

Improving Access to Opioid Analgesics for Palliative Care in India

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Introduction

Approximately one million people in India experience cancer pain every year.¹ As in many developing countries, it is typical that cancer is diagnosed in the late stages, when pain is prevalent and often severe.² Severe pain destroys a person's quality of life and dignity. Severe pain also affects families, neighbors and the community: a painful death leaves an indelible mark, especially in India, where the person with cancer is often cared for in the community and at home.^{1,3}

In 1986, to address the problem of unrelieved pain due to cancer in the world, the World Health Organization (WHO) announced a three-step method for treating cancer pain that relied on the use of drugs such as morphine for severe pain.⁴ However, in spite of the fact that morphine is manufactured in India, it is not available to most of the patients who need it.

India had reported some medical use of morphine for decades; it was used mainly in injection form in hospitals to relieve post-operative pain. After reaching a peak of 573 kilograms in 1985, morphine use began to decrease (see Figure 1). Between 1985 and 1997, morphine consumption decreased by 97%, reaching a low of 18 kilograms in 1997. In 1997, India's per capita consumption of morphine ranked among the lowest in the world (113th of 131 countries).⁵ During the same period, global consumption of morphine increased by 437% (see Figure 2).

In light of India's large population needing cancer pain relief, the low and decreasing trend of morphine use was tragic. It was ironic as well, because much of the supply for the rest of the world comes from licit cultivation of poppy in three Indian states,⁶ yet only a trickle was reaching India's domestic market. Adding to the irony, the decreasing use of morphine occurred during a period of major efforts to introduce cancer pain relief and palliative care. Numerous experts, including Dame Cicely Saunders and specialists associated with the WHO, traversed the subcontinent educating health professionals and promoting the development of cancer pain relief and palliative care programs. Indeed, these efforts led to the creation of a number of palliative care programs including the first, Shanti Avedna Ashram in 1986. In 1992, pain relief and availability of morphine were designated as priorities in the National Cancer Control Programme.

Consistent with WHO cancer pain relief and palliative care guidelines,^{2,4,7} the Ministry of Health (the Ministry) designated oral morphine as the medication that should be made easily available for the relief of severe cancer pain.⁸ However, the Ministry became aware of difficulties in obtaining and distributing morphine, even to government-supervised cancer hospitals. The Ministry convened a series of national workshops from 1992-1994 to identify the reasons for morphine unavailability.⁸ A clear picture of the reasons was elusive; physicians were assured that they could have the necessary licenses if only they submitted the necessary applications. The following experience, contributed by a former Narcotics Commissioner of India, was not uncommon.

... XX is a referral hospital for cancer management. The annual requirement of morphine is approximately 10,000 tablets of 20 mg. But the Institute has not been able to procure a single tablet till date, primarily due to the stringent state laws and multiplicity of licenses. After a lot of effort, the Institute had been able to obtain the licenses in 1994 and had approached [a manufacturer] for supply of tablets. At the relevant time [the manufacturer] did not have the tablets in stock and by the time the tablets could be arranged, the licenses had expired. The doctors at the Institute and the associated pain clinic have stopped prescribing morphine tablets because they would not be available.⁹

The urgency of the problem resulted in some extraordinary measures: the Ministry and WHO purchased a supply of oral morphine, only to encounter problems in acquiring the licenses needed to distribute the drug to regional cancer centers; indeed, some cancer centers did not want morphine, one indication of the low priority of pain relief in parts of the cancer care system. Morphine was successfully distributed to some centers, and this brief experiment probably accounts for the slight increase in morphine use that occurred in 1994 (see Figure 1). Meanwhile, the overall national trend in morphine use continued to decline.

In 1999, the International Narcotics Control Board (INCB), which monitors adherence of national governments to international drug control treaties and tracks both licit and illicit availability of narcotic drugs throughout the world, called international attention to the tragic situation unfolding in India:

As the domestic consumption of morphine has decreased to an extremely low level over the last few years, the Government of India should take effective measures to ensure its adequate availability for medical purposes.¹⁰

The INCB's statement of concern came midway in this collaborative initiative to study the reasons for morphine unavailability and to correct the problem.

Aims and Methods

The principal aim of this initiative is to improve availability and patient access to opioids for palliative care. The methods to accomplish this goal included developing cooperation with government and non-government organizations, identifying regulatory barriers to morphine availability through analysis of national narcotics control policies according to the principle of "balance," proposing changes in policy, developing workshops to support and implement policy change, and monitoring the effects on availability and patient access to morphine. "Balance" refers to the fundamental principle of international and national narcotics control policy which recognizes that governments have an obligation not only to prevent abuse, trafficking, and diversion of narcotic drugs, but also to ensure their adequate availability for medical and scientific purposes.¹¹⁻¹³

The Collaborators

The initiative is a work in progress and is sponsored by the WHO Collaborating Center for Policy and Communications in Cancer Care (the Center), in cooperation with the Indian Association of Palliative Care (IAPC), and the Pain and Palliative Care Society (PPCS), Calicut. The Center is an international arm

of the Pain & Policy Studies Group of the University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin, USA. The IAPC is a non-governmental national multidisciplinary association of health professionals working since 1994 to improve palliative care by disseminating knowledge through conferences and a journal. The PPCS is a non-governmental community-based organization with headquarters in Calicut, in the state of Kerala (population 32 million). PPCS operates the Pain & Palliative Care Clinic, which has been providing palliative care to out-patients and in patients' homes since 1994.⁶ A recent study showed that increased use of morphine for palliative care did not lead to misuse or diversion to illicit uses.¹⁴

The collaborators have worked to develop active cooperation with several agencies of the national Government of India, including the Narcotics Commissioner of India, the Revenue Department, the Health Department, their counterparts in a number of states, and numerous physicians and their respective pain and palliative organizations throughout India.

Step 1. Policy analysis of India's national narcotics policy

In 1994, the Director of WHO's Cancer Unit in Geneva requested the Center to study the reasons for morphine unavailability in India. We began with several visits to learn more about the need for opioids and barriers to availability and patient access. The Center participated in two national meetings in 1994 and 1995 that were sponsored by the Ministry and the WHO in New Delhi to review policies governing availability of opioids in the class of morphine. These meetings revealed that few people, if any, understood all the requirements.

These initial meetings also marked the beginning of a positive relationship between the Center and the Department of Revenue that would play an important role in addressing the problem. The Revenue Department is the principal agency of central government that enforces national narcotics laws and supervises licit poppy cultivation. Predecessor agencies licensed all legitimate handlers of narcotic drugs and supervised taxation of commerce in opium since well before India achieved independence in 1947, including before the turn of the last century when the British Indian Government promoted taxation of Indian opium exports as a major source of revenue.^{15,16}

The Center began a systematic study of the regulatory requirements for morphine, and approached the IAPC to review our work. The IAPC established a Committee on Morphine Availability and Control (IAPC Committee) to work with the Center. The Center completed its analysis of the narcotic laws in 1996. We found that the laws to control abuse of narcotic drugs interfered with making opioids available for medical and scientific purposes, and thus, were not balanced. Two major policy factors contributed to this lack of balance, one at the central level and one at the state level:

- 1) In 1985, the Government of India adopted a law to quell narcotic abuse and trafficking, the Narcotic Drugs and Psychotropic Substances Act (NDPS); it established mandatory minimum imprisonment of 10 years for violations involving narcotic drugs. Physicians informed us this law was responsible for the medical profession becoming hesitant to use morphine. Pharmacies all over the country stopped stocking morphine; and
- 2) The state narcotic rules, which varied from state to state, were complex, requiring that medical institutions obtain a number of licenses to possess opioids such as morphine. These include import, export and transport licenses to ship any amount of morphine between any

two states, as if they were countries.

India has 28 states and 7 Union Territories. In general, they have rules that require medical institutions, including palliative care programs, to obtain the following state authorizations before a narcotic drug like morphine can be legally obtained and possessed:

- a) A possession license,
- b) A quota, specifying the maximum amount that can be possessed during the period of the license,
- c) An import license, for the possessor to import the drug if the supplier is in another state,
- d) An export license from the exporting state, and
- e) A license to transport the drug.

Two different departments of state government typically issue these licenses, the Departments of Excise (the equivalent of Revenue at the national level) and Health. Review of a license application is by a bureaucratic hierarchy of sub-offices in each department. The review procedures can delay for months and even years the approval of all the necessary licenses for obtaining morphine, because the excise officers in charge may not be familiar with the medical subject of pain relief, and are likely to have a view of narcotic drugs that is limited to concern about addiction. When the last of the licenses is finally issued, it is likely that one or more of the other licenses have expired.

Step 2. Simplifying the state narcotic rules

Following consultation with the IAPC Committee, the Center prepared a proposal to simplify India narcotic control policies. The proposal was guided by authoritative sources about balanced narcotic control policy, in particular the Single Convention on Narcotic Drugs, 1961,¹¹ and INCB documents relating to national implementation of the Single Convention.¹⁷ The proposal also benefited from WHO publications about availability of opioids for cancer pain relief² and the Center's work to achieve more balanced national policies in several other countries.^{12,18}

The proposal aimed to reduce the number of licenses that would be required, extend their validity periods, and transfer the licensing authority from the State Excise Departments to the Drugs Controller in the Department of Health. It was felt that the licensing of health care facilities to use medical drugs was a function more consistent with the food and drug duties of the Drugs Controller in the Department of Health.

Early in 1997, the Center submitted the proposal to the national Revenue Secretary along with a graph showing the decreasing use of morphine. The Revenue Secretary wrote to the national Health Secretary referencing the Center's proposal. In the letter, he emphasized that the NDPS and his department's "...efforts to prevent drug abuse should not deny legitimate use of pain killing medicines to patients of cancer,"¹⁹ and expressed willingness to simplify the licensing procedures. Subsequently, the Revenue Department drafted a model that the states could use to simplify their narcotic rules. The model rule simplified the licensing procedures as had been proposed. It set forth a procedure for the state Drugs Controller to "recognize" medical institutions to possess morphine and, as a condition of this recognition, would designate at least one qualified medical practitioner to prescribe morphine, ensure adequate stock, estimate future needs, and maintain records and security. A procedure was also set forth so that the estimate of morphine requirements would reach the government in time for adequate supplies to be made

available.

On May 8, 1998, the Revenue Secretary sent the model rule to the heads of all state and territorial governments with instructions to amend state rules (letter to state executives). In his letter, the Revenue Secretary referred to the Center's proposal, and also to a petition that recently had been filed before the High Court of Delhi seeking to ease morphine availability for cancer patients. (On April 4, 1998, the High Court, acting on the petition originated by Dr. R.B. Ghooi, provided no specific relief, but stated that "We have no doubt that henceforth whenever an application for license is preferred (sic) it will be disposed of expeditiously by the authorities. Any delay would be viewed very seriously.")

Step 3. Slow state response prompts the first of many workshops

Despite the central government's request to amend the state narcotic rules, only the state of Sikkim (.05 % of India's population) had done so by the end of 1998. The Collaborators decided to experiment with a workshop in the state of Kerala (approximately 3.1% of the national population) where there was a strong palliative care program that had a relationship with state government, and where difficulties with morphine availability had been documented. A workshop at the level of state government made particular sense because the delivery of health service is a state responsibility in India. The progressive Kerala Health Secretary agreed to sponsor a workshop with all the stakeholders, including the excise officials, the Drugs Controller, and those representing palliative care.

Step 4. Monitoring results

The first state workshop on morphine availability was held on June 24, 1998, in Thiruvananthapuram, the capital city of Kerala. The workshop was co-sponsored by the PPCS and the Center. The need for morphine and the problems with licensing were discussed, and concerns about addiction were addressed. The Health Secretary agreed to simplify the Kerala narcotic rules according to the model that had been provided, and appointed a task force chaired by the Kerala Drugs Controller to prepare the rule.

The Government of Kerala adopted and published the model rule in 1999. The Task Force advised the Kerala Drugs Controller about how to implement the new licensing procedures for palliative care programs, including that the physician in charge should have at least 30 days training in pain management and palliative care, including some clinical experience.

Using the Kerala workshop as a model, the Collaborators sponsored and participated in a total of 11 workshops between 1998 and 2002 in a number of Indian states (see Table 1). In each case, the stakeholders from government and palliative care came together to review a fact sheet²⁰ and to discuss the need for pain relief and to simplify and implement the model morphine rule. Meanwhile, the central government repeated its requests to the states to amend their rules.

The state rules began to change (see Table 1). Seven states and territories adopted the model rule; some states adopted it after a workshop, some before, and several without a workshop.

The long decline in national morphine use ended in 1997. From 1997 to 1999, the most recent data available, the national consumption of morphine increased from 18 to 87 kilograms (see Figure 1), an

increase of 383%. The 2000 data for morphine consumption has not yet been reported to the INCB by the Government of India; indeed, the INCB stated in 2001 that India will have to improve the quality of its reporting, having submitted required statistical reports very late and providing incomplete information (p. 15).²¹

A number of other advances occurred that may have been stimulated by this initiative:

- The workshop in Mumbai (Bombay) was important because, even though it has not yet resulted in amended rules for the state of Maharashtra, it was attended by the head of the Government Opium and Alkaloid factory in the city of Ghazipur, and the interaction led to uninterrupted availability of morphine at the top of the supply chain in the country. A subsequent meeting with a top official in New Delhi resulted in a policy that the factory always was to maintain a “buffer stock” of 50 kilograms so that domestic orders could always be filled.
- In Kerala, the need to have a reliable and affordable source of oral morphine stimulated the development and licensing of a small manufacturing unit at a hospital that now produces low cost immediate release morphine tablets from morphine powder that is purchased from the factory at Ghazipur.
- In 1999, the Kerala Drugs Controller exempted palliative care programs from yet another state rule that required programs to have a “drug license” to dispense morphine and therefore the need to employ a pharmacist, a cost that palliative care programs could not afford. The Drugs Controller General of India followed suit, and in 2001 the Health Ministry issued a similar exemption for all palliative care programs in India if they were approved by the government (General Statutory Rules 6 (F), April 1, 2001).
- The PPCS had begun to develop satellite palliative care clinics (Link Centers) in Kerala to expand coverage to the population in need of palliative care. Before the Collaborators began their work, the PPCS and the Link Centers had to confront a painful licensing process that might result in interruptions in morphine availability. Since 1997, the PPCS as well as the Link Centers have been able to avoid any interruptions in supply of morphine.¹⁴ In 2000, the PPCS and the 21 Link Centers served 4, 425 new palliative care patients and used approximately 12.87 kg of morphine.²² The PPCS estimates that in 2002, the PPCS and the Link Centres will reach coverage of 15-20% of the cancer patients in pain in Kerala.

On September 10, 2001, the Collaborators participated in a special national Workshop on Availability of Morphine for Alleviation of Pain (see Figure 3), sponsored by the Ministry of Health and the Department of Revenue in New Delhi to review progress and discuss the next steps. A number of recommendations were made, including that the model rule be adopted and implemented immediately by all states and Union Territories with workshops to facilitate the process, that states establish policies and training for palliative care and use of opioids, that additional opioids should be covered by the model rule, that the WHO and the National Cancer Control Programme should give higher priority to palliative care and opioid availability, and that national guidelines be developed for pain relief, palliative care and opioid availability.

Discussion

Born of committed leaders from the country and abroad, cancer pain relief and palliative care in India are still in their infancy but growing.⁶ However, palliative care anywhere can succeed only if these services can relieve severe pain; thus, the adequate and continuous availability and correct use of opioids such as morphine is critically important. Simplified regulatory policy has been adopted in several Indian states; the prescription for improving opioid availability is beginning to work.

In 2001, the situation in India again drew attention from the INCB:

The Board notes with satisfaction that several governments have taken steps to improve the availability of narcotic drugs. For example, in India, model regulations aimed at simplifying access to morphine for use in palliative care were developed by the Government, in cooperation with WHO, in 1998 and have since been introduced in several states in that country (p. 31).²¹

The tragic downward national trend of morphine use in India has been arrested, due to a combined local, national and international initiative. However, this reversal represents progress in only a few palliative care programs and cancer centers, including in Kerala, the only state that so far is actively implementing the amended rule and spreading coverage of palliative care and opioid availability. Only a small percentage of the needy patients in the country can benefit. Patients will not have pain relief until there are policies in every state, and all facilities that care for cancer and AIDS patients have health professionals trained in palliative care and in how to gain access to opioids.

Health professionals and regulators in other countries are also making efforts to improve availability of opioid analgesics. They are using new WHO guidelines to evaluate their national policy and administration for “balance,” and to determine what steps should be taken to ensure availability of opioids for the relief of pain and suffering.¹³ For example, the WHO and the Center have organized regional workshops for teams of regulatory and palliative care specialists from several countries to use the guidelines to develop national action plans to improve opioid availability²³ and the Italian government recently approved more balanced regulatory requirements for prescribing opioid analgesics.²⁴

Conclusions

In the face of visible yet very modest progress, years of frustration are giving way to renewed hope and even enthusiasm that palliative care workers in India may finally be able to have the morphine they need to relieve pain in the million cancer patients with unrelieved pain. There is a long way to go. Experience with this initiative has shown that it is possible to effect positive changes by facilitating interaction between health professionals and government administrators. But the experience has also shown that it is difficult to obtain and maintain the attention of government administrators: lack of understanding of the need for pain relief and palliative care is easily overshadowed by exaggerated but deep-rooted fears of addiction and respiratory depression. Sustained and persistent efforts will be needed to induce further improvements in state policy for opioid availability and palliative care.

It must be noted that despite repeated requests from the central government, and despite the ruling of the Delhi High Court, the Union Territory of Delhi and most of the other state and territorial governments have yet to amend and implement their rules. As a consequence, palliative care programs in New Delhi and other parts of the country have yet to obtain the morphine they need. Indeed, opioid availability has not improved in many of the states in which the rules have been amended; policy changes

in these states must now be implemented, and coupled with education for professionals, administrators and the public.

The major question is, how much longer will it take to provide access to pain relief for the many cancer patients in India if the matter is to be pursued with such limited resources, and only on a state-by-state basis? More can and should be done to improve education and institutional practices aimed at relieving pain, but also to change and implement policy aimed at making essential drugs available and accessible. Doing this will take much greater political commitment from national and state government leaders, as well as some additional health resources.

Our society cares deeply about curing cancer, and so we invest a great deal in prevention and treatment. How much do we care about the quality of life of people who live and die with cancer?

Table 1: Improving morphine availability for cancer pain: State and Union Territory workshops and new rules

State and Union Territories (and City)	Held workshop	Adopted simplified rule
Andhra Pradesh (Hyderabad)	September 2000	
Assam (Guwahati)	September 2001	
Gujarat (Ahmadabad)	February 2000	
Haryana		July 2000
Karnataka (Bangalore)	February 1999	
Kerala (Thiruvananthavuram)	June 1998	November 1999
Madhya Pradesh (Gwalior) (Bhopal)	February 2000; September 2000	May 1999
Maharashtra (Mumbai)	October 1999	
Orissa (Cuttack)	October 1999	June 1999
Rajasthan (Jaipur)	February 2002	
Sikkim		December 1998
Tamil Nadu (Chennai)	April 2000	December 2000
Tripura		December 1999

Note: Source of population data was 2001 Census Report of India

Figure 1: Consumption of Morphine in India

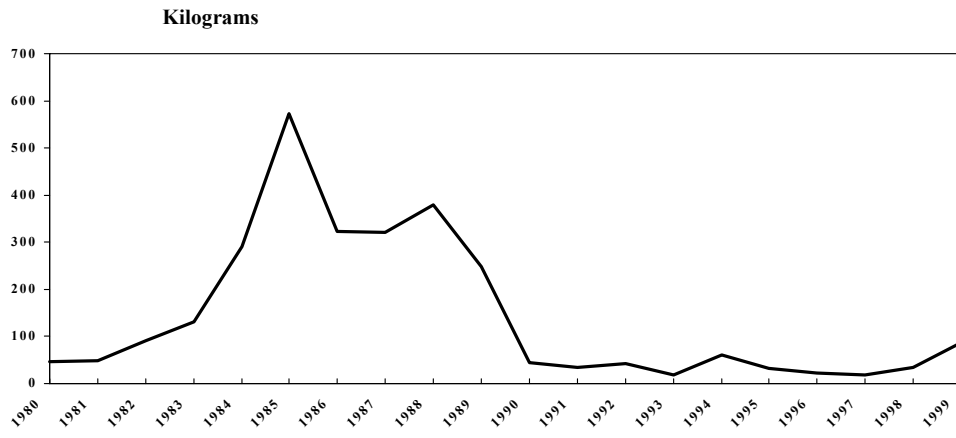
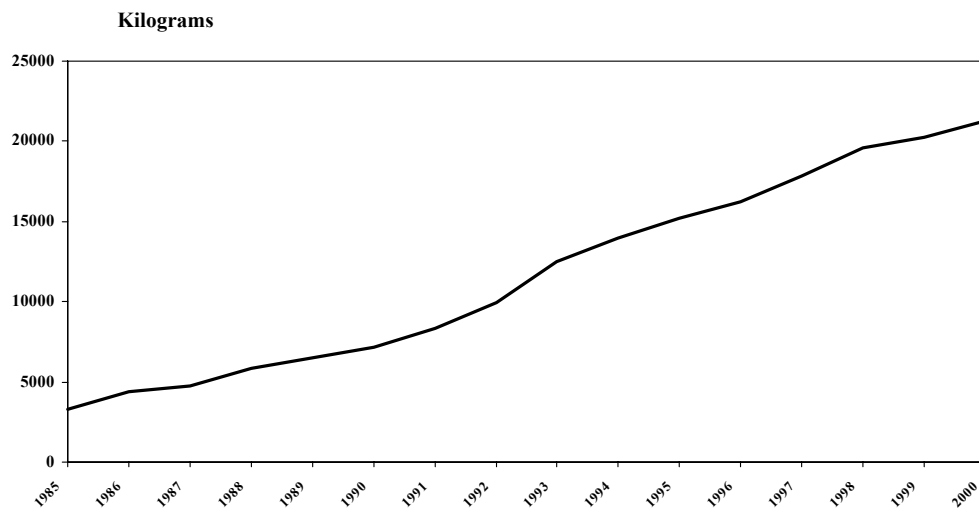


Figure 2: Global Consumption of Morphine





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