# Access to controlled medicines for pain management in the WHO South-East Asia Region



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# **Background**

Every year, more than 61 million people across the world experience about six billion days of serious health-related suffering (SHS) that could be alleviated with access to palliative care and pain relief.<sup>1</sup> The SHS burden is expected to double by 2060, with the fastest spikes occurring in low-income countries.<sup>2</sup> SHS is greatly exacerbated by lack of access to pain relief.

Palliative care is limited or non-existent in most parts of the world. The access gap is so wide that 50% of the world populations live in countries that receive only 1% of the opioid analgesics distributed worldwide.<sup>3</sup> A World Health Organization (WHO) study in 2015 estimated that the average morphine equivalence, which is a proxy indicator of the palliative care provision of a country, was only 1.7 mg per capita in Asia, compared with the global average of 61.5 mg per capita. It pegged the per capita consumption of morphine in Asia at 36 times lower than the global average.<sup>4</sup>

The Single Convention on Narcotic Drugs of 1961 (Amended by the 1972 Protocol) places on Member States the dual obligation of preventing non-medical use of controlled substances and ensuring adequate availability of controlled substances for medical and scientific purposes.

The Special Session of the United Nations General Assembly convened on the international drug problem in 2016 acknowledged that the availability of internationally controlled opioids for medical and scientific purposes, including for relief of pain and suffering, remains from low or non-existent, especially in low- and middle-income countries (LMICs).

The 2017 report of the Lancet Commission on Palliative Care and Pain Relief Study Group<sup>1</sup> called this low availability a "medical, public health, and moral failing, and a travesty of justice". An estimated 15 million people in South and South-East Asia continue to experience severe, persistent pain and suffering.<sup>5</sup>

<sup>1</sup> Knaul FM, Farmer PE, Krakauer EL, De Lima L, Bhadelia A, Jiang Kwete X et al. Lancet Commission on Palliative Care and Pain Relief Study Group. Alleviating the access abyss in palliative care and pain relief – an imperative of universal health coverage: the Lancet Commission report. *Lancet*, 2017, 391(10128):1391–454. doi:10.1016/S0140-6736(17)32513-8.

<sup>2</sup> Sleeman KE, Brito M, Etkind S, Nkhoma K, Guo P et.al. The escalating global burden of serious health-related suffering: projections to 2060 by world regions, age groups, and health conditions. The Lance Global Health. *Lancet*, 2019, 7(7): e883-892, https://doi.org/10.1016/S2214-109X(19)30172-X.

<sup>3</sup> Bhadelia A, De Lima L, Arreola-Ornelas H, Jiang Kwete X, Rodriguez NM, Knaul FN. Solving the global crisis in access to pain relief: lessons from country actions, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6301382/pdf/AJPH.2018.304769. pdf.

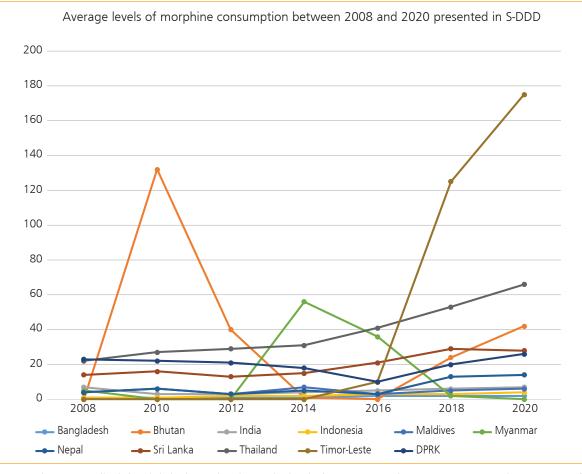
<sup>4</sup> United Nations. Report of the international narcotics control board for 2018. New York, 2018, https://www.incb.org/documents/Publications/AnnualReports/AR2018/Annual\_Report/Annual\_Report\_2018\_E\_.pdf- accessed 25 June 2019.

Vallath N, Rajagopal MR, Perera S, Khan F, Paudel BD, Tisocki K. Access to pain relief and essential opioids in the WHO South-East Asia Region: challenges in implementing drug reforms. WHO South-East Asia J Public Health 2018,7:67-72.

Access to distributed opioids, measured in morphine consumption equivalence, compared with the need for palliative care shows considerable inequity across countries. WHO has committed to increasing the availability of oral morphine at facilities, providing palliative care, from 25% to 50%.<sup>6</sup> This demonstrates an increased attention to improving access to pain relief and palliative care.

Major access gaps continue to exist. This report provides a country-specific situational analysis of policies and programmes for improving access to quality, affordable controlled medicines for pain management in the WHO South-East (SE) Asia Region. The report highlights the current barriers and challenges to delivering palliative care services.

Fig. 1. Average Morphine consumption by countries in the South-East Asia Region



S-DDD is the statistically defined daily dose. This shows the level of average morphine consumption in the countries of the Region.

A regional survey was conducted in 2020–2021, using a set of indicators, including the current status of access to opioid analgesics, existing policies, social/cultural/professional attitudes, services in place and the readiness of the countries with regard to safe and rational use of opioid analgesics. It also

World Health Organization. Strengthening of palliative care as a component of comprehensive care throughout the life course. Geneva, 2014, http://apps.who.int/gb/ebwha/pdf\_files/WHA67/ A67\_R19-en.pdf, accessed 25 June 2019.

sought to collate information that can assist in facilitating better calibrated, smart regulatory systems and fit-for-purpose supply chains for access to controlled medicines in these countries.

The following themes emerged from countries, as per the study, with some exceptions:

**Gaps in policy implementation:** Major barriers to implementation include poor understanding of legislation, lack of dialogue between law enforcement and health-care providers, and inadequate sensitization and training with health-care workers.

Lack of integration with pre-service training at the national level: Palliative care is not part of the national medical curricula in most countries. However, India, Nepal and Sri Lanka have taken steps to integrate palliative care into the national medical curricula.

**Weak referral chains:** Most countries do not have structured referral systems for palliative care. Patients have a poor understanding of the palliative care referral system.

**Champion-driven successes rather than systemic facilitation:** The importance of champions among the health workforce, government officials or policy-makers, who understand the need for improved access to controlled medicines, has been a critical factor in improving access to opioid analgesics.

**Cultural beliefs:** There is an inherent belief that pain medication should be taken only in extreme cases. This behaviour continues even with serious illnesses, as some communities are not comfortable with accessing controlled medicines for palliative care.

**Inaccurate estimation of opioid analgesics that are required:** This results in a shortage of adequate opioid analgesics for pain relief in the country.

**Inequitable distribution across the country:** Availability of opioid analgesics, especially morphine, tends to be concentrated in big cities, usually the capital. Availability of opioid analgesics in urban centres is markedly better than that in rural areas.

**Preferential access to higher-cost formulations:** The choice of an opioid analysesic formulation is largely dependent on the preference of the health facility concerned. Public-sector hospitals tend to stock more affordable formulations whereas private-sector hospitals tend to stock more expensive ones.

Poor understanding of and/or prescription of opioid analgesics outside of oncology and anaesthesia departments at hospitals: In most places, opioid analgesics are the domain of oncology and surgery departments at hospitals and are considered to be of little or no use in other departments.

Association of dependence with overuse of opioid analgesics: There is less coverage and understanding of the current lack of access to controlled medicines for pain relief, compared with that accorded to issues around high instances of dependence in communities. The differences between non-medical use of narcotics that cause dependence and opioid analgesics that can be used safely for medical purposes are often not clearly defined.

Key recommendations to improve access to controlled medicines for pain management are:

- context-specific policy and regulations to ensure fit-for-purpose supply chains, along with measurable input, process and output indicators to monitor and evaluate these policies;
- better training and education programmes that are integrated with the national-level curricula, with a special mention of education for pharmacists for safe use of opioid analgesics; and
- strategic partnerships between the government, the private sector, civil society actors and faith-based organizations and campaigns to create a counternarrative to "opiophobia".

# **Country profiles**



# **Bangladesh**

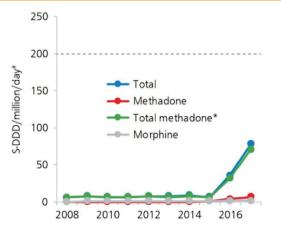
Population	Life expectancy	GDP/capita (US\$)
163.04 million	73 years	1855.77

# **Background**

- Sustained release oral morphine tablets became available in Bangladesh in 2006.<sup>2</sup>
- Sustained efforts by champions led to introduction of palliative care at the Bangabandhu Sheikh Mujib Medical University(BSMMU) in Dhaka in 2006–2007.
- Since then, Bangladesh has witnessed a slow change in the availability and use of opioid analgesics.
- Immediate release oral morphine became available in 2014 when a domestic pharmaceutical company began to manufacture 10-mg immediate release oral morphine tablets as well as morphine syrup.

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 0.439 mg/capita



\*S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

			Public sector		
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIC	OID ANALGESICS				
Morphine	Oral morphine (IR, SR and syrup)	*	✓	✓	<ul><li>Largely urban-centric</li><li>Narcotic licence required</li></ul>
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li><li>Fentanyl buccal tablets</li></ul>	*	×	✓	<ul><li>Urban-centric</li><li>Narcotic licence required</li></ul>
Pethidine	– Injectable	✓	✓	✓	Accessible
Methadone		×	*	*	Not available
STEP 2 OPIOID ANALGESICS					
Tramadol		✓	✓	✓	Accessible
Codeine		NA	NA	NA	Not available

- The Narcotics Control Act of 1990 was amended in 2002 to include stricter enforcement of drug-related violations.<sup>4</sup>
- The law was revised in 2018 to allow only physicians to prescribe opioid analgesics, with no allowance to reuse the same prescription.
- Furthermore, as per the revised law and regulations, special authorization (or licence) is no longer necessary for prescription of opioids.
- The National Guidelines for Palliative Care were published in 2018.

# Palliative care education and training

- Two MoUs were signed between 2009 and 2010 to support the Basic Certificate Course in Palliative Medicine (BCCPM) and the Basic Certificate Course in Palliative Nursing (BCCPN).<sup>3</sup>
- The impact created by these programmes led to the recognition of a five-year MD (residency course) programme in palliative medicine and an independent department of palliative medicine in BSMMU by 2016.
- Palliative training opportunities were offered to doctors and nurses in primary health care in 2022 through a programme initiated by the Prime Minister's Office.

### **Barriers to access**

- The idea that only people, who are terminally ill and have given up hope of survival, turn to palliative care is a deterrent to families and influences the referral system as well.
- While there is some level of availability of controlled medicines, most physicians prefer to not prescribe morphine.
- Lack of information and the well-intended decision of family members to prolong the patient's life through intensive care and/or other expensive and often futile interventions hinder access.
- Lack of knowledge and skill in pain assessment, unavailability of morphine and a fear of opioid dependence also act as barriers.
- A fear of drug dependence with regard to use of opioid analgesics has a detrimental effect on both prescriptive practices and patient uptake.
- Pharmacies without pharmacists are deterred by administrative barriers from stocking morphine.

- 1. International Narcotics Control Board. Narcotic drugs: estimated world requirements 2021, Statistics for 2019, Statistical information on narcotic drugs. *INCB Report 2021* (https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2020/Narcotic\_Drugs\_Technical\_publication\_2020.pdf).
- 2. Certain observation and recommendation on morphine pethidine injections and morphine tablets. Report of the Narcotic Department, Dhaka, Bangladesh, 23-1-08.
- 3. The questions have been taken from the World Map of Palliative Care Development (http://researchdata.gla.ac.uk/779/1/Questionnaire.pdf).
- 4. UN Office on Drugs and Crime. South Asia regional profile Bangladesh. *UNODC Country profiles 2015*, https://www.unodc.org/pdf/india/publications/south\_Asia\_Regional\_Profile\_Sept\_2005/08\_bangladesh.pdf.



# **Bhutan**

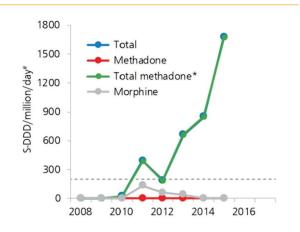
Population	Life expectancy	GDP/capita (US\$)
763 090	72 years	3316.2

# **Background**

- Palliative care services were started in 2016 by trained nurse educators from the Faculty of Nursing and Public Health, Khesar Gyalpo University.
- In 2020, the Ministry of Health launched a palliative care service package, integrating traditional medicinal practices into palliative care
- The focus of palliative care is largely on endof-life and cancer care.
- In addition, three beds were allocated for palliative care in the oncology ward of Jigme Dorji Wangchuk National Referral Hospital (JDWNRH).<sup>3</sup>

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 2.412 mg/capita<sup>2</sup>



"S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

	- 1 m	Public sector Priv		Private	
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIO	ID ANALGESICS				
Morphine	Oral morphine (IR and SR)	×	<b>✓</b>	<b>√</b>	– Access dependent on supply chain
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	×	✓	✓	– Urban-centric
Pethidine	– Injection	×	✓	$\checkmark$	Accessible
Methadone		×	×	×	
STEP 2 OPIO	ID ANALGESICS				
Tramadol	<ul><li>Injection</li><li>Tablet formulation not authorized for use</li></ul>	×	<b>√</b>	✓	Accessible
Codeine		NA	NA	NA	Not available

- Bhutan does not have a policy document, specific to palliative care. The Bhutan Cancer Control Strategy 2019-2025 highlighted the need for strengthening palliative care.<sup>5</sup>
- The Narcotic Drugs and Psychotropic Substances and Substance Abuse (NDPSSA) Act was enacted in 2005. A major amendment to the NDPSSA Act in 2015 added legal availability for 19 drugs and psychotropic substances with "medicinal value", categorized under Schedule IV of the Act.<sup>5</sup>

# Palliative care education and training

- In January 2019, the Asia-Pacific Hospice and Palliative Care Network (AHPN) conducted training of trainers at the Jigme Dorji Wangchuk National Referral Hospital (JDWNRH) in Thimphu.<sup>4</sup>
- The University of Bhutan introduced a module integrating palliative care into their traditional and allopathic medical courses in September 2021.
- Palliative care is yet to be integrated into nursing.

#### **Barriers to access**

- There are supply challenges as the country is heavily dependent on imported medicines.
   Delays in delivery of medicines affect availability.
- There are distribution challenges with regard to access to medicines in mountainous and difficult terrains.
- Health system acceptance of opioid analgesics is low. Apart from the national referral hospitals, most physicians across the country are not comfortable with prescribing opioid analgesics.
- Lack of knowledge and skill in pain assessment and a fear of opioid dependence on part of prescribers are leading to low acceptance of opioid analgesics.
- Substance abuse is a growing problem among the youth in the country. Families of patients are worried about dependency and are afraid of long-term use of opioid analgesics. A fear of drug dependence with regard to use of opioid analgesics has a detrimental effect on both prescriptive practices and patient uptake.

- 1. International Narcotics Control Board. *Narcotic Drugs-Technical Report*, http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Data from INCB report 2020 for data collected in 2019. Calculation by Pallium indiappsg ME calculation method using conversion factors devised by the WHO CC for Drugs Statistics Methodology, Oslo, Norway.
- 3. Laabar TD, Saunders C, Auret K et al. Palliative care needs among patients with advanced illnesses in Bhutan. BMC Palliat Care 20, 8 (2021), https://doi.org/10.1186/s12904-020-00697-9.
- 4. Lien Collaborative for Palliative Care Bhutan Module 2 of 6, Trip Report for 28 January to 2 February 2019.
- 5. Tshering Palden. Bhutan the laws and drugs. Kuensel Online 2019 (https://kuenselonline.com/the-laws-drugs/).



# India

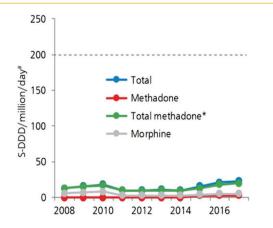
Population	Life expectancy	GDP/capita (US\$)
1360 million	70 years	2099.6

# **Background**

- The Indian Association of Palliative Care (IAPC) was formed on 16 March 1994 in consultation with WHO and the Government of India.<sup>3</sup>
- IAPC has been working as the national umbrella organization for palliative care in India since its inception.
- In March 2017, palliative care was included in the National Health Policy of India.

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 0.506 mg/capita<sup>2</sup>



\*S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

		Public	sector	Private	
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIO	ID ANALGESICS				
Morphine	<ul><li>Oral morphine (IR and SR)</li><li>Injectable</li></ul>	×	<b>√</b>	<b>√</b>	
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	*	✓	✓	- Better access in the private sector
Pethidine	– Injection	*	✓	$\checkmark$	Accessible
Methadone		×	$\checkmark$	$\checkmark$	
STEP 2 OPIO	ID ANALGESICS				
Tramadol	<ul><li>Injectable</li><li>Oral formulation</li></ul>	*	✓	✓	
Codeine		NA	NA	NA	Not available for use in pain management

- The Narcotic Drugs and Psychotropic Substances (NDPS) Act of 1985 prescribed a system of regulations. The Act, however, contains punitive action for errors in managing opioid analgesics.
- A category of Essential Narcotic Drugs (ENDs) was introduced. It includes codeine, fentanyl, hydrocodone, methadone and morphine.
- However, by 2021, not all states had implemented the NDPS amendments of 2014.

# Palliative care education and training

- A three-year postgraduate degree course (Doctor of Medicine, MD) in palliative medicine commenced in India in 2012.
- In March 2019, the Medical Council of India included pain management, end-of-life care and AETCOM (attitude, ethics and communication) in its undergraduate medical curriculum.
- There are, currently, five centres that offer the MD programme and another five have received approval for Diplomate in National Board (DNB) for palliative care.<sup>4</sup>

#### **Barriers to access**

- There is inadequate awareness about the facilitatory aspects of the NDPS amendments of 2014 among state governments as well as health-care providers.
- The inherent fear of punitive action for minor clerical errors in management of opioid analgesics has resulted in pervasive "opiophobia".
- The misconceptions that palliative care is only for terminally ill cancer patients, that morphine is only to be used at the end of life and that use of morphine hastens death, and palliative care and treatments aimed at cure cannot go hand in hand.
- Referrals to palliative care services and medical teams remain relatively low.
- Not all pharmacies are run by pharmacists. They are driven by retail decisions and are deterred by administrative barriers from stocking morphine.

### References

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*, http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Data from INCB report 2020 for data collected in 2019. Calculation by Pallium indiappsg ME calculation method using conversion factors devised by the WHO CC for Drugs Statistics Methodology, Oslo, Norway.
- 3. https://www.palliativecare.in/about-iapc/
- 4. Kiss-Lane T, Spruijt O, Day T, Lam V, Ramchandran KJ, Chan S, et al. Palliative care clinicians and online education in India: A survey. BMJ Support Palliat Care. 2019, 9:e35 (https://pubmed.ncbi.nlm.nih.gov/30301753/).

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# <u>Indonesia</u>

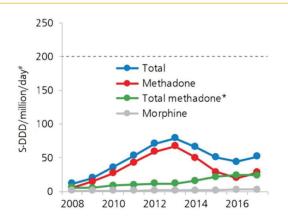
Population	Life expectancy	GDP/capita (US\$)
270.62 million	72 years	4135.6

# **Background**

- The not-for profit organization Cancer Society has been one of the pioneers in palliative care since the 1990s, when they established home care.
- Surabaya has emerged as a palliative care focal point and there are efforts to expand palliative care to other regions, including Bandung in the West Java and Bali.
- However, services are largely centred around hospitals.<sup>2</sup>

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 1.337 mg/capita



"S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

		Public sector Private	Private		
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIC	OID ANALGESICS				
Morphine	<ul><li>Oral Morphine (IR and SR)</li><li>Injectable</li></ul>	*	✓	✓	
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	*	✓	✓	
Pethidine	– Injectable	×	✓	✓	Accessible
Methadone		<b>√</b>	✓	✓	Methadone is not used for pain relief at hospitals, primarily used for managing drug dependency
STEP 2 OPIC	OID ANALGESICS				
Tramadol		×	✓	✓	Accessible
Codeine	– Oral	✓	✓	✓	

- The country had announced a national policy for palliative care in 2007. But it has not been fully implemented to date.
- The law lays down strict penalties for possession and trafficking of narcotic drugs. There is no clear distinction between a user and a trafficker.
- All opioids, including those for medical purposes, are regulated by the National Narcotics Agency (BNN) under the national formulary.<sup>5</sup>

# Palliative care education and training

- Currently, a few physicians are certified in palliative care. The Faculty of Medicine at Universitas Airlangga in Surabaya is currently working to establish a specialist programme for palliative medicine to produce more palliative care experts. The university currently offers palliative care as an elective to its medical doctor programme.<sup>3</sup>
- In nursing education, palliative care has been incorporated in undergraduate curricula since 2017.4

### **Barriers to access**

- Both medical professionals and patients are not comfortable with prescription and use of morphine. Some physicians are worried that patients, who receive morphine, are not adequately monitored. They may experience side-effects, such as respiratory depression, or develop dependence.
- Thanks to the stringent stance of the country on drug control, with such punitive measures as the death penalty in the amended Criminal Code, controlled medicines are difficult to access in the country.
- Unavailability of palliative care modules in medical curricula has become a major challenge.
   A lack of knowledge and skill in pain assessment and the belief that palliative care is an option only when active treatment is no longer continued are also hindrances.
- The existence of many isolated islands in the country, coupled with multiplicity of departments and ministries involved in the supply of opioid analgesics, has a detrimental effect on use of opioid analgesics for pain relief.

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Pongparadee Chaudakshetrin, Mary Suma Cardosa, Cynthia Ruth Goh. Establishment of multidisciplinary pain management clinics and training programmes in the developing world: experiences from South-East Asia. Biennial Review of Pain. September 2020.
- 3. Dlah Martina. Revisiting palliative care in Indonesia: How far are we? American Society of Clinical Oncology, 2017, (https://connection.asco.org/magazine/asco-international/revisiting-palliative-care-indonesia-how-far-are-we.
- 4. Curriculum Medical Doctor Programme 2016. Clinical Posting I Curriculum. Universitas Airlangga, https://profesi.dokter.fk.unair.ac.id/en/education/curriculum.
- 5. Muhamad Romdoni. Overview on the role of national anti-narcotics agency and the constraints of law enforcement based on Criminal Law Number 35 of 2009 on Narcotics. *International Journal of Scientific and Technology Research*, 2019, http://www.ijstr.org/final-print/nov2019/Overview-On-The-Role-Of-National-Anti-narcotics-Agency-And-The-Constraints-Of-Law-Enforcement-Based-On-Criminal-Law-Number-35-Of-2009-On-Narcotics.pdf.



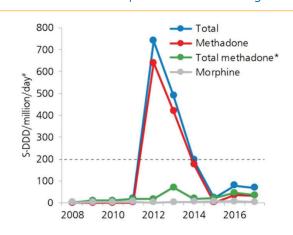
# **Maldives**

Population	Life expectancy	GDP/capita (US\$)
530 950	79 years	10 626.5

# **Background**

No information provided

# Levels of consumption of narcotic drugs<sup>1</sup>



"S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

		Public sector		Private	
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIC	OID ANALGESICS				
Morphine	Oral Morphine (IR and SR)				
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li><li>Fentanyl buccal tablets found in very limited quantities</li></ul>				
Pethidine					
Methadone					
STEP 2 OPIOID ANALGESICS					
Tramadol					
Codeine					

Legislation and policy	Palliative care education and training
• The Maldives Food and Drug Administration (MFDA) under the Ministry of Health approves a list of controlled substances to be imported. The State Trading Organization (STO) has the sole right to import the controlled medicines on the list. <sup>3</sup>	No official training is available in the country. Doctors and nurses, who are trained in palliative care, have all received their training from other countries. <sup>2</sup>
<ul> <li>Pharmacies that have received approval from MFDA can procure these medicines directly from STO.<sup>3</sup></li> </ul>	

# **Barriers to access**

Not provided

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Bee Wee, Nic Hughes. Education in palliative care: building a culture of learning. Oxford University Press.
- 3. UN Office on Drugs and Crime. Misuse of prescription drugs: a South Asia perspective. *UNODC Report* 2011, https://www.unodc.org/documents/southasia/reports/Misuse\_of\_Prescription\_Drugs\_-\_A\_South\_Asia\_Perspective\_UNODC\_2011.pdf.



# Myanmar

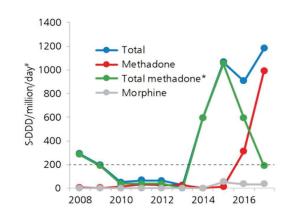
Population	Life expectancy	GDP/capita (US\$)
54.04 million	67 years	1407.80

# **Background**

No information available

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 17.343 mg/capita



"\$-DDD; Statistical defined daily dose/million/day; "Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

# Availability and accessibility – information not provided

Bar distant	F	Public	sector	Private	A
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIO	OID ANALGESICS				
Morphine	– Injectable				
Fentanyl	- Fentanyl injections				
	– Fentanyl patches				
Pethidine					
Methadone					
STEP 2 OPIO	OID ANALGESICS				
Tramadol	- Oral formulation				
	– Injectable				
Codeine	– Oral formulation				

LAMIC	Intion	and	nal	ICV
LEUIS	lation	anu	DOI:	ILV

- The 1993 Narcotic Drugs and Psychotropic Substances Law and the 1995 Rules to the law remain in force, with a restrictive nature, which also includes rehabilitative intent.<sup>4</sup>
- Apart from their inclusion in the National Essential Medicines List, controlled medicines are still subject to the restrictive drug policies of the country.<sup>4</sup>

### Palliative care education and training

- There are a few physicians in Myanmar, who are trained in palliative care, and localorganizations are attempting to address knowledge gaps.<sup>2</sup>
- The Asia-Pacific Hospice Palliative Care Network (AHPN) and the LIEN Foundation in Singapore are building educational programmes in the country and have trained 28 providers from Myanmar through a partnership with the Myanmar Medical Association.<sup>3</sup>

#### **Barriers to access**

- Myanmar does not have any national policy or programme, dedicated specifically to palliative care. However, palliative care has been integrated in cancer treatment and pain management at tertiary-level health care in the country.
- Myanmar has a limited number of well-trained palliative care medical professionals, whose services are still not able to meet the rising needs of the population.
- Training in palliative care is still subject to external assistance and the non-profit sector.
- There is a general lack of access to medication, due to inadequate supply and unaffordable cost.

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- Earl-Royal E, Feltes M, Gisondi MA et al. Physicians in Myanmar provide palliative care despite limited training and low confidence in their abilities. Palliative Medicine Reports. December 2020, 314-320, http://doi.org/10.1089/ pmr.2020.0090.
- 3. What does the project entail? Asia-Pacific hospice palliative care network: LIEN collaborative, http://aphn.org/lien-collaborative-for-palliative-care/what-does-the-project-entail/.
- 4. UN Office on Drugs and Crime. South Asia Regional Profile Myanmar. *UNODC Country Profiles* 2015, https://www.unodc.org/pdf/india/publications/south\_Asia\_Regional\_Profile\_Sept\_2005/11\_maldives.pdf.



# Nepal

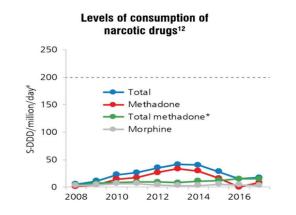
Population	Life expectancy	GDP/capita (US\$)
28.6 million	71 years	1071.1

# **Background**

- B.P. Koirala Memorial Cancer Hospital (BPKMCH), Bharatpur, the first cancer hospital in Nepal, was established in 1992 and palliative care services were made available.
- Palliative care was carried out in silos in the country until 2009, when the Nepalese Association of PalliativeCare (NAPCare) was created as an umbrella organization for palliative care.<sup>2</sup>
- NAPCare in collaboration with the Ministry of Health and WHO has developed the national strategy for palliative care, which focuses on pain management. This initiative was supported by the Two Worlds Cancer Collaboration, Canada.<sup>2</sup>

Levels of consumption of narcotic drugs1

Morphine consumption equivalence
= 1.815 mg/capita



\*S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

No. of the con-	F. wood at ou	Public sector		Private	A
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIC	OID ANALGESICS				
Morphine	<ul><li>Oral morphine (IR and SR)</li><li>Injectable</li></ul>	×	✓	✓	– Largely urban-centric
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	×	✓	✓	<ul> <li>Not readily available in the public sector</li> </ul>
Pethidine	– Injection	×	✓	✓	Accessible
Methadone		*	×	*	Methadone is not used for pain relief at hospitals
STEP 2 OPIOID ANALGESICS					
Tramadol		*	✓	*	Available mainly in tertiary institutions
Codeine		NA	NA	NA	Not available

- The Public Health Service Act 2018 has included palliative services in the definition of "health service", providing a legal framework for palliative care development.<sup>5</sup>
- The Narcotic Drugs (Control) Act, 2033 (1976), under Section 5, allows medical practitioners to prescribe drugs that may contain substances that are otherwise prohibited in Nepal.<sup>6</sup>

# Palliative care education and training

- Undergraduate medical education does not yet include palliative care, but the postgraduate curriculum included palliative care in 2008.<sup>3</sup>
- NAPCare also conducts introductory palliative care courses for doctors, nurses and paramedical professionals. These are short-term courses, which last for a week or two.<sup>4</sup>
- The National Health Training Centre has encouraged organizations, such as NAPCare, to conduct training programmes for health professionals in the country under its capacity-building initiatives.

#### **Barriers to access**

- Doctors are reluctant to prescribe opioid analgesics unless they have been trained in palliative care. There is a fear of respiratory distress, which prevents them from prescribing morphine.
- There is a tendency to be influenced by advice of unqualified personnel, who work in retail
- pharmacies. They tend to push other over-the-counter medications to patients due to lack of knowledge.
- Lack of information and the well-intended decision of family members to prolong the patient's life through intensive care and/or other expensive and often futile interventions are barriers.
- Lack of knowledge and skill in pain assessment, unavailability of morphine and a fear of opioid dependence lead to mistreatment of pain.
- A fear of drug dependence with regard to use of opioid analgesics has a detrimental effect on both prescriptive practices and patient uptake.
- There are no barriers to stocking opioid analgesics, but pharmacists do not want to stock them due to the tedious administrative process involved.

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Gautam, D, Adhikari, S (2021). Palliative care services for cancer patients in Nepal, a lower-middle-income country. *Palliative care and social practice*, *15*, 26323524211021105, https://doi.org/10.1177/26323524211021105.
- 3. Pandey S, Gaire D, Dhakal S. Perception of palliative care among medical students in a teaching hospital. *Journal of Nepal Medical Association* 2015, (https://doi.org/10.31729/jnma.2772).
- 4. Ghimire YC. Delivery of palliative care in Nepal: a journey towards the community level care. National Health Training Centre, Nepal, 2020.
- 5. The Public Health Service Act, 2075. 2018, http://www.lawcommission.gov.np/en/wp-content/uploads/2019/07/ The-Public-Health-Service-Act-2075-2018.pdf (2018, accessed 22 February 2021).
- 6. Nepal Law Commission. Narcotic Drugs (Control) Act, 2033 (1976). Government of Nepal, 2018, https://www.lawcommission.gov.np/en/archives/category/documents/prevailing-law/statutes-acts/narcotic-drugs-control-act-2033-1976.



# Sri Lanka

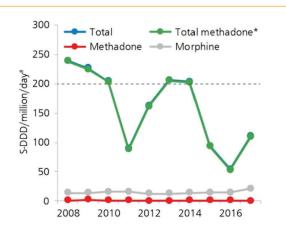
Population	Life expectancy	GDP/capita (US\$)
21.8 million	77 years	3853.1

# **Background**

- Palliative care was primarily associated with oncology in the 1960s and was provided by the Sri Lanka Cancer Society.
- In the 1990s, a hospice centre was set up by the Sri Lanka Cancer Society, adjacent to the National Cancer Institute. The Satya Sai Association established a hospice care centre in 2003. Major reforms in palliative care began only in the late 2000s.
- The Palliative Care Association of Sri Lanka, which included both medical and nonmedical services, was established in 2011.
- Palliative care initiatives in government hospital settings were started after the ToT programme, conducted by NCCP in collaboration with APHN, in 2014.

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 1.36 mg/capita



\*S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

		Public	sector	Private	
Medicine	Formulation	Primary	Tertiary	sector	Accessibility
STEP 3 OPIC	OID ANALGESICS				
Morphine	<ul><li>Oral Morphine (IR and SR)</li><li>Injectable</li></ul>	<b>√</b>	<b>√</b>	✓	– Largely dependent on supply cain
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	✓	✓	✓	
Pethidine		✓	✓	✓	Accessible
Methadone		*	×	*	Methadone is not used for pain relief at hospitals
STEP 2 OPIOID ANALGESICS					
Tramadol		✓	✓	✓	Accessible
Codeine		NA	NA	NA	Not used in pain management

- Schedule III of the Cosmetics, Devices and Drugs Act No. 27 of 1980 includes narcotic medicines. Procurement of narcotics is allowed only through the National Medical Supplies Division (MSD).<sup>3</sup>
- Oral morphine under Schedule IIB is an exemption. Oral morphine is a valuable medication in palliative care and controls are relaxed for the convenience of cancer patients.
- Opioids are made available for medical use exclusively through Registered Medical Institutions (RMI) licence holders.
- In 2015, a general circular allowed prescription of oral morphine for a month for cancer patients.<sup>4</sup>

### Palliative care education and training

- Sri Lanka has officially included palliative care education at the national level, with both medical and nursing courses. A postgraduate diploma course in palliative medicine of one-year duration was started for medical officers from PGIM, University of Colombo, Sri Lanka, since 2019.<sup>2</sup>
- An MD course in palliative medicine at the same university is currently at the final stage of curriculum development.
- Post Basic Diploma in Palliative Nursing was initiated in 2022.
- Palliative medicine is included as part of clinical training. A formal one-week clinical series of lectures are conducted at the Faculty of Medicine, Sabaragamuwa University.

### **Barriers to access**

- Sri Lanka does not produce opioid analgesics in the country. Imports are based on estimates,
   which often lead to shortages.
- Opioid analgesics are mainly available through the government hospital and pharmacy system.
   There are very few private hospitals, which are allowed to stock opioid analgesics.
- Despite awareness programmes run by the government and palliative care experts, prescription of opioid analgesics remains suboptimal. Opioid analgesics are still viewed as the last option for severe pain in the end stages of life.

### References

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Postgraduate Institute of Medicine, University of Colombo. Prospectus: Postgraduate Diploma in Palliative Medicine. University of Colombo, 2015, https://pgim.cmb.ac.lk/wp-content/uploads/2016/07/Palliative-Medicine.pdf.
- 3. National Medicines Regulatory Authority. Controlled Substances, NMRA Sri Lanka, 2017, https://nmra.gov.lk/index.php?option=com\_content&view=article&id=88&Itemid=227&lang=en#importation-of-psychotropic-substances-to-sri-lanka.
- 4. 01-14/2015 Circular. Prescribing and issuing of morphine for cancer pain management.

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# **Thailand**

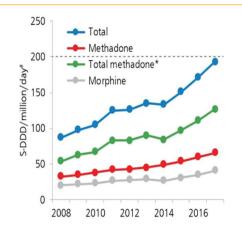
Population	Life expectancy	GDP/capita (US\$)
69.6 million	77 years	7806.70

# **Background**

- Civil society in the country has spearheaded a successful advocacy and capacity-building campaign to make palliative care medicine a mainstay in Thai health care.
- Major NGOs in the country have formed a network of palliative care organizations that have been at the forefront of policy advocacy in Thailand.
- While there is still a long way to go before high standards and excellence of care for all patients at the end of life are achieved, the progress has been significant.<sup>2</sup>

Levels of consumption of narcotic drugs<sup>1</sup>

Morphine consumption equivalence
= 7.562 mg/capita



"S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

Ba - di sissa	Famoulation	Public	sector	Private	Ail-ilian		
Medicine	Formulation	Primary	Tertiary	sector	Accessibility		
STEP 3 OPIC	STEP 3 OPIOID ANALGESICS						
Morphine	Oral morphine (IR and SR)	<b>√</b>	<b>✓</b>	<b>√</b>	– Accessible		
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li></ul>	✓	✓	✓			
Pethidine			✓	✓	- Accessible		
Methadone		*	*	*			
STEP 2 OPIOID ANALGESICS							
Tramadol		✓	*	✓	– Accessible		
Codeine		✓	NA	✓			

- The 1979 Narcotics Act had criminalized use and possession of all narcotic substances, which included morphine.
- A November 2020 Amendment to the law decriminalized the use and possession of 102 narcotic drugs with medical value, including morphine, and categorized them as Category II drugs for medical and research use.
- This came into effect in July 2021.<sup>4</sup>

### Palliative care education and training

- The Thai Palliative Care Society (THAPS) and the Thai Palliative Care Nurses Society (PCNS) were established in 2012 to act as umbrella organizations for palliative care capacity-building in the country.<sup>3</sup>
- In order to prepare students to achieve a basic level of competency in palliative care, each medical school has to include palliative care content into the undergraduate curriculum.

### **Barriers to access**

- There is a perception among medical professionals that a morphine injection can be
- administered only at a hospital, despite the law allowing for all kinds of medical use. Culturally, opioid analgesics have been viewed as something abhorrent and addictive.
- Palliative care is not a part of the standard medical curriculum in Thailand. The education
  programmes and courses that are available with regard to palliative care are usually shorterterm courses and are organized by independent organizations rather than by the government.
- The process of the Thai FDA for laying down rules and regulations for stocking morphine at hospitals that hold relevant narcotics licences is a long-drawn one (can take up to three weeks) and needs to be repeated every six months.
- In addition to the long-drawn process mentioned above, the licence is issued for only one year at a time. A combination of these factors severely affects availability of opioid analysesics.

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Nilmanat, Kittikorn. Palliative care in Thailand: development and challenges. *Canadian Oncology Nursing Journal = Revue Canadienne de Nursing Oncologique*, vol. 26,3 262-264 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6516295/.
- 3. Suvarnabhumi K, Sowanna N, Jiraniramai S, et al. Situational analysis of palliative care education in Thai medical schools. Palliat Care. 2013, 7:25-29. Published 2013 October 16, doi:10.4137/PCRT.S12532 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147768/.
- 4. Kingdom of Thailand National Legislative Assembly. Narcotics Act B.E. 2522 (1979) as amended up to Narcotics Act (No.7) B.E. 2562 (2019). The Kingdom of Thailand, 2019, https://www.theworldlawgroup.com/writable/resources/Practice-Groups/Cannabis/Thailand-Narcotics-Act.pdf.



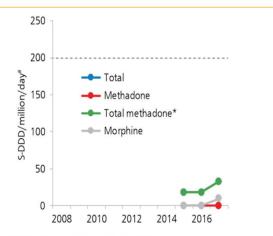
# **Timor-Leste**

Population	Life expectancy	GDP/capita (US\$)
1.29 million	69 years	1560.50

# **Background**

- In June 2008, three health professionals from Australia visited Timor-Leste to assess palliative care needs in the country. They reported that there was no palliative care service provision in Timor-Leste.<sup>2</sup>
- However, one home care service exists (Casa Esperanca), run by a former minister.
   The team comprises doctors, nurses, physiotherapists and nutritionists, who started seeing patients in March 2018.
- The organization has now signed an agreement with the Ministry of Health to improve access to palliative care.

# Levels of consumption of narcotic drugs<sup>1</sup> Morphine consumption equivalence = 6.975 mg/capita



\*S-DDD; Statistical defined daily dose/million/day; \*Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

Medicine	Formulation	Public sector		Private	
		Primary	Tertiary	sector	Accessibility
STEP 3 OPIOID ANALGESICS					
Morphine	Oral morphine (IR and SR)	*	✓	NA	– Used only by specialists
Fentanyl	<ul><li>Fentanyl injections</li><li>Fentanyl patches</li><li>Fentanyl buccal tablets found in very limited quantities</li></ul>	×	✓	NA	
Pethidine		×	✓	NA	Accessible
Methadone		*	×	×	Methadone is not used for pain relief at hospitals
STEP 2 OPIOID ANALGESICS					
Tramadol		✓	✓	NA	Accessible
Codeine		NA	NA	NA	Not available

- There is no policy or programme for palliative care in Timor-Leste. The National Drugs and Medicine Policy of 2010 and the Timor-Leste Essential Medicine List of 2015, both drafted as per UN Convention guidelines and with the assistance of the UN, have provisions in place for access of controlled medicines.<sup>3</sup>
- The Timor-Leste Essential Medicine List (TLEML) was revised in 2015 and includes morphine and methadone. However, these also remain on the watchlist of the Police Scientific Investigation of Criminal Office (PCIC).

### Palliative care education and training

- The country is still highly dependent on foreign interventions and has a high proportion of doctors trained abroad, especially in Indonesia, Fiji and Australia.
- A significant percentage of expatriate health professionals work in the country, who are employed at hospitals and CHCs.
   Much of the clinical work as well as inservice training is provided by them.

# **Barriers to access**

- Lack of knowledge and skill in pain assessment and unavailability of opioid analgesics are major barriers. Dependence on experts from other countries remains high; this is not sustainable.
- While morphine and methadone are listed in TLEML, health professionals are not trained in TLEML at the university level. There is no orientation course on TLEML for doctors who have studied abroad and have come to work in Timor-Leste. Not much emphasis is placed on TLEML during in-service training.
- Opioid analgesics for pain relief are required to be prescribed by specialists, such as internists, oncologists and intensivists, but the country does not have an adequate number of trained specialists, who can prescribe these medicines.
- The onerous procurement tendering system lacking clarity on narcotic and psychotropic drugs, compounded by poor training in palliative care, leads to inadequate availability of or lack of awareness about opioid analgesics for pain relief.

- 1. International Narcotics Control Board. *Narcotic Drugs Technical Report*. http://www.incb.org/incb/en/narcotic-drugs/Technical\_Reports/narcotic\_drugs\_reports.html, accessed on 23 May 2019.
- 2. Maggie Huff-Rousselle. Starting from scratch in Timor-Leste: Establishing a pharmaceutical and medical supplies system in a post-conflict context. Health Nutrition and Population The World Bank 2009, https://openknowledge.worldbank.org/bitstream/handle/10986/13760/498270WP0HNP0d110EastTimorCaseStudy.pdf?sequence=1&isAllowed=y.
- 3. Ministry of Health. National Drugs and Medicine Policy. Republic of Timor-Leste, 2010, https://www.who.int/docs/default-source/searo/hsd/edm/nmp-tls-2010-govweb-ok.pdf?sfvrsn=381fa9f5\_2.

The availability of controlled medicines is crucial for patients requiring palliative care, pain relief and symptom management. Many individuals worldwide, especially in low- and middle-income countries, continue to experience limited access to these essential medicines. Enhancing access to controlled medicines is paramount in promoting universal health coverage.

This report offers a detailed situational analysis of policies and programmes aimed at improving access to affordable, high-quality controlled medicines for pain management in the WHO South-East Asia Region. The report identifies the existing barriers, challenges and possible solutions to facilitate access to such medicines across all Member States.



