

GDPO Situation Analysis

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Opioid Analgesics in India: Low Access and Hope for Change¹

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Subject

Rising cancer rates in the second most populated country on earth evidences that while the disease is no longer specific to the developed world, the availability of World Health Organization recommended medicines that can treat extreme pain nevertheless remains confined to the Global North. Despite India's position as a leading global producer of medical opioids, hundreds of thousands of patients in the country suffer unnecessary pain; access to opioid analgesics remains low and uneven across the country. Multiple factors account for this, including India's regulatory regime, the lack of implementation of positive legislative changes, and training issues and stigma associated with opioids. In spite of these barriers, the Indian state of Kerala provides positive examples which may present lessons for broader nationwide reform.

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Significance

Opioid analgesics are the only medicines that can effectively control severe to extreme pain the terminally-ill may experience.⁴ The ease of administration of the gold-standard morphine and its affordability could have a significant impact on the quality of life of patients worldwide. Access to them, however, is uneven in the developing world.⁵

India's situation is beset by a paradox; the country ranks among the world's six highest producers of opioids for the legal medical market.⁶ Cultivation happens under state-owned companies and is prominent in the states of Uttar Pradesh, Madhya Pradesh and Rajasthan.⁷ Still, India ranked 102nd globally for the availability of morphine -a gold standard drug in palliation for severe pain- according to the International Narcotic Control Board in 2014.⁸

In India, the vast majority of cancers are detected at late stage where treatment options are limited. Cancer rates in the country have been increasing with more than 1 million cases diagnosed annually by 2014, projected to increase to 1.7 million by 2035.⁹ Nearly 70,000 deaths are caused by cancer annually in India¹⁰ and currently an estimated 10 million people are in need of essential controlled opioid analgesics¹¹ underlying the gravity of the lack of access.¹²

In contrast to the evident demand for opioid analgesics, availability is low and uneven in the public health care system¹³ especially in rural areas¹⁴ and largely confined to large cities such as Delhi. Considering that the poor are more likely to die of cancer in the country,¹⁵ the lack of access to opioids disproportionately affects the rural poor in India (with a rural poverty rate of 25.7%)¹⁶ and contributes to reinforcing inequalities and marginalization.¹⁷

Patients from rural areas must travel large distances for pain medication. The need to travel with relatives (caretakers) frequently requires caretakers to miss work, terminate employment and/or take loans to afford

⁴ WHO. 2011. 'Achieving Balance in National Opioids Policy.' Available at http://apps.who.int/iris/bitstream/10665/44519/1/9789241564175_eng.pdf

⁵ Global Alliance to Pain Relief Initiative (GAPRI). 2010. Access to Essential Medicines Brief. Available from: <https://www.esmo.org/content/download/14123/252826/file/Global-Access-to-Pain-Relief-Evidence-for-Action.pdf>; European Society for Medical Oncology (ESMO). 2014. 'Global access to pain relief: Evidence for action.' Available at <http://www.esmo.org/content/download/14123/252826/file/Global-Access-to-Pain-Relief-Evidence-for-Action.pdf>

⁶ International Narcotic Control Board. 2015. "Supply of opiate raw materials and demand for opiates for medical and scientific purposes." Available at https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2015/part_3_SandD_E.pdf

⁷ Rajagopal, M.R & Joranson, David E. 2007. "India: Opioid Availability – An Update." *Journal of Pain and Symptom Management*. Vol 33, pp. 615-622. Available at <http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/india07.pdf>

⁸ Pain and Policy Studies Group, University of Wisconsin/WHO Collaborating Centre. 2015. "2014 Global Consumption of Morphine (mg/capita)." Available at http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/global_morphine.pdf

⁹ Mallath K., Mohandas et. al. 2014. "Cancer Burden and Health System in India: The Growing Burden of Cancer in India: Epidemiology and Social Context."

¹⁰ Ibid 2014

¹¹ Knaul, Felicia MarieKnaul, Felicia Marie et al. 2017. "Alleviating the access abyss in palliative care and pain relief—an imperative of universal health coverage: the Lancet Commission report." *The Lancet*, Vol. 0 Issue 0. Available at [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(17\)32513-8.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)32513-8.pdf), Accessed on 29/01/2018

¹² World Health Organization. 2014. Cancer Country Profiles 2014: India. Available at http://www.who.int/cancer/country-profiles/ind_en.pdf?ua=1

¹³ Ibid 2014

¹⁴ Human Rights Watch. 2009. "Unbearable Pain: India's Obligation to Ensure Palliative Care." Available at https://www.opensocietyfoundations.org/sites/default/files/palliativecare_20091106.pdf

¹⁵ Mallath K., Mohandas et. al. 2014. "Cancer Burden and Health System in India: The Growing Burden of Cancer in India: Epidemiology and Social Context."

¹⁶ Government of India, Planning Commission. 2013. "Press Note on Poverty Estimates 2011-2012". Available at <http://indiamicrofinance.com/wp-content/uploads/2014/06/povert-in-india-2014-205.pdf>

¹⁷ Sneha, Latha M et al. 2017. "Financial Burden Faced by Families due to Out-of-Pocket Expenses during the Treatment of Their Cancer Children: An Indian Perspective." *Indian Journal of Medical and Paediatric Oncology : Official Journal of Indian Society of Medical & Paediatric Oncology* 38.1 (2017): 4–9. *PMc*.

the long travel for medicine for terminally ill relatives.¹⁸ Untreated severe pain can have a psychological impact on family members¹⁹ as well as a wider socio-economic impact.²⁰ This becomes very relevant in consideration of cyclical problems of rural poverty.

Analysis

- The International Narcotics Control Board (INCB), a treaty body established by the 1961 Single Convention on Narcotic Drugs, issues permissions for governments to purchase a certain quantity of medical opioids annually based on needs reported by state parties. Estimated needs are calculated on the basis of data provided by national health authorities and complex epidemiological surveys taking account of aggregate and disease specific population information.²¹ The quality and coverage of data are influenced by the capacity and interest of states to accurately monitor and report needs for medical opioids across health institutions, local governments and central state bodies. These can be low especially in developing countries such as India,²² with implications for the supply and availability of medical opioids nationally. INCB also considers past consumption rates as a proxy for future needs, thus re-creating the circle of low availability in the Global South.
- Access to medical opioids was legally restricted by the 1985 Narcotic Drugs and Psychotropic Substances (NDPS) Act in India. Incentivized by the international drug treaty framework that focuses on demand reduction in the illicit drug market,²³ NDPS introduced penalties of possible prison sentences even for minor clerical mistakes in medical prescription. As a result, many pharmacies and hospitals do not stock morphine,²⁴ limiting pain treatment options. Reinforcing the severity of this public health problem, as only up to a 4% (43 mg per patient)²⁵ of patients' need can be met on current stock levels.
- Human Rights Watch in 2009 published a report on social and health impact of the lack of access,²⁶ prompting a visit by the INCB. The Indian government developed a National Programme for Palliative Care in 2012²⁷ and in 2014 amended the 1985 NDPS Act removing some punitive measures. However,

¹⁸ Emanuel, Natalia et. al. 2010. "Economic Impact of Terminal Illness and the Willingness to Change it." *Journal of Palliative Medicine*, Vol. 13, No. 8.; Mohanti B. K. et. al. 2010. "Estimating the Economic Burden of Cancer at a Tertiary Public Hospital: A Study at the All India Institute of Medical Sciences" Indian Statistical Institute, Delhi Centre Available at http://www.isid.ac.in/~abhiroop/res_papers/WORKING_PAPERS_files/cancer.pdf

¹⁹ Pandey M. & Thomas B. C et. al. 2006. "Factors influencing distress in Indian cancer patients." *Psychooncology*, Vol. 15, pp. 547–550.; Chatuverdi K. S. & Chitra, V. 2008. "New Research in Psycho-oncology." *Current Opinions in Psychiatry*. Vol 21, pp. 206-2010

²⁰ Emanuel, Natalia et. al. 2010. "Economic Impact of Terminal Illness and the Willingness to Change it." *Journal of Palliative Medicine*, Vol. 13, No. 8.

²¹ INCB. 2005. 1961 Single Convention on Narcotic Drugs: Training Material: The Estimates system for narcotic drugs, Available at https://www.incb.org/documents/Narcotic-Drugs/Training-Materials/English/NAR_2_English_2005.pdf pp. 7, 9-11

²² Pandey, Arvind & Roy, Nandini & Bhawsar, Rahul & Mishra, Ram. (2010). Health Information System in India: Issues of Data Availability and Quality. *Demography India*. 39. 111-128. Available at https://www.researchgate.net/publication/232084914_Health_Information_System_in_India_Issues_of_Data_Availability_and_Quality_1

²³ Pettus, Katherina. 2013. "Untreated pain in the lower and middle-income countries: GDPO Situation Analysis. Global Drug Policy Observatory. Available at <http://www.swansea.ac.uk/media/GDPO%20Situation%20Analysis%20Essential%20Med.pdf>, Accessed on 29/01/2017

²⁴ Rajagopal, M.R & Joranson, David E. 2007. "India: Opioid Availability – An Update." *Journal of Pain and Symptom Management*. Vol 33, pp. 615-622. Available at <http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/india07.pdf>

²⁵ Knaul, Felicia Marie, Paul E Farmer, Eric L Krakauer et al. "Alleviating the access abyss in palliative care and pain relief—an imperative of universal health coverage: the Lancet Commission report" *The Lancet Commissions*. Published October 12, 2017. P. 35. [http://dx.doi.org/10.1016/S0140-6736\(17\)32513-8](http://dx.doi.org/10.1016/S0140-6736(17)32513-8)

²⁶ Human Rights Watch. 2009. "Unbearable pain: India's obligation to ensure palliative care." Available at <https://www.hrw.org/report/2009/10/28/unbearable-pain/indias-obligation-ensure-palliative-care>

²⁷ Ministry of Health & Family Welfare. 2012. "Proposal Of Strategies For Palliative Care In India". Directorate General of Health Services, India.

the legislation has not yet been transposed to state level with large differences between states,²⁸ including in the prescription and use of opioid analgesics for the terminally-ill.²⁹

- Even if opioid analgesics are available, there is a problem of non-use by healthcare professionals. Associated with the strictly regulated environment on opioid medicines, health care professionals are not well trained in palliative medicine, and there are misconceptions about the use of morphine for pain treatment. Healthcare professionals in India have reported not being versed in palliative care, not knowing how to administer morphine (dosage), and they have misconceptions about use of morphine, including fear of patient addiction and ineffectiveness in pain management.³⁰
- The state of Kerala stands out as an example of achieving a good level of access to essential medical opioids in contrast to other states in India's federal system. The influence of national institutions such as the Pain and Palliative Care Society and the Indian Association of Palliative Care led to the creation of Pallium India in Kerala in 2003.³¹ It supported regulatory and policy changes for increasing access to effective pain relief for the terminally-ill³² for example through proposing a state-level palliative care policy in 2005,³³ and by submitting a petition in 2007 before the Supreme Court of India.³⁴ Advocacy efforts coupled the engagement of local media for awareness-raising and sensitization.³⁵ As a result, Kerala saw the introduction of community-based palliative care services such as 'Neighbourhood Network in Palliative Care' covering nearly 12 million people.³⁶ By 2012, 841 centres for palliative care were found in Kerala from a total of approximately 908 in the whole territory of India.³⁷ Today more than 75% of the palliative care centres found in India are in Kerala.³⁸ In addition to the active participation of local communities and civil society, the enabling policy and political environment in the Communist-led coalition government of the state of Kerala was instrumental for allowing these initiatives to be implemented in practice.

²⁸ Rajagopal, M. 2016. "Access to palliative care: insights into ground realities post-2014 amendment to NDPS Act. *Indian Journal of Medical Ethics*. 2016. Jan-Mar; NS1(1): 25-30

²⁹ Cleary, J. & Simha N. et. al. 2013. "Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in India: a report from the Global Opioid Policy Initiative (GOPI)." *Annals of Oncology*. Vol. 24, issue 11. Available at https://academic.oup.com/annonc/article/24/suppl_11/xi24/214976/Formulary-availability-and-regulatory-barriers-to

³⁰ LeBaron, V., S. L. Beck, M. Maurer, F. Black, and G. Palat. 2014. "An Ethnographic Study Of Barriers To Cancer Pain Management And Opioid Availability In India". *The Oncologist* 19 (5): 515-522. P 518 doi:10.1634/theoncologist.2013-0435.; "Palliative Patients Need Special Care". 2018. *The Hindu*. <http://www.thehindu.com/news/cities/Visakhapatnam/palliative-patients-need-special-care/article22199896.ece>.

³¹ Rajagopal MR. Access to palliative care: insights into ground realities post-2014 amendment to NDPS Act. *Indian J Med Ethics*. 2016 Jan-Mar; NS1(1): 25-30.

³² Rajagopal MR, Joranson DE. India: Opioid availability - An update. *J Pain Symptom Manage*. 2007;33:615-622

³³ Rajagopal, M. R. 2015. "The Current Status Of Palliative Care In India". *Cancercontrol.Info*. <http://www.cancercontrol.info/wp-content/uploads/2015/07/57-62-MR-Rajagopal-.pdf>.

³⁴ Rajagopal MR. Access to palliative care: insights into ground realities post-2014 amendment to NDPS Act. *Indian J Med Ethics*. 2016 Jan-Mar; NS1(1): 25-30.

³⁵ Nair, M. Krishnan. 2018. "50 Years Of Cancer Control In Kerala, India". <https://pdfs.semanticscholar.org/a1b8/8c6947621894514d1999b182d972cc69390e.pdf>.

³⁶ Kumar, Suresh K. 2007. "Kerala, India: A Regional Community-Based Palliative Care Model". *Journal Of Pain And Symptom Management* 33 (5): 623-627. doi:10.1016/j.jpainsymman.2007.02.005.

³⁷ Ministry of Health & Family Welfare. 2012. "Proposal Of Strategies For Palliative Care In India". Directorate General of Health Services, India.

³⁸ Cleary, J., N. Simha, A. Panieri, W. Scholten, L. Radbruch, J. Torode, and N. I. Cherny. 2013. "Formulary Availability And Regulatory Barriers To Accessibility Of Opioids For Cancer Pain In India: A Report From The Global Opioid Policy Initiative (GOPI)". *Annals Of Oncology* 24 (suppl 11): xi33-xi40. doi:10.1093/annonc/mdt501.

What's Next?

India has shown that there is an open window in which big changes can eventually be achieved. It is well known and reported that in the state of Kerala, palliative care is integrated in the state's healthcare system with community participation³⁹ and there are plans to extend to all community centres.⁴⁰ Civil society has also played an important role in advancing this agenda. Organizations such as the Pain and Palliative Care Society, the Indian Association of Palliative Care and Pallium India advocated for expanding palliative care services and legislative changes.

Kerala is a proof of success and demonstrates that palliative medicine can be feasible if there is community and authority involvement. The successful state-level healthcare policy should be transferred across India. Access to opioids medicines should not be regulated from a criminal-enforcement policy perspective, and it urgently needs to be addressed as a public health issue.

³⁹ Bollini, P., Venkateswaran C & Sureshkumar, K. 2004. "Palliative Care in Kerala, India: A Model for Resource-Poor." *Onkologie* 2004;27:138-142.

⁴⁰ The Hindu. 2017. "Palliative care services in Kerala CHCs soon." Available at <http://www.thehindu.com/news/cities/Thiruvananthapuram/palliative-care-services-in-chcs-soon/article19983873.ece>, Accessed on 30/01/2018

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