

Amendment of Narcotic Regulation in Andhra Pradesh, A Milestone in Palliative Care Movement in India

AN INCTR PAX, Pallium India & MNJIO joint achievement.

In brief: Andhra Pradesh becomes the 14th state of India to amend and simplify its narcotic regulations. This is the consequence of about 10 years of efforts. The amendment means that all palliative care centers in Andhra Pradesh can get the required morphine without the complicated licensing process and that the Drugs Controller is the only agency involved in the process.

Background information

Need for Oral Morphine

In 1986, the World Health Organization (WHO) published guidelines for cancer pain management based on the three-step analgesic ladder. They recommended morphine as the mainstay of treatment and it to be listed as an “essential drug.”

There are around 2.4 million people in India with cancer. 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.

Opioid Availability in India

India is the only country authorised by the United Nations Single Convention on Narcotic Drugs (1961) to produce gum opium. Eleven (11) other countries, i.e., Australia, Austria, France, China, Hungary, the Netherlands, Poland, Slovenia, Spain Turkey and Czech Republic cultivate opium poppy, but they do not extract gum⁽¹⁾.

India grows poppy under license in the three Northern states of Uttar Pradesh, Madhya Pradesh, and Rajasthan. 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 less than 0.4% of the needy. It is indeed paradoxical that two decades after palliative care was introduced in India, most people in pain in a major opium exporting country have no access to it for medical use⁽²⁾.

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. 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). During the same period, global consumption of morphine increased by 437 %⁽³⁾.

As a result, the International Narcotics Control Board, called attention to the decline in consumption of morphine in India and made a recommendation: "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⁽⁴⁾."

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 Government of India created the Narcotic Drugs and Psychotropic Substances (NDPS) Act. This act and the stated 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. It is very difficult (or sometimes impossible) for doctors and hospitals to obtain all the licenses necessary to procure morphine. Because of these regulations, many hospitals do not want to commit the amount of time it takes to go through the bureaucratic steps required to obtain morphine, and thus simply do not stock it. Others find that the bureaucratic intricacies frequently result in shortages and delays interrupting the supply.

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. Problems related to attitude and knowledge

Concerns about addiction, excessive sedation, and respiratory depression have resulted in widespread avoidance or underdosing.

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. At present, the undergraduate or post graduate curricula for medical education does not include any specific instruction on palliative care or pain management.

b. The general public, including government officials, associates morphine with inevitable addiction and are reluctant to accept the drug for medical needs even though extensive, carefully documented clinical experience has shown that these fears are unfounded^(4, 5).

Policy, education and drug availability barriers have created a vicious cycle: Because pain treatment and palliative care are not priorities for the government, healthcare workers do not receive the necessary training to provide these services. This leads to widespread under-treatment, including of pain, and to low demand for morphine. At the same time, complex procurement regulations discourage pharmacies and hospitals from stocking and healthcare workers from prescribing it, again resulting in low demand.

Amendment of Regulations Related to Opioid Availability

Due to these complicating license procedures and due to many reasons as said above, the morphine consumption came down. As a result, the Department of Revenue of Government of India(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 Indian Association of Palliative Care and Pain and Policy Study Group, Madison, Wisconsin. 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.⁽⁶⁾

Some states/Union territories have amended their narcotic regulations following the guidelines given by the central government. The states with the amended regulations are Arunachalpradesh, Dadra & Nagar Haveli, Delhi , Goa, Jammu and Kashmir, Karnataka, Kerala, Madhyapradesh , Mizoram, Orissa, Sikkim and Tamil Nadu. But two-thirds of India's states have failed to do so and maintain older regulations for opioid medications denying easy availability of morphine to even terminally ill patients and cause undue sufferings and harassment. The total opioid consumption in India from the year 1998 to 2008 increased to 1569.825 but if the estimate that if all Indians with cancer pain were to get pain relief, we would need 36,500 Kg of morphine!^(2, 7)

Andhra Pradesh, the 14th State to Amend the Narcotic Regulation

Andhra Pradesh becomes the 14th state of India to amend and simplify its narcotic regulations. This is the consequence of about 10 years of efforts. Following the Government of India order in 1998 to all states to amend their narcotic regulations the Indian Association of Palliative Care (IAPC) and the Pain and Policy Studies Group had worked together to effect the change in Andhra Pradesh, but despite two workshops with Government officials and professionals, it had not materialised. Following the establishment of a palliative care training center at MNJ Institute of Oncology (MNJIO) as a joint initiative of MNJIO, International Network for Cancer Treatment and Research (INCTR) and Pallium India, the MNJIO team made renewed efforts. The public interest litigation filed by The Indian Association of Palliative care represented by the chairman of its opioid availability committee, Dr M.R.Rajagopal to the Supreme Court of India gave added strength to the movement. The amendment means that all palliative care centers in Andhra Pradesh can get the required morphine without the complicated licensing process and that the Drugs Controller is the only agency involved in the process.

Challenges ahead:

1. The various government officials involved in the amendment process were generally very supportive of the cause and understood the need for it but at the same time expressed the apprehension about the misuse. The onus is now on the professionals and patients who are going to use morphine to ensure a strict practice of adequate usage, proper documentation and supervised dispensing to avoid any chance of diversion.
2. The biggest challenge is to increase the demand by the professionals and the community. It will require aggressive advocacy, training and education. The Ministry of Health and Family Welfare, the Medical Council of India, State Directorates of Medical Education, representatives of medical colleges, and palliative care providers should jointly develop a plan of action for the gradual introduction of palliative care instruction into curriculums for medical and nursing education. The government should integrate palliative care into the primary care system of health as has happened in the state of Kerala to improve the access to care.

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