Access to pain relief and essential opioids in the WHO South-East Asia Region: challenges in implementing drug reforms

Nandini Vallath¹, MR Rajagopal², Suraj Perera³, Farzana Khan⁴, Bishnu Dutta Paudel⁵, Klara Tisocki⁶

¹Tata Trusts, Maharashtra, India, ²Trivandum Institute of Palliative Sciences, Thiruvananthapuram, India, ³National Cancer Control Programme, Ministry of Health, Colombo, Sri Lanka, ⁴Centre for Palliative Care, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, ⁵National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal, ⁶World Health Organization Regional Office for South-East Asia, New Delhi, India

Correspondence to: Dr Nandini Vallath (aanandini@gmail.com)

Abstract

It is a justifiable assumption that more than 15 million people in the World Health Organization South-East Asia Region are experiencing serious health-related suffering, much of it caused by persistent, severe pain. Despite this burden of suffering, overall access to pain relief and palliative care services is abysmal. The lack of access to controlled drugs for pain management is striking: the average morphine equivalence in the region in 2015 was just 1.7 mg per capita, while the global average was 61.5 mg per capita. Until recently, implementation of national legislation to facilitate medical and scientific use of opioids has proven to be very complex and difficult to achieve. The effects on the region of the exploitative British opium trade in previous centuries prompted countries to adopt draconian legislation on opioids, focused on restricting illicit use. In India, the Narcotic Drugs and Psychotropic Substances Act of 1985, for example, stipulated harsh custodial sentences for even minor clerical errors in hospitals stocking opioids. Decades of persistent efforts by civil society resulted in the landmark amendment of the Act in 2014 to improve medical access, but implementation remains highly protracted. Although some progress has been made in recent years in Bangladesh, India, Nepal, Sri Lanka and Thailand, pain is a symptom that is grossly undertreated in most parts of the region. On both human rights and public health grounds, there is an urgent need for well-formulated drug policies to increase access to opioid medications, coupled with capacity-building and comprehensive public health systems incorporating palliative care.

Keywords: essential opioids, legislation, opioid analgesics, pain, palliative care, South-East Asia

Background

The World Health Organization (WHO) South-East Asia Region is home to one quarter of the population of the world. Although the overall average lifespan in the region has increased, the last few decades have seen transitions in the patterns of morbidity.¹ While communicable diseases, including the chronic stages of HIV and tuberculosis, continue to challenge the region, there is an additional burden of noncommunicable diseases, with increasing prevalence of cancer, cardiovascular diseases, diabetes and stroke. This is attributed to factors such as changing lifestyles, increasing urbanization, changes in reproductive patterns and diet, obesity, and use of tobacco and alcohol. The escalation in the disease burden is projected to be highest in low- and middle-income countries, such as those of the WHO South-East Asia Region.² The cancer disease burden in the region is high, with 1.1 million cancer-related deaths and 1.7 million new cancer cases in 2012.³

Recognizing the global burden of chronic disease conditions, and, consequently, the role of pain relief and palliative care in alleviating suffering, WHO passed a landmark resolution during the 67th World Health Assembly in 2014.⁴ It recommended that all Member States should strengthen palliative care as a component of comprehensive care throughout the life-course, through integration within the public health-care system. Although the resolution suggested specific measures and strategies to implement the change, committed policies on, or investment in, developing palliative care in the WHO South-East Asia Region has been generally lacking.

In October 2017, The Lancet Commission on Global Access to Palliative Care and Pain Relief analysed the issue further and focused on “serious health-related suffering” as a real entity requiring global attention.⁵ The commission estimated that, in 2015, more than 61 million people experienced serious health-related suffering. Given that the population of the WHO South-East Asia Region is around one quarter of the global
Access to and availability of essential opioids in the WHO South-East Asia Region

Persistent, severe pain is one of the major causes of serious health-related suffering. In low-income countries, most patients with long term illnesses, such as cancer, present at advanced stages, with a high burden of suffering and severe pain. Opioids are included in the WHO model list of essential medicines for both adults and children, as they are safe and effective medications for relieving persistent severe pain.

Opioid analgesics are also controlled medicines. National governments report data on annual opioid consumption to the International Narcotics Control Board (INCB), an independent and quasi-judicial monitoring body for implementation of the United Nations international conventions on drug control. Consumption is not a measure of the amounts dispensed to or used by patients, but quantifies the amount of opioids distributed legally in a country for medical and scientific purposes, to those health-care institutions and programmes that are licensed to dispense to patients, such as hospitals, nursing homes, pharmacies, hospices and palliative care programmes.

The annual opioid consumption per capita of a country has emerged as an indicator of the national capacity for commitment to providing pain relief. As pain management is a critical component of quality care, the data on opioid consumption serve as a surrogate indicator of countries’ provision of palliative care.

Since 1996, the University of Wisconsin School of Medicine and Public Health, United States of America, has housed the WHO Collaborating Centre, the Pain and Policy Studies Group (PPSG). Using the annual INCB data, and applying conversion factors from the WHO Collaborating Centre for Drug Statistics and Methodology, PPSG developed a morphine equivalence (ME) metric, adjusted for population, for six principal opioids used to treat moderate to severe pain: fentanyl, hydromorphone, methadone, morphine, oxycodone and pethidine. The ME of a country is therefore more reflective of its capacity to treat pain than its morphine consumption alone, and allows comparisons among countries.

The ME consumption for the WHO South-East Asia Region in 2015 was around 1.7 mg per capita; this was one hundredth of the average ME consumption in the WHO European Region of around 170 mg ME per capita. Furthermore, the average ME in the region without methadone, which is used for opioid agonist therapy, is even more alarming, at around 0.55 mg per capita in 2015. In all instances, the ME data in this article may be seen as an overestimation of the capacity of countries for pain relief, since it includes figures for methadone, which is used for opioid agonist therapy rather than pain relief. Human Rights Watch, an international nongovernmental organization, combined the INCB data with modified epidemiological factors in the region influencing the medical need for opioid analgesics. Their report categorized many of the countries of the WHO South-East Asia Region as having a severe shortage of opioid analgesics, with very few people having access to adequate pain relief. The countries in the region with better metrics for 2015, namely Sri Lanka and Thailand at 1.21 mg and 5.85 mg per capita respectively, are still very significantly below the global average of 61.5 mg per capita.

An alternative metric is the adequate consumption measure (ACM). This method calculates the gap of the unmet need for opioid analgesia. It assumes that the mean per capita opioid consumption of the top 20 countries of the Human Development Index represents an “adequate consumption level”. The ACM is the actual consumption expressed as a percentage of the adequate consumption level. Based on 2010 data, India consumed 0.22% of what would be considered adequate. Even in the state of Kerala, which stands out as the most progressive state for palliative care in India, with more than 170 dispensing units for oral morphine, has a morphine consumption far below the global average.

Contributors to poor access to and availability of opioids for medical use

Several factors have contributed to the poor availability of opioids for medical use in the WHO South-East Asia Region, not least the historical context. Historically, opium has been a trade crop in the region, and a drug of abuse. For over a century, the region was exploited by the British for the production, consumption or commercial passage of opium. India was a major producer under the British rule. Several other present-day countries of the region – Myanmar, Thailand and parts of Bangladesh – were part of the iniquitous golden triangle, an area implicated in the illicit historical trade. The region witnessed two opium wars in the 19th century, initiated by China against Britain, to put an end to the enforced trade by the British, when the proportion of young addicts in the country had risen to alarming levels. A civilized closure to the conflicts was achieved in the 20th century, through United Nations treaties and declarations.
The United Nations Single Convention on Narcotic Drugs in 1961 had the dual purpose of ensuring that the production, cultivation and trade of controlled substances including opioids was for medical and scientific use only, while their diversion and misuse were prevented. All countries that were signatories to the Single Convention were obliged to ensure balance within their own national narcotic policies. However, owing to the traumatic past, the countries from the WHO South-East Asia Region interpreted the mandates of the Single Convention more in terms of restricting illicit use, and developed intensely prohibitory national policies.

Despite the changing global perspectives and scientific evidence to support safe medical use of opioids, implementation of national legislation to facilitate medical and scientific use of opioids has proven to be very complex and difficult to achieve. The complexities of implementing regulatory reforms are illustrated next, using the example of India.

India’s National Drug and Psychotropic Substances (NDPS) Act of 1985

The National Drug and Psychotropic Substances (NDPS) Act of 1985 governs the access to and availability of opioid analgesics in India. It is heavily prohibitory in nature.

The important barriers came to light when a team that was commissioned by the WHO cancer unit in the mid-1990s conducted a study of the poor access to and availability of opioids in India – the country that produced most of the opium substrate for rest of the world. This team unearthed the restrictive clauses in the country’s drug policy, as well as its long-term consequences. They linked the issue of poor treatment of cancer pain in India with the multiple and complex licensing requirements stipulated under the NDPS Act and rules mandated for stocking and dispensing them in medical institutions.

The NDPS Act of 1985 had retained components of the 19th century British opium law, which was specially designed to ensure the Empire’s monopoly on opium trade in the region, by levying taxes and imposing licensing for every movement of opium across its administrative boundaries.

By retaining similar licensure procedures, the NDPS Act obliged medical institutions that needed to stock opioids to maintain import, export and transport licences, to be obtained from different government agencies – such as excise, revenue, health and others, for each of the states involved in transport and transit of the consignment.

The task of maintaining the validity of multiple licences, and the complexity of procedures stipulated by the law, discouraged most hospitals from stocking opioid medications. Further, the punishments were disproportionate, with rigorous imprisonment for even minor errors. The poor supply of opioid formulations in medical institutions affected the exposure and training of health-care professionals, who had no chance to experience the use of opioids for treating persistent pain. As such, generations of doctors qualified from medical school without having had any exposure to assessing chronic persistent pain, or in using opioids. The fear of causing addiction and respiratory depression overridden clinical judgement, when faced with severe pain requiring use of oral opioid formulations. The propagation of these drugs by the popular media as substances of abuse fostered the fears and misconceptions further. The overall lack of awareness about medical use of opioids led to opiophobia and resulted in very low demand for opioids as prescription medicines.

The lack of knowledge and experience to assess and treat pain gradually transformed into apathy towards evaluating and responding to persisting pain. Pain became a grossly underestimated, undertreated symptom. A study in 2012–2013 on the predictors and prevalence of pain and its management in four major cancer hospitals of India found that the presence or severity of pain were not parameters that were routinely assessed, documented or managed, even in tertiary cancer-care settings. The study surveyed 1600 patients waiting to see oncology consultants and found that nearly 9 out of 10 patients (88%) reported pain. At the end of their consultation, two thirds (67%) of these patients received no analgesics or were given inadequate medications. Ironically, opioids have been included in India’s National list of essential medicines since 2003.

The policy has changed – but implementation lags behind

Significant changes in recent years, which sought to redress the dysfunctional demand–supply framework for essential opioids described, have influenced the drug policies of the region. PPSG has provided the model, resources and technical assistance to countries that sought support to analyse and amend their legislation to facilitate access to and availability of opioids. Working with PPSG, several countries in the WHO South-East Asia Region have identified the negative influence of draconian regulations on the availability of essential opioids. Many are in the process of modifying or implementing new policies in line with the international mandates to ensure balance, for improving access to and availability of opioids for medical use, while preventing non-medical use.

In India, concerted efforts by civil society over two decades led to parliamentary amendment of the NDPS Act of 1985 in February 2014. The amended Act expanded the scope of the law and incorporated an additional mandate – that of improving access to and availability of opioids for medical and scientific use. This was a landmark achievement. As per the new law, procedural rules were made uniform and standardized across the country, as the federal government took control of the opioid medicines that it designated as “essential narcotic drugs”. The state drug controller became the single agency at the state level authorized to designate the status of recognized medical institution (RMI). The RMI status is for a period of 3 years and gives the designated institution the authority to stock and dispense essential narcotic drugs in alignment with the central government regulations, without need for any additional licences. In order to ensure development of capacity for safe and appropriate utilization of essential narcotic drugs, a RMI is required to have at least one doctor trained in the medical use of opioids.

However, in the 4 years that have elapsed since the amendment, the law is yet to be implemented in full in India’s 29 states and 6 union territories. Opioid availability in India remains abysmal, and awareness about chronic persistent pain, its presentations and management using opioids remains
very poor among medical professionals. The punitive clauses in the law, meant for illicit users, apply in equal measure to licit prescribers, users, dealers and recognized medical institutions. Punishment continues to be disproportionate in relation to error.

**What can help improve the safe access to and availability of opioids in India?**

This section considers possible strategies to ensure safe access to and availability of opioid medications in India, based on the barriers described.

**Changes needed at governance level**

In India, and in most countries of the WHO South-East Asia Region, the controls for illicit usage and the new regulations on medical use are under the single central government agency. For decades, the conventional mandates of these offices have been to prevent illicit use and are therefore strongly prohibitive in nature. It may be difficult for this machinery to internalize and incorporate a new purpose and translate the intentions of the amendment for improving availability for medical use. Hence, acknowledging the need for a “licit entity” for governing opioids for medical use is a primary strategy that is necessary to support the implementation of the expanded scope of the reformed law. Creation of a distinct governance system under this entity, with the specific mandate to govern and specific measures to facilitate safe medical and scientific use of opioids, is critical. This would not only streamline implementation, but could also tackle the apathy and barriers that are prevalent at the highest level.

**Changes needed at the executive level**

As per the current law, the state drug controller is responsible for execution of the mandate of the amended federal law. However, officers of most states are unfamiliar with the new mandate. Official orders, through proper channels and unambiguous information on standard operating procedures, with printed manuals for clarity, would help them fulfil their mandate. The officers may also fear that implementation of the new law allowing easier access could trigger an epidemic of diversion of medical opioids to non-medical and inappropriate use. This fear is justifiably high amongst officials in regions where there is an existing problem of drug abuse. This concern of officers is valid and needs to be acknowledged and addressed effectively and creatively. Facilitation of an interagency collaborative action would be essential at executive level, involving revenue intelligence, surveillance agencies and quality technologies. Such a collaborative venture could aim at developing strategies to monitor the supply chain, as well as to track the prescribers, dispensing units and users. If such a strategy were to become active, the total opioid consumption of each region, and the patterns of licit usage, could be accurately recorded, thus addressing the balancing measure, that of preventing misuse and diversion.

**Changes needed at the institutional, practitioner and patient levels**

The stakeholders in the context of opioid regulations at this level include: (i) medical institutions that have to stock and dispense the medicines according to the rules; (ii) professionals who would prescribe and administer opioids to patients for medical use; and (iii) the patients who need to use the drugs to relieve their pain.

**Institutions**

Medical institutions in the country that stock opioids are largely unaware of the changed procedures for procuring, stocking and dispensing opioids as per the amended regulations. Despite a declaration of new national rules for essential narcotic drugs in 2015, most institutions continue to procure opioid medications using procedures and licences as per the nullified, old state-level regulations. Worse still, state agencies such as excise departments continue to participate, despite no longer having the authority. Medical institutions need to be made aware of the change in procedures for stocking and dispensing opioids and the steps required to be authorized as RMIs, as per the 2014 amendment. Also, the state departments, such as excise, that are no longer part of the RMI procedure, need to be made aware of the new authority as per the amended law, namely the office of the state drug controller.

**Professionals and the public**

Bridge training programmes for medical professionals on the evaluation and management of pain, and on best practices for using opioids, would counteract negative attitudes and the tendency for opioiphobia. Prescribers should also be updated on the requirements for record-keeping stipulated by the regulations, such that essential narcotic drugs are prescribed appropriately and patients are managed safely. In addition, public advocacy on their right to access pain relief and on the safety and effectiveness of opioids in managing severe pain is essential. The safety and efficacy of these drugs would become more clearly evident to the public, once medical prescriptions on opioids become mainstreamed into clinical practice.

Civil society, which successfully achieved the landmark policy change, continues to be active in raising awareness of this important topic in many parts of India. It has succeeded in sensitizing several state governments through workshops on the need for improved access to opioids. The scene of access to pain relief and palliative care is changing in India – very gradually, but definitely. Resources have been developed for prescribers and to help medical institutions follow the new regulations on opioids for medical use.

**Lessons learnt from other countries in the region**

The country examples provided next stand testimony to the impact that concerted efforts at the national level can have on tackling poor access to pain relief.

**Thailand**

Pain relief and palliative care in Thailand has improved in recent years. In 2006, palliative care was included in the hospital accreditation standard of the Healthcare Accreditation Institute. In the same year, the Ministry of Public Health issued notification that allowed for a notable increase in the maximum amount of opioids available for hospitals. Policies implemented by the Thai Food and Drug Administration (FDA)
further facilitated improved opioid availability and lowered prices. Since 2009, the National Health Security Office has supported networking among palliative care services within hospitals and the communities they serve. Since 2010, the Government Pharmaceutical Organization has been able to produce immediate-release oral morphine tablets and the liquid formulation, both of which have been endorsed by the Thai FDA. There was a clear impact on the annual ME consumption, which rose from 3.96 mg per capita in 2010 to 5.85 mg per capita in 2015, the highest in the region. Although impressive, there is still a long way to go towards equitable levels of usage. The regulation of opioids in government hospitals is mainly dependent on physician judgement, and pain remains under-assessed and undertreated in the majority of cancer patients, even in tertiary care services.23

Sri Lanka

Sri Lanka has demonstrated the impact of concerted programmes in activating the human welfare element of the opioid law.24 Morphone is available in all 25 districts, at teaching hospitals, provincial general hospitals, district general hospitals and base hospitals, but the drug is prescribed mainly by cancer units – at 9 provincial units and 11 district units. There is a policy for community-based hospices to access morphine from the adjacent cancer centres. The State Pharmaceutical Corporation, a parastatal organization accountable to government, runs pharmaceutical retail shops – Raja Osu Sala – and the government allows these retail shops to stock morphine. There is additional provision for general practitioners to dispense morphine for their palliative care patients, through a special allocation from the Medical Supplies Division. From an annual ME consumption of zero in 1988, the gradual improvement to the modest but significant figure of 1.21 mg per capita in 2015 may be attributed to the efforts put in by the government of Sri Lanka in building capacity in the field of palliative care. Examples include a policy of mandatory proactive assessment of patients presenting at clinics or hospitals with moderate-to-severe pain; development and dissemination of pain management guidelines; and establishment of dedicated pain management clinics at the National Hospital of Sri Lanka and National Cancer Institute Maharagama.

Bangladesh

In Bangladesh, after much effort, opioid availability has improved in regions in and around the capital city. Eight medical institutions and four pharmacies in Dhaka currently have licences to dispense oral morphine. The Centre for Palliative Care, Bangabandhu Sheikh Mujib Medical University, in the capital city, is the largest prescriber of morphine for cancer patients in the country. Opiophobia among both medical professionals and the public is still a major barrier to access.25

Nepal

Combined efforts by the Nepalese Government and civil society have improved the situation in recent years. A significant barrier to reliable access to opioids in Nepal was overcome in 2009, when a licence was issued for a Nepalese company to manufacture morphine.26 There is a marginal but definite improvement in the ME consumption in Nepal, which in 2015 was 0.27 mg per capita. In 2017, Nepal adopted a National Strategy for Palliative Care, to guide the development of palliative care
countrywide over the next decade, and its integration into the health system.27 Further work is needed, however, to educate physicians and improve attitudes and knowledge on opioids among health professionals, policy-makers and the public.28

Conclusion

Caring for patients with serious health-related suffering related to chronic conditions is not fully represented within the public health-care models prevalent in the WHO South-East Asia Region, and the majority of the professional community continues to be oblivious to the constituents, scope and benefits of palliative care. Pain, a significant component of serious health-related suffering, is grossly undertreated in most countries of the region. The presence and severity of pain continues to be a parameter that is not routinely assessed, documented or responded to in conventional health-care settings in the region. Patients and their families are affected physically, psychosocially and economically by this avoidable health-related suffering. The needs for pain relief and palliative care remain critically high.

In 2011, WHO noted that, despite 50 years of the United Nations Single Convention on Narcotic Drugs, the obligation to ensure adequate availability of these drugs for medical and scientific purposes has been neglected and countries have adopted laws and regulations that consistently and severely impede the accessibility of controlled medicines.29 A review of the evidence by the Johns Hopkins–Lancet Commission in 2016 highlighted the wide range of impediments to access to and use of controlled drugs as a result of drug-control policy and regulations.30 The commission recommends ensuring “access to controlled medicines, establishing inter-sectoral national authorities to determine levels of need and giving WHO the resources to assist the INCB in using the best science to determine the level of need for controlled medicines in all countries”.30 It has called for drug law reforms centred on health and human welfare.

A well-formulated drug policy can positively influence the access to and availability of opioid medications to treat severe persistent pain. This aspect is especially critical for the WHO South-East Asia Region, although the complexities of implementation in each country may differ. Once this is coupled with capacity-building and a comprehensive palliative care policy in line with the WHO recommendations, the region may look forward to a reduction in its current levels of serious health-related suffering, which at present are unacceptably high.

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