in major hospitals but were seldom used, and clinicians lacked adequate training in pain relief and palliative care.<sup>30</sup> Based on the need for palliative care demonstrated by situation analysis, national Guidelines on Palliative Care for Cancer and HIV/AIDS Patients were drafted with assistance from foreign experts and issued by the MoH in 2006.<sup>32,33</sup>

### *Improving Accessibility of Opioid Pain Medicines*

In 2006, two of us who are MoH officials (L. N. K. and N. T. P. C.) participated in the International Pain Policy Fellowship (IPPF) offered by the PPSG. Two of us (D. E. J. and E. L. K.) provided mentoring and technical assistance. The balanced policy method devised for the IPPF was used in Vietnam as follows:

- All Vietnamese laws and regulations affecting opioid accessibility, 38 in total, were identified and translated into English.
- During a weeklong training course and conference on opioid policy in Madison, required of all IPPF fellows, we reviewed together all these laws and regulations to identify all passages inconsistent with the WHO concept of balance or that created barriers to safe opioid accessibility.
- We then drafted an action plan for making opioids safely accessible by seeking the path of least resistance past the barriers. We decided that it was not necessary to change laws or Prime Ministerial decrees—both of which are difficult to change—but only MoH regulations.
- Next, two of us (L. N. K. and N. T. P. C.) arranged for the MoH to hold a workshop in early 2007 on opioid policy in Vietnam where all major stakeholders could discuss and, if possible, agree on the final action plan. Given the strong and historically determined opiophobia and the epidemic of illicit heroin use, these stakeholders included the Ministry of Police and the United Nations Office of Drugs and Crime as well as the WHO, the Vietnam Drug Administration, the Vietnam national institutes of cancer and infectious disease, and international nongovernmental organizations.
- An action plan was agreed on by all workshop participants. It called for the Palliative Care Working Group and MoH to pursue several key objectives:
  - Revise the MoH opioid prescribing regulations according to WHO guidelines to achieve greater balance in Vietnam's national opioid policies.
  - Work with the Drug Administration of Vietnam (DAV) and the domestic pharmaceutical industry to increase production or importation of morphine in the most useful preparations, including 10 mg scored immediate-release tablets.
  - Educate physicians, nurses, and health care officials throughout the country on the importance and safety of opioid analgesics, on the low risk of dependency syndrome among patients with advanced life-threatening illnesses and no history of substance abuse, on the national Guidelines

on Palliative Care and, once officially issued, on the new opioid prescribing regulations.

Within one year of this workshop, the MoH issued two regulations to improve accessibility of opioids for medical uses: Vietnam's first ever guidelines for methadone substitution therapy for treating psychological dependence on opioids,<sup>34</sup> and greatly liberalized opioid prescribing regulations for treating pain that approximate international standards<sup>35</sup> (Table 2).

In response to the revised opioid prescribing regulations, the DAV revised its regulations on procurement, purchase, distribution, storage, and dispensing of narcotic and psychotropic drugs. The revision removed tight restrictions on the number of pharmacies allowed to dispense opioids such that any pharmacy that meets the standards of "Good Pharmacy Practice" and "Good Storage Practice" could retail opioids. In addition, the revised opioid prescribing regulations stipulate that, if a district lacks a pharmacy that stocks opioids, the district hospital pharmacy must stock opioids. As yet, however, district hospital pharmacies are not permitted to dispense medicines directly to the public. While working on making opioid pain medicines more available, the MoH also collaborated with the Harvard Medical School Center for Palliative Care and with Family Health International to develop and implement training on pain relief and palliative care for physicians and nurses, and, more recently on the new opioid prescribing regulations for health care officials (Table 3).

In our view, the assertion that opioid therapy is safe if guidelines are followed is unlikely in itself to fully allay opiophobia among Vietnam's clinicians, health officials, or public, nor to dispel the opiophobic understanding of opioids as a social evil. To achieve this, we believe it is crucial to bring to light the roots of this fear in the sordid history of nonmedical uses of opioids in Vietnam. Thus, we now address this history in our training activities. We also discuss any current risks for diversion or nonmedical use along with the most effective methods of securing the supply chain and minimizing the risk. Further details of the clinical training courses and clinician trainees have been published elsewhere,<sup>32,35</sup> and data on changes in the opioid analgesia-related knowledge,

attitudes, and practices of our physician trainees after basic training in palliative care will be reported separately. The training courses for health care officials—mainly provincial public health department leaders and provincial hospital directors and department chairpersons—were organized by the MoH to familiarize the officials with the MoH guidelines on palliative care and opioid prescribing regulations and to dispel opiophobia.

We have found that it is crucial to coordinate availability of opioids and training of clinicians in their use. Failure to coordinate well may result in trainee frustration from hearing about medicines that are not available to them or in medicines expiring on the shelves because of clinicians not having been taught how to use them. We also have found that the physicians most likely to prescribe opioids whenever indicated according to national and international guidelines are those who receive long-term clinical mentoring from experienced palliative care trainers.

## Results

Available data indicate that progress is being made toward greater accessibility of opioids for medical uses. Between 2003 and 2010, morphine consumption per capita in Vietnam increased each year, ninefold in total (0.06–0.46 mg/year).<sup>36</sup> This increase was more than twice as rapid as in China or any Southeast Asian country for which data are available.<sup>37</sup> By 2011, per capita medical consumption of all opioids, including methadone, had increased 29-fold since 2003 (from 0.25 to 7.35 mg/year).<sup>38</sup> In addition, since the beginning of the MoH palliative care initiative, the number of hospitals offering some type of palliative care has quintupled from three to 15, and more hospitals plan to begin palliative care services in 2014. As yet, no data are available on changes in the number of retail pharmacies that stock opioids.

## Lessons Learned, Persistent Challenges, Ways Forward

Vietnam is demonstrating that a developing country can improve accessibility to opioid pain relief

Table 2  
Summary of Old and New Vietnam Ministry of Health Opioid Prescribing Regulations for Outpatients

Aspect of Opioid Prescribing Regulations	Old Opioid Prescribing Regulations	New Opioid Prescribing Regulations (2008)
Maximum prescription period	7 days	30 days
Maximum dose	30 mg/day	No limit
Required prescription record retention	5 years	2 years
Plan for morphine availability	None	Every district
Restriction based on diagnosis	No cancer or AIDS diagnosis = no opioid prescription	No cancer or AIDS diagnosis = 7 day maximum prescription

Table 3  
Types of Palliative Care Training, Main MoH Collaborator, and Approximate Number of Trainees as of April 2014

Type of Training	Main MoH Collaborator	Number Trained
Basic course in palliative medicine	HMS	>1000 physicians
Advanced course in palliative medicine	HMS	208 physicians
Specialty certificate training in palliative medicine	HMS	13 physicians
Palliative care nursing	Multiple curricula: Hanoi HIV/AIDS Hospital, Ho Chi Minh City Cancer Hospital, FHI	340 nurses
Workshops for health care officials on the national Guidelines on Palliative Care and the new opioid prescribing regulations	PPSG	1469 provincial health care officials
Workshops for pharmacists on the national Guidelines on Palliative Care and the new opioid prescribing regulations	San Diego Institute of Palliative Medicine, U.S.	>300 pharmacists

MoH = Ministry of Health; HMS = Harvard Medical School Center for Palliative Care; FHI = Family Health International; PPSG = Pain & Policy Studies Group at the University of Wisconsin-Madison.

even when there is strong sociohistorically based opiophobia. Important contributors to this progress include strong and consistent leadership at the MoH, consistent and readily available technical assistance from one or more experts in clinical palliative care and opioid policy, sensitivity to the sociohistorical determinants of opiophobia, a modicum of financial assistance, attention to WHO guidelines on balance in national opioid policy, and adoption of the WHO public health strategy for national palliative care programs. The PPSG balanced policy method proved acceptable to Vietnamese colleagues and government officials and effective at overcoming multiple major barriers to opioid availability.

Despite this progress, Vietnam is still in the early stages of its quest for universal access to effective pain relief. Persistent opiophobia among health care officials, clinicians, patients, and patients' families could be reduced in two ways: 1) by scaling up training for officials, clinicians, and health care students in pain relief, the importance and safety of opioids, palliative care, the national Guidelines on Palliative Care, and the MoH opioid prescribing regulations and 2) by a national campaign for pain relief aimed at the public and supported by the Ministry of Police that addresses sociohistorically determined fears and negative connotations of opioids. The lack of oral morphine in most of Vietnam's 525 districts could be addressed by training as mentioned previously, by requiring each district hospital to have at least two physicians with basic training in pain relief and palliative care, by creating incentives for provincial health officials to ensure accessibility of oral morphine in each of their districts, and by creating a simple system to monitor morphine availability and consumption down to the district level. Recently, the DAV did issue regulations requiring better monitoring of opioid consumption and better estimation of the next year's opioid requirements by taking into account both consumption trends and anticipated scale-up of palliative

care training and services. But the regulation has not yet been changed that forbids district hospital pharmacies from dispensing opioids to the public, even when no pharmacy in the district stocks opioids. Given that most patients dying of any illness in Vietnam are at home, government health insurance regulations also should be changed so that palliative home care is covered. This not only would make possible rapid scale-up of palliative home care and likely increase opioid accessibility but also may help reduce overcrowding in central hospitals, a major goal of the MoH.

Universal access to opioid pain medicines in general and to oral immediate-release morphine in particular is not an end in itself. The most important result of progress in opioid accessibility will be a reduction in patients' levels of pain and dyspnea and improvement in their quality of life. A project is now underway to validate a Vietnamese Palliative Outcomes Scale to make these measurements possible.

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