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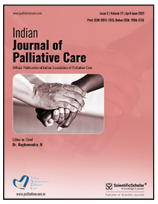

Short Communication

Opioid Accessibility for Palliative Care in Nepal: A Review of Achievement and Remaining Challenges

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ABSTRACT

This study aimed to explore current opioid availability and accessibility for palliative care (PC) practice in Nepal. A narrative review was conducted by performing literature searches in electronic databases, grey literature, policy documents, and pharmaceutical websites. This was supplemented by utilising the authors' expertise and experience in this field. Six different opioids are available in Nepal, including oral immediate and modified-release morphine formulations. Morphine is produced and distributed by only one manufacturer, which imports all raw materials from Europe. Access to morphine in rural areas is poor, with rural-level healthcare centres rarely stocking morphine, particularly in PC formulations. Fentanyl transdermal (TD) patch and methadone syrup are available in Nepal but are imported. The Fentanyl TD patch is extremely expensive, and methadone syrup is only available for the management of addiction. While opioid availability has increased in Nepal, there is a need to improve opioid accessibility for PC services, particularly in rural areas. Several approaches are explored in this review.

Keywords: Morphine, Nepal, Opioids, Palliative care

INTRODUCTION

The need for palliative care (PC) is increasing in Nepal, attributable to rising life expectancy and increasing prevalence of non-communicable diseases.[1,2] Studies in Nepal have demonstrated a considerable need for PC, including in rural settings,[1,3,4] where the majority of the population lives.[5] Mountainous terrain, poverty, lack of infrastructure, political instability, constrained healthcare resources and limited workforce hinder healthcare development in Nepal, particularly in rural areas. Although the government is committed to Universal Health Coverage and is rolling out a health insurance system, progress in achieving this is slow.

Timely and proper pain management is vital for maintaining the quality of life of PC patients, and opioids are essential medicines for this.[6-8] The International Pain Policy Fellowship, University of Wisconsin, between 2008 and 2012, facilitated the manufacture and availability of opioids for PC in Nepal.[9] However, Nepal, like other LMICs, still has problems with the adequate and consistent supply of morphine.[10] Nepal signed the 2014 World Health Assembly declaration committing to incorporate PC into the National Health Policy.[11] In 2017, the Nepal government adopted a National Strategy for PC, which included a commitment to ensure access to essential PC medicines, including opioids, for all in need.[12]

This article reviews the progress on opioid accessibility for PC patients in Nepal and discusses what needs to be done further to ensure that opioids are accessible to all who need them.

MATERIALS AND METHODS

Articles from electronic databases were accessed from PubMed and Google Scholar from their inception to December 2023 using relevant keywords including: 'opioid,' 'morphine,' 'Nepal,' 'palliative,' 'hospice,' 'terminal' and 'end-of-life'. Official websites of Nepal government, pharmaceutical bodies and pharmaceutical companies involved in the production and distribution of opioids were also searched to understand the policies, programmes and

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practices for opioid access in Nepal. Synthesis was performed to explore opioid accessibility in terms of availability, usage, distribution and control practices, as well as the facilitators and barriers to making opioids widely available and used for PC in Nepal.

RESULTS

Opioids availability and usage in Nepal

Table 1 provides the details of opioid formulations and manufacturers registered with the Department of Drug Administration (DDA) of Nepal. DDA is the authorised government body that regulates and controls the quality, safety and availability of medicines in Nepal.[13]

Morphine is acknowledged as an essential medicine in locally published resources, including the Pain Management Guidelines for PC in Nepal, and has been licensed for manufacture since 2009.[7,9,14] However, morphine is not included in the essential medicine list for government primary-level healthcare centres, where some medicines are available free of cost.[15] For cancer patients, morphine is reported as the most commonly prescribed and administered opioid.[16] Morphine is locally manufactured in immediate and sustained-release formulations but only produced by a single manufacturer. Raw materials for morphine production are imported from Europe.[9] Occasional morphine shortages have occurred, including during the COVID-19 pandemic, reportedly due to delays in issuing import licenses for raw materials.

Fentanyl transdermal (TD) is imported and is the most expensive opioid available. One month's supply of fentanyl TD 25 mcg/h costs the equivalent of 2582.2 times the minimum daily wage in Nepal, and it is not available on the government health insurance scheme.[15] Codeine, tapentadol and tramadol are manufactured in Nepal. At present, tramadol injection is only manufactured by one Nepalese pharmaceutical company, although other companies are also registered.[17] Methadone is available in Nepal for the management of addiction through a special import licence for the National Centre for Acquired Immunodeficiency Syndrome and sexually transmitted disease (STD) Control. It is not registered for use in chronic pain management. Oxycodone is not available.[17,18]

Nepal's morphine consumption was negligible before import from India started in 2005.[9] Despite morphine manufacture starting in 2009, use did not increase substantially until 2016. By 2020, it had increased significantly but still fell far below the average global consumption (Average Global 6.1478 mg per capita; 0.88 mg per capita in Nepal) [Figure 1].[9,19,20]

Opioid distribution and regulatory practices

Morphine and other opioids are primarily used in tertiary hospitals, cancer hospital, hospices or PC centres, but their availability is minimal or absent in rural healthcare facilities.[16] Government hospitals procure medicines through a single tendering system, while private hospitals have the flexibility to choose suppliers.[21] The hospital must submit an authorised request to supplier with signature from its medical director or prescriber in order to obtain opioids.[13] Manufacturers strongly retain control over which hospitals receive supplies (supplementary file for the morphine distribution channel in Nepal).

Opioid use in Nepal regulated through the Drug, and Narcotic and Psychotropic Act, and Drugs Category Rules.[13] They limit prescribing to registered medical doctors and dispensing to registered pharmacy personnel, with regulations for storage and recording. Details of the patient (name and signature), prescriber (approval signature), dispenser (name and signature), dispensed medicine (name, dispensed quantity, remaining stock in pharmacy) and the dispensing date are required to be recorded and retained in pharmacies (see supplementary file for DDA recording template).[13] The DDA inspects pharmacies to ensure compliance. There is no specific regulation for recording opioid usage in hospital wards.[13]

Facilitators and barriers to opioid use in PC

Many healthcare personnel in primary and secondary healthcare, particularly in rural areas, are not trained or adequately aware of PC and the appropriate use of opioids in pain management. They are reluctant to prescribe due to the risk of adverse effects and drug addiction, even if morphine is available.[16,22] Clinicians working in cancer care institutions have been reported to prescribe opioids and to be aware of their benefits and pharmacology.[16,23]

PC and pain management are inadequately covered in undergraduate health care training, perpetuating a lack of awareness and clinical competence.[16,24] Current programmes to increase PC clinical education, pain management awareness and systems for enabling access to opioid medicines are ongoing.[25-27] However, involvement of a multidisciplinary team for patient care in Nepal is rare, limiting effective use and reduction of risks associated with opioid use.

DISCUSSION

This is the first review of opioid access in Nepal since Paudel *et al*. (2014) described the influence of the International Pain Policy Fellowship on morphine availability in Nepal.[9] It demonstrates that progress is being made, but only slowly. While compared to the global average, Nepal's morphine consumption per person in 2020 was low, it was comparable to Sri Lanka and well above other South Asian countries (Nepal 0.88 mg; Sri Lanka 0.9 mg; India 0.24 mg; Bangladesh 0.11 mg and Pakistan <0.1 mg).[19]

Although morphine is locally manufactured and regulations for prescribing and supply are less stringent than in other South Asian countries, its access is limited to larger cities,

Table 1: Details of opioid preparations registered and available in Nepal.[17]

Classification	Name of medicine	Available strength and dosage form (Price in Nepalese rupee per unit)	Manufacturer in Nepal
Natural opioids	Codeine	15 mg IR Tablet (NPR 6)	Vijayadeep Laboratories, CTL Pharmaceuticals, Pharmaco Industries, Omnica Laboratories, Lomus Pharmaceuticals, SR Drug Laboratories, Amtech Med (All are private limited and from Nepal)
	Codeine	3 mg/5 mL Syrup (NPR 90)	Lomus Pharmaceuticals Pvt Ltd, Nepal
	Codeine and Paracetamol combination	10+500 MG IR Tablet (NPR 6.5)	National Healthcare, Vijayadeep Laboratories, CTL Pharmaceuticals, Pharmaco Industries, Omnica Laboratories, Lomus Pharmaceuticals, SR Drug Laboratories, Amtech Med, Alliance Pharmaceuticals, Quest Pharmaceuticals, Florid Laboratories (All are private limited and from Nepal)
	Morphine	10 mg IR* (NPR 4.5), 10 mg PR* (NPR 6), 30 mg PR* (NPR 12)	National Healthcare Pvt. Ltd. Nepal, Vijayadeep Laboratories, CTL Pharmaceuticals,
	Morphine	10 mg injection* (NPR 100)	National Healthcare Pvt. Ltd., Nepal
	Morphine	10 mg/5 mL, 60 Ml Syrup* (NPR 100)	National Healthcare Pvt. Ltd. Nepal
Synthetic Opioids	Pethidine (Meperidine)	50 mg injection* (NPR 120)	National Healthcare Pvt. Ltd. Nepal
	Tramadol	50 mg IR Tablet (NPR 14.3 Average)	National Healthcare, Siddhartha Pharmaceuticals, Florid Laboratories, Vega Pharmaceuticals, Time Pharmaceuticals, Vijayadeep Laboratories, Asian Pharmaceuticals, Pharmaco Industries, Qmed Formulation, S R Drug Laboratories, Kasturi Pharmaceuticals, Accord Pharmaceuticals (All are private limited and from Nepal)
	Tramadol	50 mg injection* (NPR 29), 100 Mg injection* (NPR 55)	National Healthcare, Everest Parenteral, Nepal Pharmaceuticals Laboratory (Private limited and from Nepal) Troikaa Pharmaceuticals, Square pharmaceuticals, Tablets limited, Umedica laboratories, Beximco pharmaceuticals, UNichem Laboratories, Win-Medicare, Candila Health Care, Neon Laboratories, Themis medicare, Systacare Remedies (Outside Nepal)
	Tramadol and Paracetamol combination	37.5+325 mg IR Tablet (12)	Vega Pharmaceuticals, Nova Genetica, Florid Laboratories, Vijaydeep Laboratories, Apple International Pharmaceuticals, Omnica Laboratories, Accord Pharmaceuticals, Amtech Med (All are private limited and from Nepal)
	Tapentadol	50 mg (NPR 15), 75 mg (NPR 20) and 100 mg (NPR 25)	National healthcare, Royal Pharmaceuticals, Kasturi Pharmaceuticals, Apple international Pharmaceuticals, Alive Pharmaceutical, Maruti Pharma, Accord Pharmaceuticals, Lomus Pharmaceuticals, QbD Pharmaceuticals, Amtech Med, Aadee Remedies, Arrow Pharmaceuticals, Samar Pharma Company, Apex Pharmaceuticals, Prime Pharmaceuticals (All are private limited and from Nepal)
	Fentanyl	100 mcg Injection* (NPR 75)	National Healthcare Pvt. Ltd, Nepal
	Fentanyl	25 mcg Transdermal Patch (1034.7 For One Patch), 50 mcg Transdermal Patches (NPR 1984 for one patch)	Janssen Pharmaceutica N.V, Belgium

PR: Prolonged release, IR: Immediate release. *Are the medicines manufactured by the same manufacturing company in Nepal; The price of the medicine was taken from hospital pharmacy of Green Pasture Hospital on March 13th, 2024, when 1 Nepali Rupee (NPR)=0.007 United States dollars

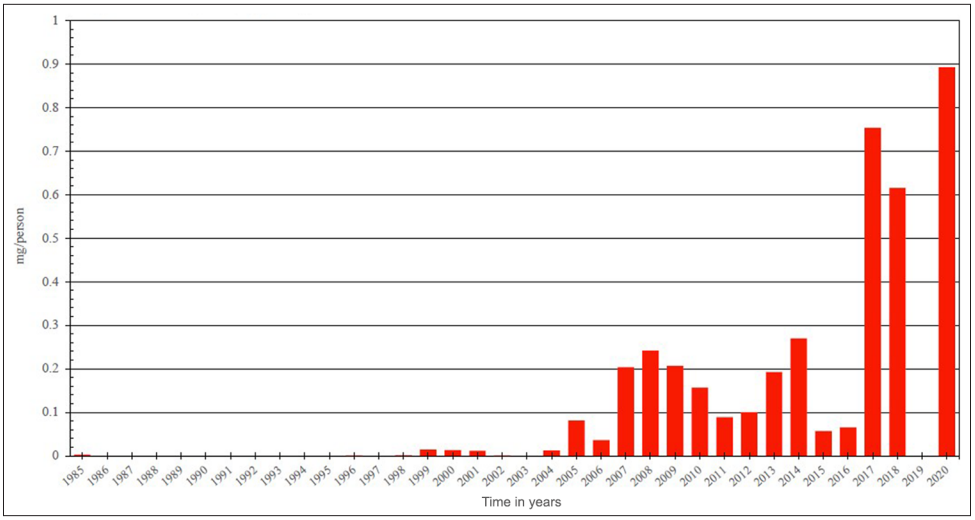

Figure 1: Morphine consumption (mg/person) in Nepal from 1985 to 2020.

cancer centres and few PC sites due to a lack of training and poor systems for procurement and supply.[28]

Fentanyl TD is exorbitantly expensive and is only available through out-of-pocket expenditure making it unaffordable to the majority population who are on low incomes.[15] Methadone is relatively cheap but not available for PC.[17,18,29] As it is considered an essential medicine for PC by the WHO and recommended in many PC guidelines, the DDA should consider extending the licence for methadone to the management of chronic pain under the clinical direction of PC and pain specialists.[6-8,14,30]

The government has aimed to make Nepal self-reliant in producing all essential medicines and making them available throughout the country.[31] Having only one licenced manufacturer to produce and distribute morphine and delays in obtaining import licences for raw materials from Europe[19] might explain sudden shortages and untimely and inadequate availability.

Effective systems for opioid supply are urgently needed, particularly to enable access in rural areas. These should focus on making opioids available in all areas while including effective governance to prevent misuse. Training of health personnel should be a priority so that opioids accessible through local health facilities might be effectively prescribed and dispensed. Based on population size, geography and the government health system, district and municipal hospitals would be appropriate centres to stock and dispense opioids. Without addressing these issues, morphine will remain unavailable to many people and national drug policies will remain unaligned with the National PC Strategy.[31,32]

Government regulations for opioids are robust and allow effective prescribing while preventing misuse.[13] However, they lack guidance on self-administration at home for extended periods or how opioids can be prescribed and delivered to patients who cannot physically attend a health facility that dispenses these medicines. These issues need to be addressed with some urgency.

Access to opioids for pain control is recognised as an urgent and often inadequately addressed issue in LMICs.[29,33,34] While Nepal has made some progress in addressing these issues,[12] further work is urgently needed. The concept of opioid stewardship guideline development, regular monitoring, education on safe prescribing and using multidisciplinary approaches to optimise pain management while minimising misuse, needs to be developed. Particularly, systems for opioid supply to rural healthcare centres and effective access for patients even in remote areas, along with effective training for clinicians, need to be designed and evaluated to ensure safe and accessible supply. These challenges are currently being addressed by the three-year Sunita Project, which is developing a rural model of PC as well as a national PC formulary.[27]

CONCLUSION

Morphine is manufactured in Nepal and all medical practitioners are legally able to prescribe it. There has been some increase in morphine accessibility over the past 10 years; however, lack of training and poor systems for supply to health facilities, especially in rural areas, means that it is not available close to home for most patients. Work needs to be done to ensure accessibility by increasing the number of pharmaceutical companies that manufacture and distribute morphine. Developing opioid stewardship and testing an effective system to ensure safe and effective accessibility to opioids in rural areas is currently underway.

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