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End-of-Life Care and Opioid Use in India: Challenges and Opportunities

In 2011, the WHO estimated that 20 million people required end-of-life palliative care, of whom 78% lived in low- and middle-income countries.¹ In a country like India, which contains 17.5% of the world population, end-of-life palliative care is almost nonexistent, as was noted in the 2015 Quality of Death Index by The Economist Intelligence Unit.^{2,3} According to estimates from India, approximately 10 million people may require palliative care services, of whom 1 million have cancer and 7 million have other life-limiting conditions.⁴ It is estimated that the yearly incidence of cancer in India will increase from 1 million in 2015 to 1.7 million by 2035.⁵ The 2015 Global Burden of Disease data estimated that 675,000 persons die with a diagnosis of cancer every year in India.⁶ The gravity of the situation could not be any more evident than in the fact that more than 26,000 individuals suffering from cancer, AIDS, paralysis, and other chronic illnesses ended their life in 2013, accounting for nearly 20% of all deaths caused by self-harm in India.⁷

Ease of access to opioid pain medications is an integral component of effective palliative care service. In India, poppy plants are grown only in three states and are under strict government licensing.⁸ The government-owned company Opium and Alkaloid Works has only two factories processing raw materials from poppy plants into morphine sulfate powder for the entire country.⁹ Manufacturers obtain the compound from the factory, which is then converted into tablets and injections. Total morphine consumption in India was a paltry 278 kg in 2014.¹⁰ If a patient with terminal cancer requires 75 mg of morphine per day for pain relief for approximately 90 days, this amount of 278 kg is only sufficient to adequately treat 40,000 patients.¹¹

In the initial phases of palliative care in India, morphine and pethidine were the only opioid pain medications available, and pethidine is not recommended for chronic pain.¹² Awareness about opioid medications increased during the early 1980s, and morphine use increased during the time. This raised concerns regarding diversion of the medication and prompted the government to

institute the Narcotic Drugs and Psychotropic Substances (NDPS) Act in 1985.

Although cancer pain relief was identified as one of the basic services provided at the primary health centers in the country in the National Cancer Control Program in 1984, the practicality of this goal was negated with the new NDPS Act. As many as six licenses were required for every consignment of morphine, and physicians possessing opiates after expiry of license could face arrest without bail and a jail term of up to 20 years. The use of morphine decreased from 716 kg in 1985 to a mere 18 kg by 1997 (data obtained through Pain and Policy Studies Group: University of Wisconsin/WHO Collaborating Center from annual consumption report submitted by countries to International Narcotics Control Board). This drastic decrease raised concerns, and the International Narcotics Control Board forewarned the government and advised to ensure the availability of opioids for medical purposes.^{13,14}

For the palliative care community, management of accounts regarding storage of morphine and its dispensing was also cumbersome as a result of the frequent regulatory procedures. Even when demand started to increase by the early 2000s, supply was a limiting factor. As a result of the difficulty in obtaining a license for the manufacture of morphine and the need for frequent renewal, there was a significant shortage of opiate medications. Soon, physicians moved to alternate analgesic options.¹⁵ Even in places where morphine was available, patients were only given short supplies of medications. The ban on dextropropoxyphene in India further complicated the situation for patients and health care providers.¹⁶ However, strong and persistent advocacy from palliative care providers and patient support groups led to the amendment of the NDPS Act in 2014 (Table 1). Opioid medication licensing was unified and brought under the purview of the federal government. Under the current law, to procure and dispense morphine, only a single license is now necessary. As a result, it has become significantly easier to obtain morphine for use in palliative care.

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Table 1. Major Legislation Regarding Use of Opiates in India

Year	Major Legislation Regarding Use of Opiates in India
1857	Opium Act: Nationalizing cultivation of poppy and manufacture of opium in British Colonial India.
1878	Opium Act amendment: Aimed to decrease opium use in India primarily to promote export. Sale authorized only to registered Chinese opium smokers and Indian opium eaters. Ban of opium in Burma.
1906	England and China sign treaty to restrict Sino-Indian opium trade as opiate addiction reaches alarming levels.
1930	The Dangerous Drugs Act: Unifying the opium rules across Indian Union as per adoption of Geneva Convention.
1985	The Narcotic Drugs and Psychotropic Substances Act supersedes all previous acts. Strict rules enforced for production, manufacture, storage, prescription, and use of morphine and other psychotropic substances.
2014	Amendment to Narcotic Drugs and Psychotropic Substances Act: Important provisions and changes include the following: <ul style="list-style-type: none"> a. Uniform narcotic regulations in all states and union territories across the country b. To ensure uniformity, the power for any further amendment of the rules regarding essential narcotic drugs is vested with the central government only c. An institution will require only a single license approving them as a recognized medical institution instead of the previous requirement of 4-5 licenses d. The drugs controller of each state will be responsible for licensing instead of multiple departmental licenses, which were required earlier e. Ensure availability of pain medications in hospitals and its accessibility to patients with severe pain f. Instituting evidence-based and human right-compliant standards for facilities treating drug dependence g. Opening up private sector in processing of opium and concentrated poppy straw h. Punishment for holding opiates without license will be 6 months to 1 year imprisonment for a small quantity and 20 years for a commercial quantity; an alternative 30-year imprisonment instead of the mandatory death sentence for subsequent offenses involving significant quantity of drugs

NOTE. Information was obtained from the Central Bureau of Narcotics at www.cbn.nic.in.

Despite the amendment in laws, reports suggest that palliative care services in India remain dismal.³ Focus has since shifted to understanding the barriers for effective implementation of the law. A significant hurdle in improving the access to pain medications lies at the feet of the medical community in India. Physicians and medical professionals lack appropriate knowledge regarding opioid pain medications. For instance, a study found that nearly 90% of 326 medical students thought that morphine use in palliative care would result in drug addiction.¹⁷ It is important for medical students to understand that terms such as physiologic dependence and tolerance are obsolete in the case of end-stage palliative care treatment. Integration of palliative care as an

academic discipline into the undergraduate medical curriculum and establishment of more postgraduate educational programs in palliative care would greatly improve provision of appropriate pain relief to thousands of patients suffering from cancer and other life-limiting illnesses. Another barrier to effective implementation is centered on a purported concern for opioid misuse or diversion. We suggest that this issue is not valid in India, where no apparent discrepancies occur during stages of morphine production and distribution.¹⁵ Sociocultural influences make people consider pain medications as toxic, sometimes even to the extent of hiding their symptoms from physicians. Improved awareness of the benefits of palliative care services can effectively address these sociocultural barriers to seeking pain relief near the end of life.

In 2008, the southern Indian state of Kerala emulated a palliative care policy, prompting other states to enact similar policies. The policy was aimed at training more providers and volunteers and establishing more palliative care programs, especially in the primary care setting.¹⁸ The contribution of community-based organizations resulted in a great advance in palliative care delivery; Kerala state now has more palliative care centers than the rest of the country put together, despite having just 3% of the country's population. The World Palliative Care Alliance and WHO advocated this as a highly sustainable palliative care model.¹ The program had approximately 50,000 beneficiaries in 2014 and obtained budgetary support from local and state governments. However, the situation has improved only marginally in the rest of the country, with only a nominal increase in the number of palliative care centers.¹⁹

Balancing these virtues and vices in a cost-effective setting within this multicultural society is a gargantuan task that the Indian government and palliative care community has currently undertaken. Any positive or negative outcomes from the different models launched in various sociopolitical, geographic, and cultural conditions of the country would help formulate a palliative care model for low- and middle-income countries with minimal palliative care activities.¹ The palliative care community is optimistic about the new NDPS amendment, which may help make pain relief accessible to millions. However, it is faced with the task of restructuring medical education to equip the hundreds of thousands of doctors and ancillary medical personnel who have never seen or ordered opioid pain medications in their lives.

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