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REVIEW

Access to Controlled Medications: Three Country Case Reports

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Three country case reports are presented on patient access to medications controlled under the international substance control treaties. The countries discussed are Egypt, Kyrgyzstan and Guatemala. They are compared between themselves and with a small number of other countries. Actions to overcome the impeded access in these countries are suggested. This manuscript elaborates further on a review published in this journal in 2020.

Keywords: analgesics; opioids; pain management; health policy; Egypt; Guatemala; Kyrgyzstan

Introduction

Access to Controlled Medications is an almost world-wide problem in spite of the objectives of the international substance control conventions, which are to ensure their medical and scientific availability while preventing non-medical use. This is widely documented (INCB 1989; Seya et al. 2011; Cherny et al. 2013; Cleary et al. 2013; Duthey and Scholten 2014; Berterame et al. 2016; Knaul et al. 2018; Scholten et al. 2019; Scholten et al. 2020). Not only access to opioids for a wide range of acute and chronic moderate and severe types of pain is problematic, but also to medications made from other psychoactive substances e.g. for applications, conditions and diseases like anaesthesia, opioid use disorder, dyspnoea, epilepsy, obstetric emergencies and psychological crises (Milani and Scholten 2011; Häuser et al. 2015; Moisset and Martinez 2016).

In a review article in this journal, the backgrounds, theory of measuring access rates and consequences were discussed (Scholten 2020). The current article will elaborate on three country cases: Egypt, Guatemala and Kyrgyzstan. These countries were selected, because they are examples of three countries from three different continents where access is very difficult for patients in need. The author is more familiar with these three countries, but for many other countries the situation is similar (Scholten et al. 2019; Scholten et al. 2020). It is recommended that this article is read in conjunction to Scholten's article (2020).

Case 1: Egypt

In Egypt, with more than 95 million residents in 2016 and an estimated 5-year cancer prevalence of more than 215,000 cases in 2012, pain management is misunderstood among health professionals, policy makers, patients and the public (Kagawa-Singer 2011). Pain is a common symptom, especially in cancer: it is estimated that more than 50% of cancer patients experience pain (Stjernsward and Clark 2003), while 60%-90% of patients with metastatic advanced cancer experience moderate to severe pain (Daher 2012). The lack of effective and affordable analgesia is catastrophic for people with end-stage cancer. There are a number of barriers described below for access to essential pain medicines, constituted by knowledge gaps and other barriers.

Restrictive Regulatory Barrier

Morphine remains the medication recommended by the World Health Organization (WHO) for moderate to severe cancer pain control (WHO 1996), however, the only available registered oral morphine preparation in Egypt is the 30 mg slow-release morphine tablet. According to the Egyptian Narcotics Control Law, the maximum dose limit for tablets of morphine or its salts is 420 mg, which should not be exceeded in a

single prescription, and the maximum for ampoules of morphine or its salts is 60 mg (Anonymous 1999). For many advanced metastatic cancer patients, the 420 mg morphine dose may not be sufficient for one daily dose (Sykes and Thorns 2003). This dose-limiting law, in addition to fears, misconceptions, and stigma about morphine, has shaped the morphine prescribing regulations of both the Ministry of Health (MOH) and the Health Insurance Organization (HIO) within Egypt. The HIO facilities provide health services for citizens working in the government and general organizations. It is estimated that the HIO covers 44% of the Egyptian population (Egyptian Ministry of Health s.a.). Although the MOH regulations should be applied in HIO facilities, HIO created its own regulations, which further complicated the process of prescribing and dispensing slow-release morphine tablets for cancer patients. According to HIO regulations, “morphine” is not to be used except after exhausting treatment with ordinary analgesics, so the drug will not lose its efficacy from prolonged use (Egyptian Ministry of Health s.a.). This is a clear example of how misconceptions about morphine among policymakers may contribute to inadequate cancer pain control. What makes the process further complicated is that advanced cancer patients for whom no further cancer-modifying treatment is possible are not eligible for transfer to centres outside the HIO system for pain management. With this list of obstacles, access to oral morphine in HIO facilities becomes a difficult mission. In view of the regulations illustrated above, it is not surprising to have very low morphine consumption figures in Egypt. Low morphine and other opioid consumption figures indicate very inadequate cancer pain control in Egypt (Alsirafy 2010).

Medication Availability

Opioid availability in Egypt remains very limited. For more than two decades, oral slow-release morphine tablets (30 mg) is manufactured under a license by a single supplier from the United Kingdom and Northern Ireland, packed by an Egyptian company, distributed by an Egyptian governmental trading company, and then dispensed by pharmacies (Alsirafy and Faraga 2016). Immediate release and liquid morphine are not available for the treatment of pain in patients. Tramadol is often used as an immediate release treatment for moderate to severe pain, but its use is also subject to restrictions and regulations. In addition, the stigmatization and misconceptions about tramadol may have resulted in fear of tramadol among cancer patients (Alsirafy et al. 2015). Newer, more expensive opioids like transdermal fentanyl patches are registered, while cheap opioids like immediate-release oral morphine remain unavailable. Slow-release oral morphine is generally available in tertiary hospitals and major cities, but not in smaller health centres nor outpatient pharmacies. Accordingly, many patients suffering from moderate to severe pain often need to be referred to larger health facilities and get hospitalized in order to have access, thus making pain treatment less accessible and costly, especially for those living far from major cities. In the outpatient setting, opioids are only prescribed for cancer patients, and are only available in hospitals with oncology services and in government pharmacies. Patients have to get special prescription forms to receive opioid analgesics as outpatients, and the doctors have to apply for these forms at the MOH (Alsirafy et al. 2011).

The Adequacy of Opioid Consumption Index (AOC Index, see Scholten 2020) for consumption of opioids medication in Egypt, together with those of Guatemala and Kyrgyzstan are presented in **Figure 1**.

Inadequate Training

Physicians, pharmacists and nurses receive less training compared to other countries in the region and have limited adequate knowledge of pain assessment and management. Alexandria University received approval for a Supportive Diploma from the Ministry of Higher Education for physicians, but this diploma is only provided for oncologists (Osman et al. 2017). The level of public awareness is hard to assess, but at least at the professional level, cancer-care providers are now more aware of pain management and palliative care. According to International Narcotics Control Board (INCB), the lack of knowledge and training in the use and administration of opioid medications represents the largest barrier to access in most countries (INCB 2015).

Cultural Concerns

Within the Egyptian society, religion and cultural beliefs often guide healthcare professionals’ decision-making. This translates into how, when, and even if pain should be treated at all. Unfortunately, many patients and families believe that the use of opioids means death is imminent and that the administration of opioids early in the development of pain will decrease options for treatment in the future (Daher 2010). Patients may refuse opioids due to fear of dependence and the stigma associated with their use.

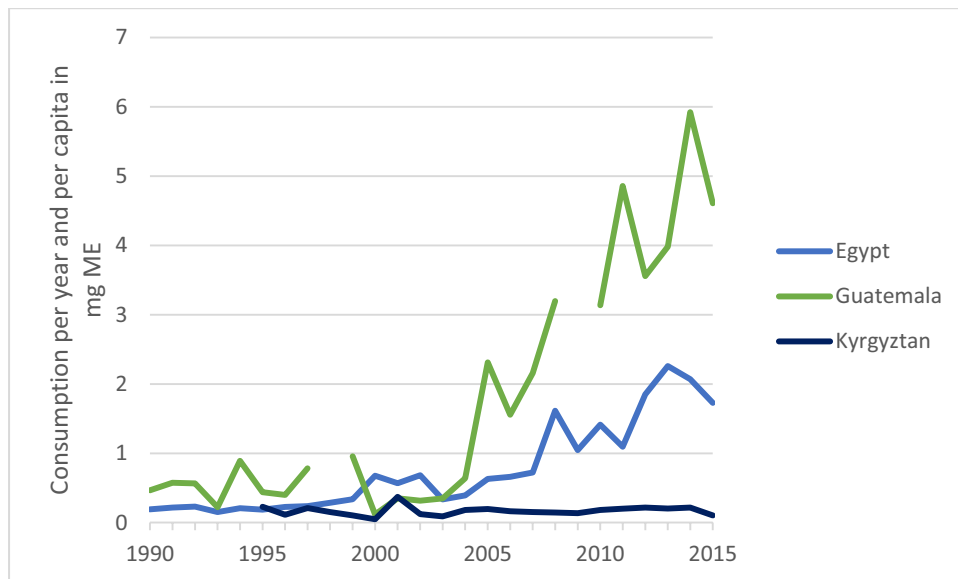


Figure 1: Total per capita consumption of controlled¹ strong opioids which are mainly used for analgesia² in Egypt (E), Guatemala (G) and Kyrgyzstan (K), 1990–2015. These countries used at least in one year: fentanyl (E, G, K), hydromorphone (E), morphine (E, G, K), oxycodone (E, G), pethidine (E, G), piritramide (K) and trimepiridine (K). Line interruption means no data available. It should be noticed that even the highest consumption of 5.92 mg ME per capita per year is negligible as compared to an adequate use level (256 mg ME per capita per year) as defined by Scholten (2020).

Case 2: Guatemala

Every year, an estimated 28,500 Guatemalans experience advanced, chronic illnesses, such as renal disease, cancer, cardiovascular or pulmonary conditions, and HIV/AIDS (HRW 2017). These conditions are often accompanied by pain. This pain can generally be treated and controlled well with low-cost medications, but due to complex regulations on controlled substances, thousands of patients suffer significant levels of pain related to their illness. Indeed, at least 5,500 Guatemalans with cancer and HIV/AIDS suffer annually due to barriers to accessing low-cost opioid medications (HRW 2017). With both life expectancy and the percentage of the population over 65 both projected to rise, the burden of chronic illness on society will only grow.

Restrictive Regulations

Guatemala's current drug regulations are unduly restrictive, inconsistent with both INCB and WHO recommendations, and discordant with regulations in other Central American countries (INCB 2016). The current system creates multiple, often challenging, hindrances for physicians, pharmacists, and patients, including a number of requirements: a physician must use a special prescription pad that is needlessly difficult to obtain, and write a second prescription form for many patients; patients must obtain a stamp to validate the prescription before a pharmacy can dispense the medications; and the patient or a family member, whom-ever will pick up the prescription, must apply for a special identification card and registration number. On this application the physician must specify the dose that will be prescribed and the estimated length of time it will be needed. The patient or family member then takes this application during certain business hours to the MOH office in the capital, Guatemala City, to obtain the card and number. Should the dose one needs change, the physician must complete a brand-new application for the patient to present at the office for a new card and number, specific for the new dose (Gilson et al. 2013). Only 50 to 60 out of around 14,000 doctors in Guatemala have special prescription pads needed to prescribe morphine, all of whom work in Guatemala City. In addition, only three pharmacies in the entire country, all in Guatemala City, consistently carry opioid analgesics, although nearly 80 percent of the population lives elsewhere (HRW 2017). As a result of these regulatory barriers, the use of opioid analgesics in Guatemala is very low (Cleary et al. 2013).

¹ Only opioids controlled under the Single Convention on Narcotic Drugs.

² Opioids which are primarily used for other purposes, such as anaesthesia or pharmacological treatment of opioid use disorder not included. Weak opioids such as codeine and tramadol also not included.

Lack of Training and Education in Pain Management

Lack of education for health professionals in Guatemala is another cause of limited access to pain management. Availability of undergraduate education in pain management and palliative care is very scarce, and is only available in few programs. The country's only public medical school does not teach palliative care and pain management as part of its undergraduate curriculum, while only one of the three private medical schools does (Garcia 2019). Moreover, physicians specializing in oncology, internal medicine, and other areas of medicine that frequently care for patients with life-limiting illnesses do not receive any academic or clinical training in pain management and palliative care. Only physicians specializing in anaesthesiology have a two-month rotation in palliative care. There are no specialized post-graduate training programs in palliative care or pain management (Pastrana, Centeno and De Lima 2015). Amongst such professionalized silence, healthcare professionals and providers may feel uncomfortable prescribing opioids and could be reluctant to do so, even for patients who need them.

Availability of Morphine

In 2012, immediate-release morphine was first registered in Guatemala for patients suffering from severe cancer pain (Cleary 2013), and pain from other serious illnesses such as AIDS, tuberculosis, and cardiovascular, degenerative neurologic, and renal diseases. Pharmacies that regularly stock opioids are embedded into national hospitals located only in the capital city, while stand-alone pharmacies outside of the capital rarely stock these medications (HRW 2017). This practice has left the poor and indigenous patients from rural areas with insurmountable obstacles to obtain morphine and proper analgesia. However, some hospitals in Guatemala City have found some solutions to bypass the complex procedure by allowing hospital pharmacies, which normally provide medicines only to hospitalized patients, to dispense morphine to patients who are not hospitalized. This practice, which several consecutive governments have tolerated, has alleviated the situation for some patients, but a permanent and country-wide solution is urgently required. Many regulations limiting morphine access are not actually required by the international drug control conventions (INCB 2015), subsequently, opioid consumption in Guatemala remains significantly low, even while elsewhere it continues to rise.

Case 3 Kyrgyzstan

In 2014, the World Bank ranked Kyrgyzstan as a low and/or middle-income country with a total population of 6,304,030. Kyrgyzstan claims to be one of the more advanced countries in the region and to have implemented reforms to the health system by introducing a transition from the Semashko post-Soviet health system to a more robust system with a stronger focus on primary health care, family medicine, and newer models of funding within the single-payer system, including establishing a state health insurance system (Mukambetov et al. 2018). However, access to pain treatment continues to remain an obstacle throughout Kyrgyzstan. There are a number of barriers described below to access to essential pain medicines constituted by knowledge gaps and other barriers, cultural and regulatory.

Restrictive Legislation Regarding Opioids

Until 2014, injectable opioids were the only option for pain relief in Kyrgyzstan. After an information campaign conducted in 2012-2014 by representatives of civil society and the Public Council of the Mandatory Medical Insurance Fund (PC MMIF), tablet morphine was registered in Kyrgyzstan, and was included in the list of medicines involved in the MMIF state guarantee program to be used by medical professionals in the primary health care system and hospitals as the primary choice for pain relief for palliative care patients (Asanalieva 2018). However, more barriers still exist such as the Health Insurance Fund only paying for 3000 mg of morphine per patient, and patients having to pay for any additional amount of morphine with a maximum of 10 days' supply per prescription (Mukambetov et al. 2018). Also, a number of other regulations within government Decrees 2 and 54 remain including restraints on procurement, prescription storage, delivery, and management of oral opioid use (Mukambetov et al. 2018). With the support of Soros Foundation-Kyrgyzstan program (SFK), more opioids were added to the medication list, including fentanyl. Most recently, the registration of oral morphine drops in June 2019 in the register of the medicines supply department of the MOH. However, with all these changes to their regulations, opioid medications still can only be prescribed to patients with advanced metastatic cancer, which does not allow adequate pain relief for patients with cancer at earlier stages, as well as with other diseases. According to expert estimates, 50% of the number of deceased patients with terminal stage of HIV infection (AIDS) and 10% of the number of dead patients with other incurable progressive diseases need analgesia with opioids (Foley, Wagner and Joranson 2006). For such patients, opioid analgesics are not available in Kyrgyzstan.

Availability

Despite legislative changes that have increased the number of opioid medications, and simplification of the prescription process, the actual absence of opioid medication for sale represents an additional barrier. In Bishkek and major cities, state-owned pharmacies provide opioid medications, but in more remote regions and rural areas, the situation is much more complex. Although morphine and fentanyl transdermal are included in the list of essential medicines, they are not covered by the program of state guarantees (Vogler et al. 2019). Consequently, these medications will not be widely prescribed to patients due to their high cost. Private retail pharmacies often do not stock opioid medications for the following reasons: the cost of the medication is not profitable; the reporting system and bureaucratic procedures are too complex (one needs to get a license from the MOH to sell medications, execute a contract that includes a mandatory health insurance plan); and fear of legal problems from narcotic drug control authorities.

Moreover, since 2006 Kyrgyzstan started opioid agonist treatment (AOT) with the long-acting methadone. Together with OAT with buprenorphine this is the only proven effective treatment for opioid use disorder. Contrary to the other two countries, AOT is now accessible in this country (**Figure 2**).

Lack of Awareness

There is a low level of public awareness, fear of opioids, and myths regarding the use of opioid medications for pain management among healthcare professionals. A significant part of the medical community does not have the knowledge and experience of opioid medications. Improper prescribing by a physician is a frequent reason for refusing to dispense opioid medications by pharmacies, which further reduces the availability of opioids to patients who need them. In Kyrgyzstan, medical organizations formulate the demand for controlled medications for the planning period based on the achieved level of consumption in past years. This is done without considering the INCB-WHO recommended methods for calculating the needs of patients for opioid medications (INCB and WHO 2012). Many state hospitals and family medicine centres in the region do not have the necessary licences required for obtaining opioid medications for medical purposes, which further exacerbates access for patients needing or receiving palliative care, especially those living in remote and rural areas.

Discussion

Scholten (2019, 2020) demonstrated already the wide-spread difficulty in accessing medications controlled under the international substance control conventions. The three case reports presented here show in more detail what this means for people with health problems at the country level.

Guatemala, and to a lesser extent Egypt, slowly improved somewhat on their consumption of controlled strong opioids mainly used for analgesia starting in 2000, while there is not any change in this respect in Kyrgyzstan (**Figure 1**).

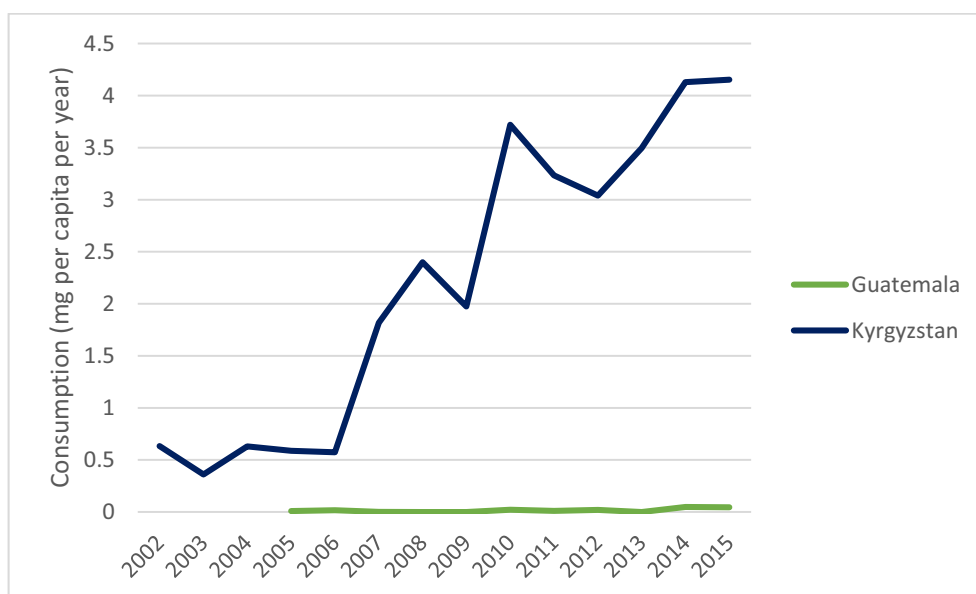


Figure 2: Per capita methadone consumption of in Kyrgyzstan, Guatemala, 2002–2015. (Egypt: No consumption).

On the other hand, the case of Egypt showed the complete absence of methadone treatment for dependence, and while Kyrgyzstan, from 2006 onward, gradually increased the consumption of methadone, in Guatemala it remained at a constant bottom low (**Figure 2**).

For all three countries it was demonstrated that these three countries have a negligible per capita consumption as compared to both industrialized countries and even to countries with a mediocre per capita consumption like Turkey, Colombia and Saudi Arabia (**Figure 3**). From stigma, to procurement, to antiquated legislation prohibiting dispensing and other, access to opioids in Egypt, Guatemala and Kyrgyzstan is very limited.

Re-designing the educational system for providers at every level, and enhancing cultural competency among patients and their caretakers, is one step toward decreasing stigma and fear of opioid medications. Reduction of costs and improving access to opioids will require changes at the governmental, legislative echelon in these countries. The support of advocates from all levels, patients, providers, government officials and many other parties, will be needed to ensure access for people in need of analgesia.

Scholten (2020) described the barriers that can prevent access to these medications. **Table 1** presents a number of actions that can be undertaken to overcome these barriers, once it is demonstrated that they are responsible for obstructing patient access.

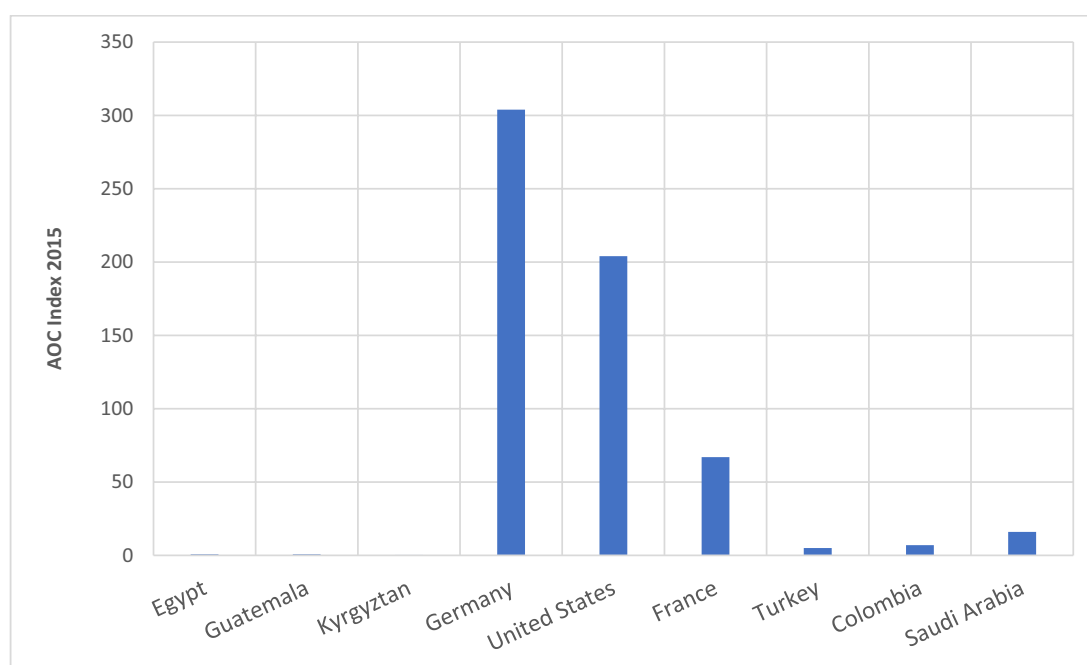


Figure 3: AOC Index of Egypt, Guatemala and Kyrgyzstan, as compared to a number of industrialized countries, and a few countries in their region, 2015. An AOC Index of ≥ 100 represents adequate consumption. (Bars for Egypt, Guatemala and Kyrgyzstan are too small for being visible).

Table 1: Implementation Considerations.

Barriers	Strategies for addressing implementation barriers
Cost of Opioids.	Importing and producing more low-cost opioid medications.
Cost is always an important factor to consider, extra resources would need to be provided at additional cost.	Widening the availability of opioids by setting up distributors to negotiate cost, and reallocation of the budget. The availability of opioids will offset the cost spent by the government on emergency hospital visits the patients inevitably will have if they do not receive adequate pain management. Gaining Access to appropriate licenses to grow poppy plants within the country to decrease the need for importation from other countries to decrease cost and provide quicker availability. Subsidizing and allocation of funds in specific patient populations such as cancer and other terminally ill patients to increase availability and resources needed to provide adequate treatment.

(Contd.)

Barriers	Strategies for addressing implementation barriers
Education of Healthcare providers in pain management and palliative care. Knowledge and safety of prescribing, dispensing, and administration of pain medication is a vital asset that needs to be more standardized throughout the profession.	Relocating the government's revenue to develop thorough programs and classes. Increase the training and education of students in undergraduate and graduate medical, pharmacy, and nursing programs. Educational hand-outs and counselling sessions available to patients, caregivers, and health-care providers.
Improving Access. Overregulation of opioids needs to be amended in order for patients to have better access to pain medication and be aware of their proper usages.	Gaining Access to medications on the essential medicines list. Increasing availability of pain medications available to patients by their providers by enforcing strategies outlined in the palliative care resolution laid out by the WHO. Improving the availability of medications, and gain collaboration with other countries to provide an international network to create workshops and strategic action plans. Providing healthcare professionals with the tools and resources to monitor the use of controlled medications by patients to expand providers the ability and knowledge to prescribe opioid medications. Increase the availability of prescribers and pharmacies able to carry pain medication by amending the laws such as the restrictive access to opioid prescription pads and verification letters required in order to obtain opioid prescriptions. Develop a formulary that contains the essential medicines list recommended by WHO to provide optimal palliative and hospice care. Ensure immediate-release oral morphine becomes available in at least one pharmacy in each hospital. Where no private pharmacies stock oral morphine, ensure that a hospital pharmacy dispenses oral morphine to outpatients.
Cultural. Deep rooted cultural prejudices against 'drugs' particularly opiate based medications.	Patient, provider, family advocacy and first-hand testimony (witnessing) to benefits of appropriate access to pain medicines.
Commercial. Inadequate procurement, stockouts and inflated prices that reflect marketing and supply chain costs.	Public procurement, supply chain strengthening, multi-agency coordination and streamlining of regulations following multi-agency review. Develop an incentive measure for private pharmacies to dispense opioid medications. Implement necessary measures to ensure the affordability of opioid medications.

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Competing Interest

The author has no competing interests to declare.

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