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Special Article

India: Opioid Availability - An Update

M.R. Rajagopal, MD, MNAMS, and David E. Joranson, MSSW

Trivandrum Institute of Palliative Sciences (M.R.R.), Trivandrum, Kerala, India; and Pain & Policy Studies Group (D.E.J.), Paul P. Carbone Comprehensive Cancer Center, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, USA

Abstract

In India, a million people with cancer and an unknown number of people with other incurable and disabling diseases, need opioids for pain relief. Only about 0.4% of the population in need have access to them. Major barriers to access to opioids are complicated regulations and problems related to attitude and knowledge regarding pain relief and opioids among professionals and the public. The Pain and Policy Studies Group at Madison Wisconsin has been collaborating with many Indian palliative care workers and government officials to improve availability of opioids to those who need them for pain relief. As a result of this collaborative effort, the Government of India asked all state governments to modify the narcotic regulations following a model given to them. To facilitate the process, the collaboration has conducted workshops in 13 states in association with local champions. Currently, 13 states in India and one union territory have simplified regulations, but opioid availability has improved only in a minority of these states. Establishment of simple standard operating procedures to implement the simplified regulations, advocacy, and improved education of professionals are essential for further improvement of the situation. The past decade has demonstrated that government policy can be changed if palliative care enthusiasts work in tandem with the government. The progress has been slow, but real and encouraging.

Key Words

Opioid availability, oral morphine, India, developing countries, palliative care, pain relief, drug regulation

The Pain & Policy Studies Group is a World Health Organization Collaborating Center for Policy and Communications in Cancer Care.

Address reprint requests to: M.R. Rajagopal, MD, PJRRA
65, Shanti, Pothujanam Lane, Kumarapuram, Medical
College P.O., Trivandrum, Kerala 695011, India.
E-mail: mrraj47@gmail.com

The Problem

The World Health Organization (WHO) estimates that there are around 2.4 million people in India with cancer.¹ Two-thirds of them, about 1.6 million, are likely to be in pain. Two-thirds of those in pain - at least one million - would need opioids belonging to step 3 of the WHO analgesic ladder. Morphine is the only available oral opioid from that step in India. If one person in pain needs an average of 100 mg of oral morphine a day, the annual quantity that would be needed for the one million people in pain from cancer alone would be 36,500 kg.

India grows poppy under license in the three Northern states of Uttar Pradesh, Madhya Pradesh, and Rajasthan (Fig. 1).

Government of India (GOI) Opium and Alkaloid Factories extract opium from these poppies, then produce and export the raw materials used to manufacture opioid analgesics around the world. A tiny fraction of the raw material is converted to morphine for domestic medical use. Eventually that morphine reaches only a tiny portion of the needy. It is indeed paradoxical that two decades after “hospice” was introduced in India, people in pain in a major opium-exporting country have no access to it for medical use.

Previously we have referred to statistics reported by the GOI.² We now question the validity of these reports and, more recently, the government has stopped reporting consumption statistics for morphine altogether, despite its obligations under the Single Convention on Narcotic Drugs (Rx). Consequently, there appear to be no reliable statistics for morphine consumption in India. No system exists to obtain consumption statistics from the states and to collate them at the national level. The one index of morphine consumption that we do have (though an indirect indicator of consumption) is the quantity of morphine

salts sold from the GOI Opium and Alkaloid Factories (that form the only agencies performing this function) to companies that manufacture various formulations of morphine in India. During the five-year period between 2000 and 2004, the average annual quantity of morphine sold by these factories was 142.32 kg - a mere 0.4% of the possible need.

The major barriers that have prevented access to opioids for medical use include the following:

1. Regulatory issues: In 1985, in an attempt to curb misuse of opioids, the GOI created the Narcotic Drugs and Psychotropic Substances (NDPS) Act.² This act and the state NDPS rules pose the following problems:

- a. Stringent NDPS rules vary from state to state and require cumbersome licensing procedures. As many as three or four licenses are typically needed to procure every consignment of morphine. Several agencies, including the Excise, Drug Control, and Health Departments, are involved in the process of licensing to obtain morphine. Frequently the validity of one license (e.g., the possession license) expires by the time another license (e.g., transport license) is obtained.³ It is very difficult (or sometimes impossible) for doctors and hospitals to obtain all the licenses necessary to procure morphine.³

- b. Harsh punishment prescribed in the NDPS Act (e.g., 10 years of rigorous imprisonment even for minor offenses) has had the effect of alienating pharmacists. Most pharmacies in the country fear punishment in the event of small discrepancies in stock and have stopped ordering opioids.

2. Interruptions in opioid availability: Until 1999, interruptions in the availability of opioids for domestic use from the only factory producing morphine were common.

This meant that even hospitals that had obtained the licenses in time were unable to procure morphine for dispensing to patients.

3. Problems related to attitude and knowledge:

a. Through decades of strict regulation, medical professionals developed a fear of morphine; they would not use it and taught students to avoid it. This attitude came out of exaggerated fears of addiction and respiratory depression and was reinforced by an unbalanced regulatory environment governing opioids.⁴

b. The general public, including government officials, associates morphine with inevitable addiction and are reluctant to accept the drug for medical needs.

c. Over decades, scientific advances in medicine have resulted in an overemphasis on “cure” and a downturn in the practice of symptom control, including pain relief.

Past Efforts at Improvement

Early efforts to educate physicians and nurses about the principles of palliative care had some success. Palliative care developed in some parts of the country, but many of the early enthusiasts found it difficult to obtain oral morphine, and when they did, to sustain an uninterrupted supply. Beginning in 1992,⁵ the GOI sponsored a number of workshops that had no positive output, as the workshops produced no clear understanding of the underlying problems or mechanisms to address them.

Using funds provided by the WHO, the GOI bought huge quantities of oral morphine twice and supplied them free to Regional Cancer Centers. But most of the purchased morphine was wasted because the majority of Regional Cancer Centers did not have staff trained to use it, and they declined to accept the morphine.

The Recommendation from the Pain & Policy Studies Group

The WHO Collaborating Center at the Pain and Policy Studies Group (PPSG), Madison, Wisconsin conducted a study of the narcotic regulations of India and discussed the problem with various government officials in the Ministries of Revenue and Health. By India’s constitution, local health care and control of “narcotic substances” are in the realm of individual state governments. In addition, state Excise Departments license interstate commerce in manufactured narcotic drugs, including medical morphine (an extension of the British Indian Government’s practice to obtain significant revenue from the taxation of opium).² At this stage, the PPSG also started working with Indian palliative care workers, notably the Indian Association for Palliative Care and Pain and Palliative Care Society of Calicut (the collaborators). As a result of the joint work that followed, the Department of Revenue of GOI, which is responsible for the manufacturing and control of opioids in the country, took a major positive step and drafted a model regulation based on a proposal made by David Joranson, director of the PPSG. In 1998, the GOI sent out an instruction to all state governments in the country to amend their narcotic regulations and simplify their licensing requirements.

The Amendment

The amendment sought to exempt institutions delivering palliative care from the need for the complicated licensing process administered by the Excise officials in the state revenue departments. The amendment shifted the licensing responsibility to the Drugs Controller in the state Health Department who would approve palliative care programs to obtain morphine as “Recognized Medical Institutions” (RMIs) and grant them a morphine quota. The difference between the older licensing process and the amendment is shown in [Table 1](#).

Joint Efforts of PPSG and the Indian Palliative Care Community

Theoretically, all a state needed to do was to give an official announcement of the amendment as recommended by the central government, but several practical problems arose. Most of the departments in charge of morphine licensing resisted any change. Although there were some exceptions, most states failed to follow the central government's instructions because of any or all of the following reasons:

1. Fear of substance abuse: Many people feared that any relaxation of the rules would result in an increase in substance abuse in the community.
2. Reluctance to give up power: Some departments felt that it would lessen the department's importance if they gave up something that had been under their control for years.
3. Attitudes of medical professionals: Senior doctors who were medical advisors to the government continued to argue against opioids.
4. Red tape: Matters that involved concurrence of several departments continued to take a lot of follow-up effort.
5. Sheer resistance to change. In an effort to persuade state governments, the collaborators developed state workshops in which stakeholders, government officials, palliative care professionals, and advocates discussed the need for palliative care and oral morphine, clarified any doubts, and tried to arrive at decisions to modify the state regulations. To this end, the collaborators identified a local champion with commitment to the cause and then worked through that person to reach out to state officials to make a workshop possible. Thanks to funding from the United States Cancer Pain Relief Committee, the workshop expenses were underwritten. The first workshop was held in Kerala in 1998.

The executive head of the state Health Department chaired the meeting. His active involvement ensured participation of senior officials of other concerned departments. At this meeting, a decision was made to adopt an amendment to simplify the narcotic rules, as recommended by the GOI. Despite this decision, it necessitated active follow-up at various departments until the amendment was finally announced at the end of 1999.

The Kerala workshop made one other important decision. At the request of the Drugs Controller, a decision was made to form an advisory panel of palliative care physicians working as a voluntary body to advise the government on approving RMI status. Individual applications for RMI status would be submitted to the advisory panel. As the advisory panel was composed only of palliative care physicians with knowledge of palliative care and a commitment to improving access to pain relief, it was hoped that unnecessary delays would be avoided. One member of the panel would visit the applying institution to assess whether it satisfied the minimum mandatory requirements, including having a doctor with at least one month of practical training in palliative care in an approved institution, facilities for safe storage, and a system to document opioid dispensing and use.

To date, similar workshops have been held in 13 states - more than one in some states (Fig. 2). Learning from the Kerala experience, the general procedure for organizing a workshop includes the following:

1. Identification of a local champion within the state and development of a team, if one does not exist already.
2. Sensitization of government officials about the need for palliative care and oral morphine and to get the commitment of a senior official in the state government to hold a workshop.

3. Interaction of the local champion and collaborators with the government officials to ensure that the agenda of the workshop is focused on the objectives, i.e., to effect the amendment, to ensure a standard operating procedure for its effective implementation, and to create plans for follow-up.

4. Participation of resource persons from the group of collaborators to facilitate the process (including members of the PPSG when possible).

Workshop Results

To date, the results of these workshops have been mixed. Thirteen states have adopted an amendment to simplify their narcotic rules (Fig. 3). Of the 13 states that had workshops, five resulted in simplification of state narcotic regulations; six have not. In the other two states, workshops were held after an amendment had been effected to develop a system for implementation of the amended rule.

Positive results from the workshops include the following:

1. The workshop held in Maharashtra did not result in amendment of the narcotic regulations. But, as a result of the discussions that took place during and after the workshop, action by the GOI Opium and Alkaloid Factories has ensured an uninterrupted morphine supply since then.

2. As a consequence of the improved awareness generated by the various workshops, the national Drugs Controller exempted all palliative care programs from the need for the drug license that is ordinarily required for any agency selling any drug. The drug license would have mandated the presence of a trained pharmacist, which most charitable institutions could not afford.

3. Informal discussions during some workshops led to a study in Calicut of all

patients who were given oral morphine. During a two-year period, 1,723 patients received oral morphine, and there was no evidence of a single instance of abuse or diversion to illicit channels. This study helped convince skeptics about the safety of using oral morphine in the home setting.⁶

4. In some states where an amendment has still not taken place (e.g., Andhra Pradesh), obtaining the required licenses has become easier under existing regulations. This has been attributed to improved awareness among administrators.

Major reasons for relative failures include the following:

1. Inadequate follow-up: The government machinery moves slowly. Without persistent efforts, it is usually difficult to achieve results.

2. Geographical factors: Border states in the north and northeast of India have more substance abuse problems than elsewhere. In these states, it has been very difficult to overcome the barriers to opioid availability.

3. Changing officials: Very often, considerable progress is made with one key official, only to find that that person gets transferred, and the work has to be repeated.

4. Lack of palliative care education: In some states that amended the narcotic regulations, there is no oral morphine use in the whole state, even after several years (e.g., Sikkim, Tripura, and Jammu-Kashmir).

5. Lack of a simple and realistic system for implementation of the amended rules.

Lessons Learned

The Indian experience over the last decade has shown us that government policy can be changed and regulatory barriers can be overcome as an organized activity by

palliative care leaders involving government officials and regulators. But to be successful, efforts need to be sustained and persistent. Simplification of narcotic regulation by itself will not improve opioid availability to the needy unless it is accompanied by advocacy, education of the health care professionals in pain management and palliative care, and the integration of palliative care programs into the health care system.

Looking to the Future

Although there has been some success so far, it has been limited to a few pockets of India. For progress to be made, it is essential that efforts to overcome regulatory barriers be coupled with efforts at professional education and advocacy for palliative care implementation. In association with the PPSG and the National Cancer Institute of the USA, Pallium India has recently undertaken a project to start palliative care services in three cancer centers located in states where effective palliative care did not exist. The project, patterned after WHO recommendations that recognize the need for policy, drug availability, and education, provides funds to a cancer center for palliative care education for a doctor and a nurse, as well as for salary support for these professionals for two years. In return, the cancer center agrees to start palliative care services and make oral morphine available (including amending state narcotic regulations, if necessary).

A recent major achievement in India has been a decision by the GOI to include palliative care in the National Cancer Control Program for the country's next five-year plan, starting in April 2007. The Government appointed a task force comprising palliative care experts from various parts of the country to devise a strategy for this program. The committee's report includes plans for improved opioid availability, palliative care education, and service development. Although limited to

cancer, the palliative care community of India is hopeful that greater impetus and more cancer control resources will expand the number of patients who receive palliative care. Concurrently, it will be a major challenge to ensure that further expansion of palliative care is matched by the simplification and implementation of each state's narcotic regulations.

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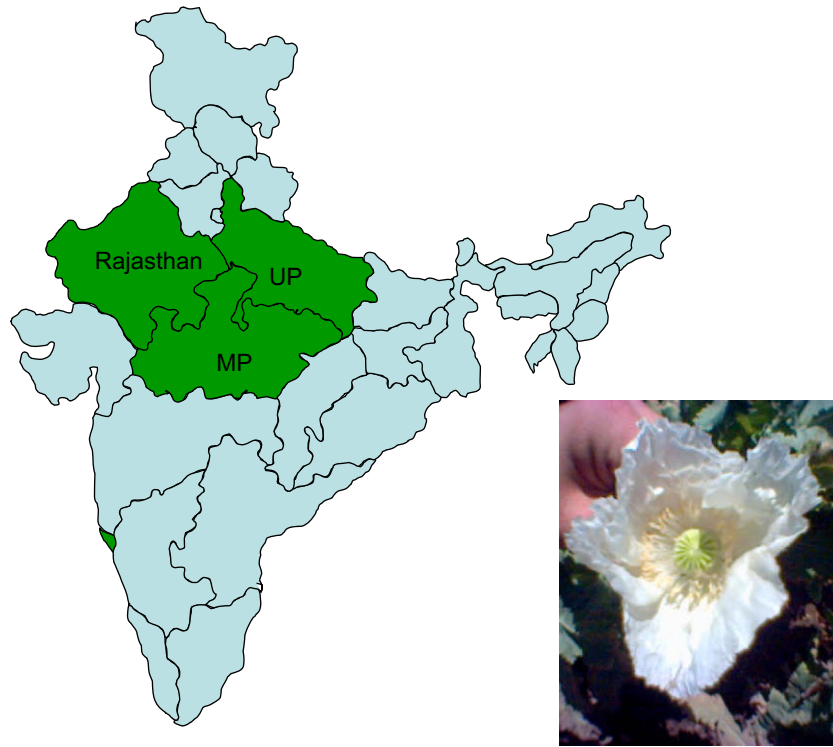


Fig. 1. The three poppy-growing states in India: Rajasthan, Uttar Pradesh, and Madhya Pradesh (Inset: the poppy flower).

Table 1

Difference Between Old Narcotic Rules in a Typical Indian State and the Amended Rules in Kerala

	Old Rules	Amended Rules as Implemented in Kerala Since 1999
Purview	All Medical Institutions	Palliative Care Institutions
Licensing needed	<ol style="list-style-type: none"> 1. Possession license (specified in terms of drug, formulation, and quantity) 2. Import permit (to bring it from the state of manufacture) 3. Export permit (to send it out of state of manufacture) 4. Transport permit from district to district within the state 	<ol style="list-style-type: none"> 1. Approval as RMI and allotment of quota
Needed formalities	<ol style="list-style-type: none"> 1. Application to local Excise office 2. Forwarding of application to Excise commissioner at state capital city 3. Forwarding of application to Drugs Controller in capital city 4. Forwarding of application to local office under Drugs Controller 5. Inspection of the institution by drugs inspector 6. Transmission of approval of drugs inspector to Drugs Controller 7. Forwarding to Health authority for approval 8. Transmission of approval from Health authority to Drugs Controller 9. Transmission of approval of Drugs Controller to Excise commissioner 10. Transmission of approval to local Excise office 11. Issue of license 	<ol style="list-style-type: none"> 1. Application to advisory panel 2. Inspection of institution by a member of advisory panel 3. Recommendation sent to Drugs Controller 4. Approval as RMI and allotment of quota by Drugs Controller
Monitoring body	<ol style="list-style-type: none"> 1. Excise Department 2. Drugs Controller's office 	<ol style="list-style-type: none"> 1. Drugs Controller's office

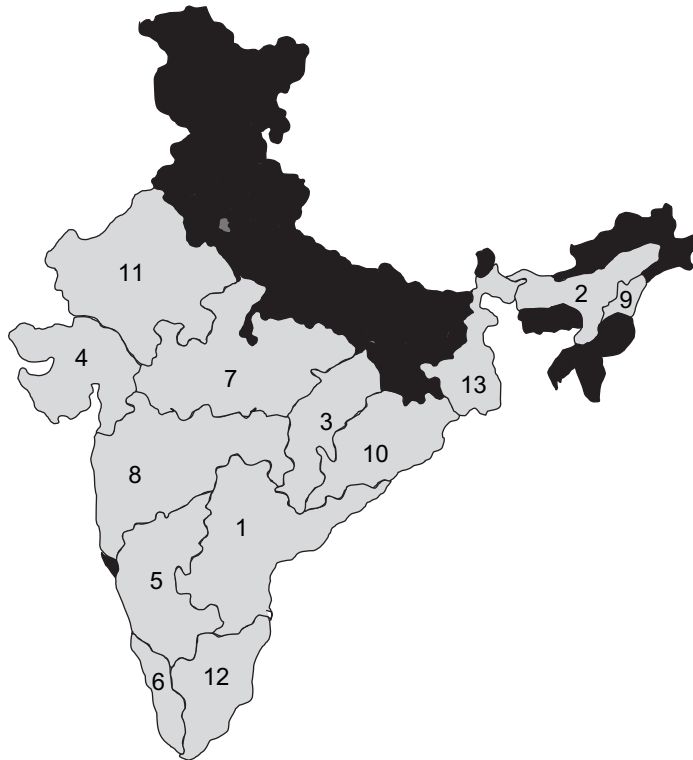


Fig. 2. Workshops by the IOAI were conducted in states in India shown in gray, namely (1) Andhra Pradesh, (2) Assam, (3) Chattisgarh, (4) Gujarat, (5) Karnataka, (6) Kerala, (7) Madhya Pradesh, (8) Maharashtra, (9) Manipur, (10) Orissa, (11) Rajasthan, (12) Tamil Nadu, and (13) West Bengal.

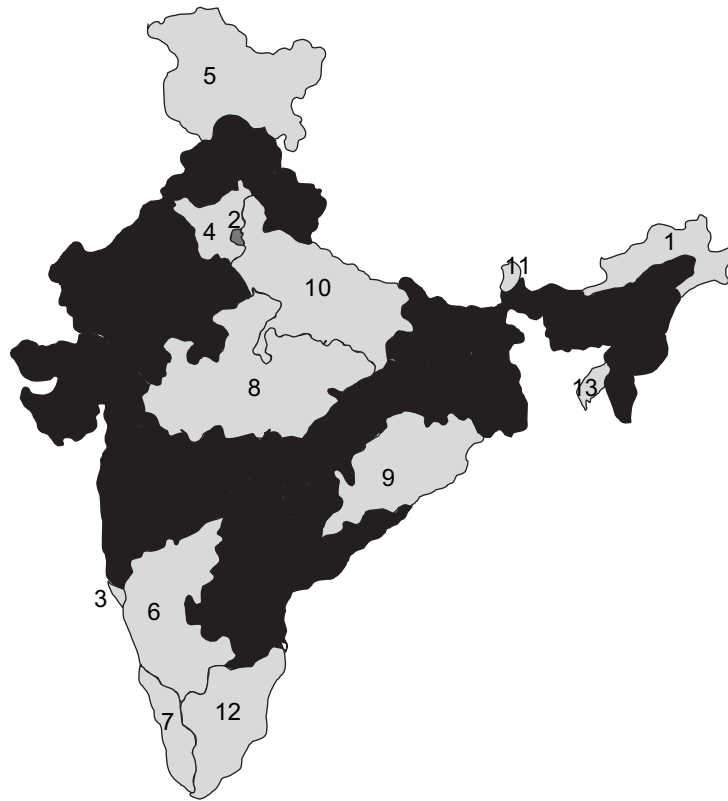


Fig. 3. States in India that simplified their narcotic rules are shown in gray, namely (1) Arunachal Pradesh, (2) Delhi, (3) Goa, (4) Haryana, (5) Jammu and Kashmir, (6) Karnataka, (7) Kerala, (8) Madhya Pradesh, (9) Orissa, (10) Uttar Pradesh, (11) Sikkim, (12) Tamil Nadu, and (13) Tripura.