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IN FOCUS ACCESS TO CONTROLLED MEDICINES

WORLD DRUG REPORT 2020

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Suggested citation:
In Focus: Access to Controlled Medicines - World Drug Report 2020.

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Comments on the report are welcome and can be sent to:

Division for Policy Analysis and Public Affairs
United Nations Office on Drugs and Crime
PO Box 500
1400 Vienna
Austria
Tel: (+43) 1 26060 0
Fax: (+43) 1 26060 5827

E-mail: wdr@un.org
Website: www.unodc.org/wdr2020

Acknowledgements

The *World Drug Report 2020* was prepared by the Research and Trend Analysis Branch, Division for Policy Analysis and Public Affairs, United Nations Office on Drugs and Crime (UNODC), under the supervision of Jean-Luc Lemahieu, Director of the Division, and Angela Me, Chief of the Research and Trend Analysis Branch, and the coordination of Chloé Carpentier, Chief of the Drug Research Section.

Content overview
Chloé Carpentier
Angela Me

Analysis and drafting
Barbara Hastie (Indiana University)
Kamran Niaz
Thomas Pietschmann

Editing
Jonathan Gibbons

Graphic design and production
Anja Korenblik
Suzanne Kunnen
Kristina Kuttnig
Federica Martinelli

Administrative support
Andrada-Maria Filip
Iulia Lazar

Review and comments
The *World Drug Report 2020* benefited from the expertise of and invaluable contributions from UNODC colleagues in all divisions.

The Research and Trend Analysis Branch acknowledges the invaluable contributions and advice provided by the *World Drug Report* Scientific Advisory Committee:

Jonathan Caulkins
Paul Griffiths
Marya Hynes
Vicknasingam B. Kasinather
Charles Parry
Afarin Rahimi-Movaghar
Peter Reuter
Alison Ritter
Francisco Thoumi

The analysis on access to controlled medicines is based on original data graciously shared by INCB and benefitted from the contribution of the Walther Center in Global Palliative Care of the University of Indiana.

EXPLANATORY NOTES

The designations employed and the presentation of the material in the *World Drug Report* do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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Since there is some scientific and legal ambiguity about the distinctions between "drug use", "drug misuse" and "drug abuse", the neutral term "drug use" is used in the *World Drug Report*. The term "misuse" is used only to denote the non-medical use of prescription drugs.

All uses of the word "drug" and the term "drug use" in the *World Drug Report* refer to substances controlled under the international drug control conventions, and their non-medical use.

All analysis contained in the *World Drug Report* is based on the official data submitted by Member States to the UNODC through the annual report questionnaire unless indicated otherwise.

The data on population used in the *World Drug Report* are taken from: *World Population Prospects: The 2019 Revision* (United Nations, Department of Economic and Social Affairs, Population Division).

References to dollars ($) are to United States dollars, unless otherwise stated.

References to tons are to metric tons, unless otherwise stated.

The following abbreviations have been used in the present booklet:

AIDS	acquired immunodeficiency syndrome
ATS	amphetamine-type stimulants
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FARC	Revolutionary Armed Forces of Colombia
ha	hectares
HIV	human immunodeficiency virus
INCB	International Narcotics Control Board
INTERPOL	International Criminal Police Organization
OECD	Organisation for Economic Co-operation and Development
REDD+	UN Programme on Reducing Emissions from Deforestation and Forest Degradation
S-DDD	defined daily doses for statistical purposes
UNDP	United Nations Development Programme
UNODC	United Nations Office on Drugs and Crime
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization

ACCESS TO CONTROLLED MEDICINES FOR PAIN MANAGEMENT

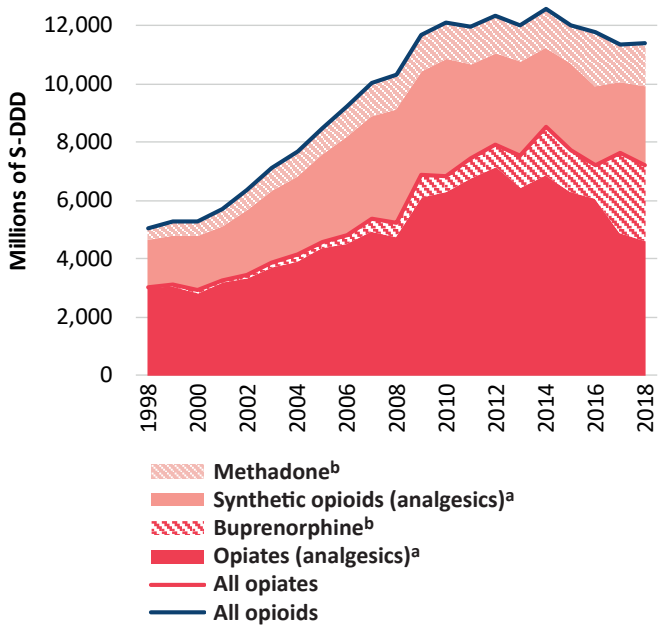
For nearly six decades, high-level declarations have been made that affirm the international community's collective goal of a balanced, integrated, comprehensive, multidisciplinary and scientific evidence-based approach to controlled medicines, especially with respect to access and availability for medical and scientific purposes. Despite recent growing global advocacy, high-level statements of intent and movements within international bodies and individual countries to address access to and availability of controlled medicines for pain management, progress has been extremely slow and significant challenges and barriers remain in improving the accessibility and availability of controlled medicines.[1, 2, 3, 4]

Global amounts of pharmaceutical opioids available for consumption

Access to and availability of controlled medicines for pain relief, i.e., opioids, are unequally distributed across the geographical regions and have had diverging trends in different regions. The amount of opioids (expressed in daily doses) available for consumption for medical purposes more than doubled globally over the period 1998–2010, followed by a period of stabilization and a decline over the period 2014–2018.

Most of the increase in the amount of pharmaceutical opioids available for medical consumption over the period 1998–2010 was of oxycodone (which experienced a tenfold growth over that period), hydromorphone (fivefold growth), hydrocodone (threefold growth) and oxymorphone (46,000-fold growth). Methadone and buprenorphine, the opioids used in medically assisted treatment of opioid use disorders, also saw marked increases in the amounts available for medical consumption at the global level. The amount of fentanyl available for medical consumption rose ninefold over the period 1998–2010.[5] Moreover, since 2000, only about 10 per cent of globally available morphine was reported to have been used for palliative care,

FIG. 1 Global amounts available for medical consumption of pharmaceutical opioids under international control, 1998–2018



Source: *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2).

Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. The statistics exclude preparations of opioids listed in Schedule III of the 1961 Convention. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report.

[a] Substances used as analgesics, i.e., excluding substances used in opioid substitution treatment.
[b] Substances used in opioid substitution treatment and as analgesics.

1 James F. Cleary and Martha A. Maurer, "Pain and policy studies group: two decades of working to address regulatory barriers to improve opioid availability and accessibility around the world", *Journal of Pain Symptoms Management*, vol. 55, No. 2 (February 2018), pp. S121–S134.

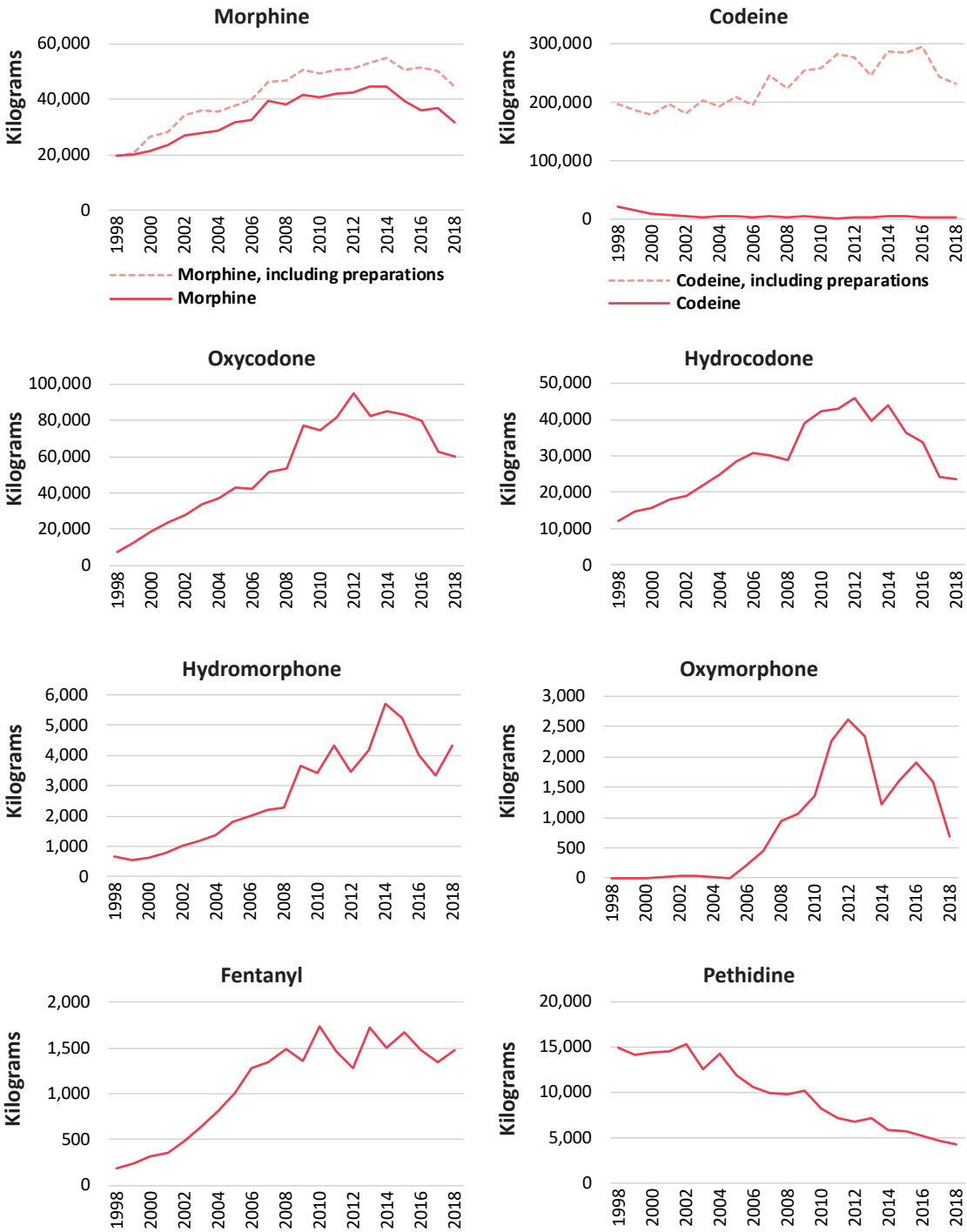
2 Lilian De Lima and Lukas Radbruch, "Palliative care in the Global Health Agenda", *Journal of Pain and Palliative Care Pharmacotherapy*, vol. 28, No. 4 (October 2014), pp. 384–389.

3 Liiz Gwyther, Frank Brennan and Richard Harding, "Advancing palliative care as a human right", *Journal of Pain Symptom Management*, vol. 38, No. 5 (September 2009), pp. 767–774.

4 Human Rights Watch, *"Please Do Not Make Us Suffer Anymore…": Access to Pain Treatment as a Human Right* (March 2009).

5 *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2), and previous years.

FIG. 2 Global amounts available for medical consumption of selected opioids (including preparations), 1998–2018



Source: *Narcotic Drugs 2018: Estimated World Requirements for 2019 – Statistics for 2017* (E/INCB/2018/2), and previous years.

Note: All these substances are controlled under the 1961 Convention.

while over 88 per cent was converted into codeine, the majority of which (89 per cent) was used to manufacture cough medicines.[6]

Since 2014, the decline in the amount of opioids available for medical consumption has been particularly pronounced for oxycodone, hydrocodone and hydromorphone, following stricter rules aimed at reducing diversion in North America. Prior to that, these substances were heavily diverted to markets for non-medical use, particularly in North America. Nonetheless, in 2018 that subregion continued to account for a major share of the global amounts available for medical consumption of hydromorphone (69 per cent), oxycodone (69 per cent) and hydrocodone (99 per cent).[7]

The amounts available for medical consumption of some of the other synthetic opioids used in pain management have been declining over the past two decades. Pethidine is one example, with a 70 per cent decline over the period 1998–2018, while amounts available for medical consumption of dextropropoxyphene, which was very popular in the 1990s, have decreased by more than 99 per cent over the past two decades as the substance was banned in a number of countries owing to concerns over serious side effects.[8] The amount of fentanyl available for medical consumption increased until 2010 but remained largely stable thereafter.[9]

By contrast, the amounts of buprenorphine and methadone available for medical consumption and used in the medically assisted treatment of opioid use disorders, have increased since 2014, especially of buprenorphine, which rose by more than 50 per cent over the period 2014–2018.[10] However, as with other pharmaceutical opioids, there are large differences from one country to another in the consumption patterns of buprenorphine and methadone for medical purposes, as seen in the coverage of opioid-agonist treatment for people with opioid use disorders.[11]

6 *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes* (E/INCB/2018/Supp.1).

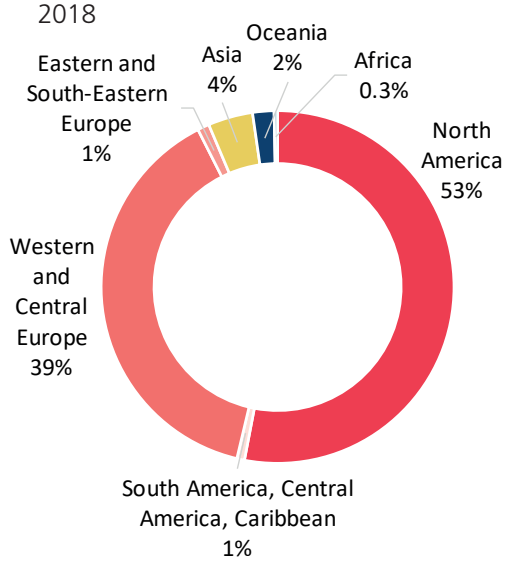
7 Ibid.

8 E/INCB/2019/2.

9 *Narcotic Drugs 2018: Estimated World Requirements for 2019 – Statistics for 2017* (E/INCB/2018/2), and previous years.

10 Ibid.

FIG. 3 Distribution of amounts available for medical consumption of codeine, fentanyl, morphine, pethidine and other opioids, expressed in standard defined daily doses (S-DDD), per subregion, 2018



Source: UNODC calculations based on *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2).

Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report.

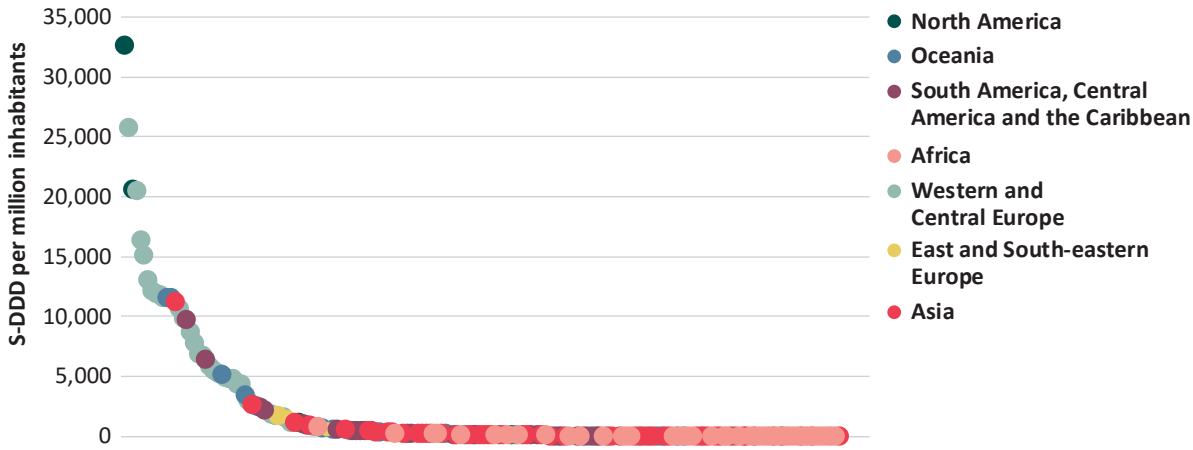
There is a gaping chasm between countries in the availability of opioids for medical purposes. On the basis of data on the amount of opioids available for medical purposes, there is a clear disparity between high-income countries versus low- and middle-income countries[12] for all opioids combined (i.e., codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine and methadone).

Data for 2018 show that more than 90 per cent of all pharmaceutical opioids that are available for medical consumption are in high-income countries: 50 per cent in North America, around 40 per cent in Europe, mostly in Western and Central Europe, and a further 2 per cent in Oceania, mostly Australia and New Zealand. Those high-income countries

11 See, for example, *World Drug Report 2018* (United Nations publication, Sales No. E.18.XI.9).

12 Based on the country classification 2014 of the World Bank Country and Lending Groups.

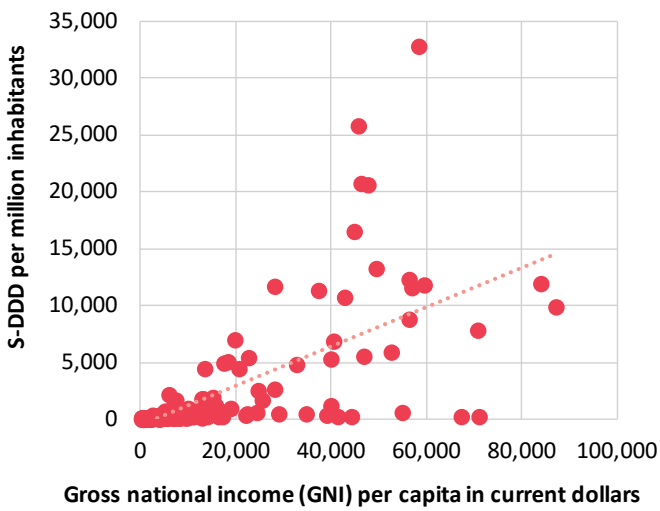
FIG. 4 Distribution of amounts available for medical consumption of codeine, fentanyl, morphine, pethidine and other opioids, per country, 2018



Source: UNODC calculations based on *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2).

Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report.

FIG. 5 Amounts available for medical consumption of codeine, fentanyl, morphine, pethidine and other opioids in individual countries, and per capita income, average 2014–2018



Source: UNODC calculations based on *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2).

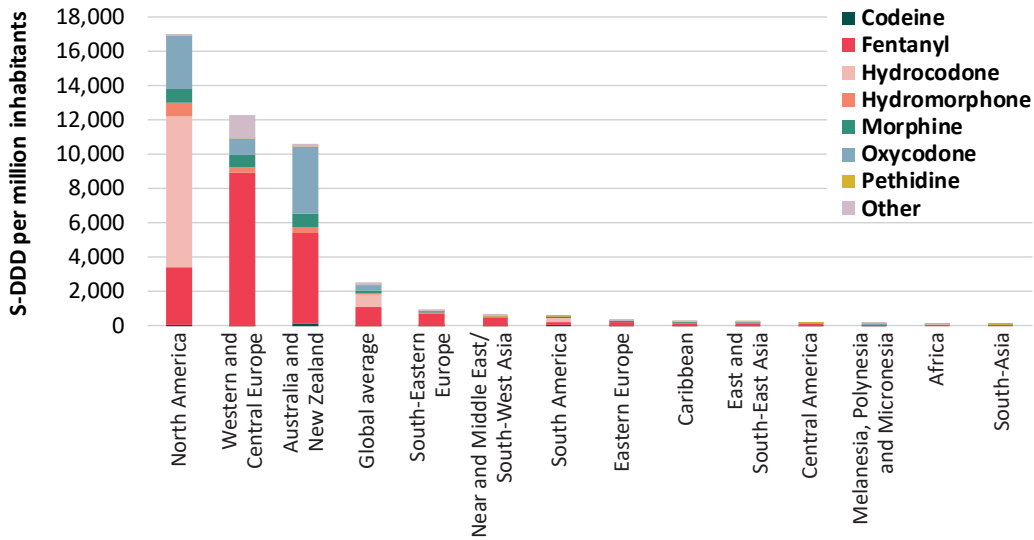
Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report.

comprise around 12 per cent of the global population. Therefore, low- and middle-income countries, which are home to some 88 per cent of the global population, are estimated to consume less than 10 per cent of the global amount of opioids available for medical consumption.

Even within each region or subregion, there is a significant disparity in the consumption of opioids for medical purposes. Over the period 2014–2018, average consumption of opioids in countries in North America ranged from some 100 defined daily doses for statistical purposes (S-DDD) per million inhabitants in Mexico to 32,700 S-DDD per million inhabitants in the United States of America. Similarly, in Western and Central Europe, estimates ranged from close to 500 S-DDD per million inhabitants in Malta to 25,800 S-DDD per million inhabitants in Germany. In Oceania, estimates ranged from, on average, 15 S-DDD per million inhabitants in Vanuatu to close to 11,600 S-DDD per million inhabitants in Australia, and in Asia, from 0.1 S-DDD per million inhabitants in Yemen to close to 11,300 S-DDD per million inhabitants in Israel.

Data show that there is a generally positive correlation between gross national income and the

FIG. 6 Amounts available for medical consumption of codeine, fentanyl, morphine, pethidine and other opioids, by region and subregion,[a] 2018



Source: UNODC calculations based on *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2).

Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report

[a] *The regions and subregions are those designated by UNODC in the World Drug Report; they may partly differ from those used by INCB in its publications.*

availability of pharmaceutical opioids for medical purposes (R=0.67 over the period 2014–2018), although a number of Asian countries and territories with high gross national income per capita (such as Macao, China, Hong Kong, China, Qatar, Singapore, Japan and Kuwait) have very low levels of opioid availability for medical purposes. This suggests that the level of national income is not the only factor that explains unequal availability across countries. A number of barriers to access to opioids for pain management are related to legislation, culture, health systems and prescribing practices.

Data also show discrepancies in the kind of pharmaceutical opioids available on the medical market. While data for North America show that hydrocodone is the most widely available pharmaceutical opioid (in terms of daily doses per inhabitant), fentanyl is the most widely available opioid in Western and Central Europe and in Australia and New Zealand. The availability for medical consumption of oxycodone is also relatively high in Australia and New Zealand and in North America. By contrast, the availability of codeine for medical consumption appears to be quite limited, although this may be a statistical artefact as most codeine is sold in the form of preparations, the sale of which – falling under Schedule III of the 1961 Single Convention – is internationally less strictly controlled and thus less well documented than the sale of other pharmaceutical opioids.

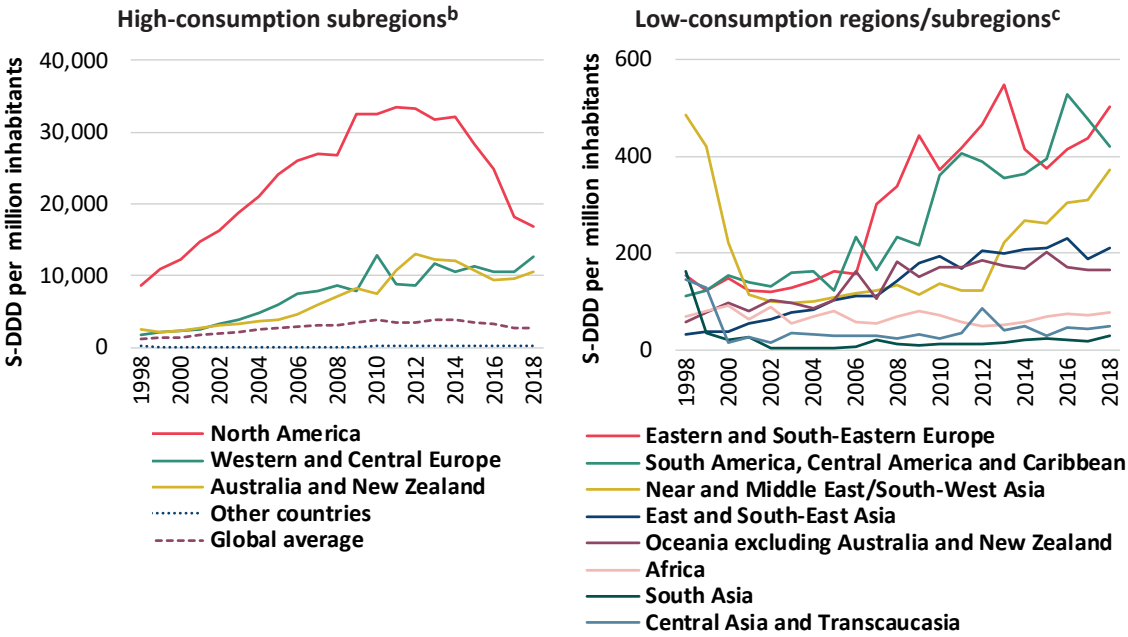
There have been concerted international and country-level efforts to address the inequity in the consumption of pharmaceutical opioids,[13] particularly in the case of morphine, which has been on the WHO Model List of Essential Medicines for management of pain due to cancer, HIV/AIDS and other serious illnesses, and due to traumatic injuries, burns and surgery, for nearly two decades.[14, 15] Despite this, morphine has not been accessible in

13 Cleary and Maurer, "Pain and policy studies group".

14 De Lima and Radbruch, "Palliative care in the Global Health Agenda".

15 WHO, *World Health Organization Model List of Essential Medicines: 21th List* (Geneva, 2019).

FIG. 7 Trends in availability of opioid analgesics for medical consumption, by region/subregion,[a] 1998–2018



Source: UNODC calculations based on *Narcotic Drugs 2019: Estimated World Requirements for 2020 – Statistics for 2018* (E/INCB/2019/2) and previous years.

Note: S-DDD refers to "defined daily doses for statistical purposes" as defined by INCB. S-DDDs are "technical units of measurement" for the purposes of statistical analysis and are not recommended daily prescription doses; actual doses may differ based on treatments required and medical practices. Details of S-DDDs used for these calculations are provided in the methodological annex of the present report.

[a] *Subregions and regions according to the classification used by UNODC in the World Drug Report; subregions and regions as defined partly differ from those used by INCB in its publications; extrapolation techniques have been used in case of missing data.*

[b] *Includes subregions above the global average, i.e., North America, Western and Central Europe, Australia and New Zealand.*

[c] *Includes regions and or subregions below the global average, i.e., Africa, Asia, Eastern Europe, South-Eastern Europe, the Caribbean, Central America and South America, as well as Melanesia, Micronesia and Polynesia, i.e., all regions and subregions except those of North America, Western and Central Europe, and Australia and New Zealand.*

adequate amounts, in the appropriate dosage forms, with assured quality and adequate information and at a price that an individual and the community can afford.[16, 17]

In 2018, 87 per cent of the global amount of morphine available for medical consumption was estimated to have been consumed in high-income countries, which are home to 12 per cent of the global population. While the relative importance of the amounts of morphine available for medical consumption in low- and middle-income countries has increased slightly since 2014 (from 9.5 to 13 per cent in 2018) the amount of morphine available per person per country is still infinitesimally small to non-existent in many developing countries, particularly in South Asia and in Africa.[18, 19] Even though countries may have morphine available for medical use, many people still have limited access to it.[20, 21] WHO estimates that globally, each year 5.5 million

16 WHO, *Integrating Palliative Care and Symptom Relief into Primary Health Care: A WHO Guide for Planners, Implementers and Managers* (Geneva, 2018).

17 Felicia Marie Knaul and others, "Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage – the *Lancet* Commission report", *Lancet*, vol. 391, No. 10128 (April 2018).

18 E/INCB/2018/Supp.1.

19 E/INCB/2019/2.

20 See section below on barriers to access to and availability of controlled medicines for pain management and palliative care.

21 E/INCB/2019/2.

The role of complementary and alternative medicine in the management of chronic non-cancer pain

The use of strong opioids, especially morphine, is generally considered the principal treatment for the management of pain in palliative care for cancer patients.[a] The treatment of chronic non-cancer pain, which is among the most prevalent health conditions in many countries, is often considered more difficult to manage, and its treatment is sometimes more controversial.[b] Chronic non-cancer pain is defined in scientific literature as pain lasting for more than three months that stems from injuries or illnesses other than cancer.[c] It is also considered that chronic pain results from a combination of biological, psychological and social factors, and thus requires a multifactorial approach to pain assessment, patient monitoring and evaluation and long-term management. Some of the common conditions that cause chronic pain include neuropathic pain, fibromyalgia that may be caused by damage to the peripheral or central nervous system, low back pain and osteoarthritis. While opioids are used extensively in the management of non-cancer chronic pain in some countries and settings, in others, other drugs, as well as complementary and alternative medicines, are used effectively in the management of chronic pain whether related to cancer or not.[d, e]

Other than opioids, non-steroidal anti-inflammatory drugs are used in patients with osteoarthritis and rheumatoid arthritis and low back pain. The efficacy of antidepressant drugs has been reported for the management of neuropathic pain, fibromyalgia, low back pain and headaches. Anti-convulsant drugs such as gabapentin, pregabalin and carbamazepine have proved effective in the treatment of chronic non-cancer pain.[f]

As part of complementary and alternative medicine, spinal manipulation is the most commonly used therapy for low back pain.[g] Massage is another modality commonly used as a supplemental treatment for patients with chronic non-cancer pain. Similarly, evidence supports the effectiveness of acupuncture for the treatment of chronic low back pain, while results on the effectiveness of acupuncture in the reduction of pain associated with fibromyalgia and neck pain are promising.[h]

Psychological interventions such as cognitive behavioural therapy, relaxation training and hypnosis are the most commonly used techniques in the management of chronic pain.[i] The aim of such interventions is to help the patient cope with the symptoms of pain, learn skills for adaptation and self-management, and reduce disability associated with symptoms, rather than eliminate physical causes of pain per se.[j]

a WHO, *Ensuring Balance in National Policies on Controlled Substances: Guidance on Availability and Accessibility of Controlled Medicines* (Geneva, 2011).

b Nora D. Volkow and A. Thomas McLellan, "Opioid abuse in chronic pain: misconceptions and mitigation strategies", *New England Journal of Medicine,* vol. 374, No. 13 (March 2016), pp. 1253–1263.

c Dennis C. Turk, Hilary D. Wilson and Alex Cahana, "Treatment of chronic non-cancer pain", *Lancet,* vol. 377, No. 9784 (June 2011), pp. 2226–2235.

d Ibid.

e Priyanka Singh and Aditi Chaturvedi, "Complementary and alternative medicine in cancer pain management: a systematic review", *Indian Journal of Palliative Care*, vol. 21, No. 1 (2015), pp. 105–115 (2015).

f Turk, Wilson and Cahana, "Treatment of chronic non-cancer pain".

g Ibid.

h Ibid.

i Singh and Chaturvedi, "Complementary and alternative medicine in cancer pain management".

j Turk, Wilson and Cahana, "Treatment of chronic non-cancer pain".

terminal cancer patients and 1 million end-stage HIV/AIDS patients do not have adequate treatment for moderate to severe pain.[22]

In recent years the huge disparity between countries in the accessibility of opioids for medical purposes has been reduced slightly: declines in opioids available for medical consumption are reported in North America, while overall increases are reported in several other subregions, most notably South America and the Near and Middle East/South-West Asia, where availability has been low. This suggests an overall increase in the availability of opioids in developing countries, although that availability was starting from, and remains at, a low level. Daily per capita availability of pharmaceutical opioids more

22 WHO, *Integrating Palliative Care and Symptom Relief into Primary Health Care.*

than doubled in the regions and subregions where availability was below the global average (i.e., Africa, Asia, South America, Central America, the Caribbean, Eastern and South-Eastern Europe, Melanesia, Micronesia and Polynesia); taken together, availability in these regions and subregions increased from an average of 70 S-DDD per million inhabitants in 2010 to 180 S-DDD in 2018 (7 per cent of the global per capita average).[23]

By contrast, the availability of pharmaceutical opioids for medical purposes declined by almost 50 per cent in North America, from 32,550 S-DDD per day per million inhabitants in 2010 to 16,910 S-DDD in 2018, thus approaching the levels reported in Western and Central Europe (12,660 S-DDD) and in Australia and New Zealand (10,530 S-DDD) in 2018. Nevertheless, per capita availability of pharmaceutical opioids for medical purposes in North America remains comparatively high (almost eight times the global average), in particular when compared with the extremely low levels in Africa and South Asia, as well as in Central Asia and Transcaucasia, where there are no signs of increases.[24]

INCB notes that the increase in the use of expensive synthetic opioids over the past two decades, which has contributed to overconsumption and an "overdose epidemic" in some developed countries, has not been matched by an increase in the use of affordable morphine, especially in low- and middle-income countries.[25]

Barriers to access to and availability of controlled medicines for pain management and palliative care

The reasons for inequities in access to and availability of opioids for pain management are extraordinarily complex and include historical vestiges across multiple systems, i.e., government, health care and society, as well as modern-day challenges, including the concerns arising out of the opioid overdose crisis.

There are several challenges and barriers to access to controlled medicines for pain management, all of which are complex, multitiered and interrelated. These include, but are not limited to, trade systems, education, justice, foreign affairs, workforce and development, but perhaps the most recognized and salient among them are legislation and regulatory systems, national supply management systems and health systems. Each of these directly and indirectly influences the barriers to both access to and availability of controlled medicines for pain management and palliative care.[26] These challenges and barriers, including the progress that has been made globally to address them, are discussed below.

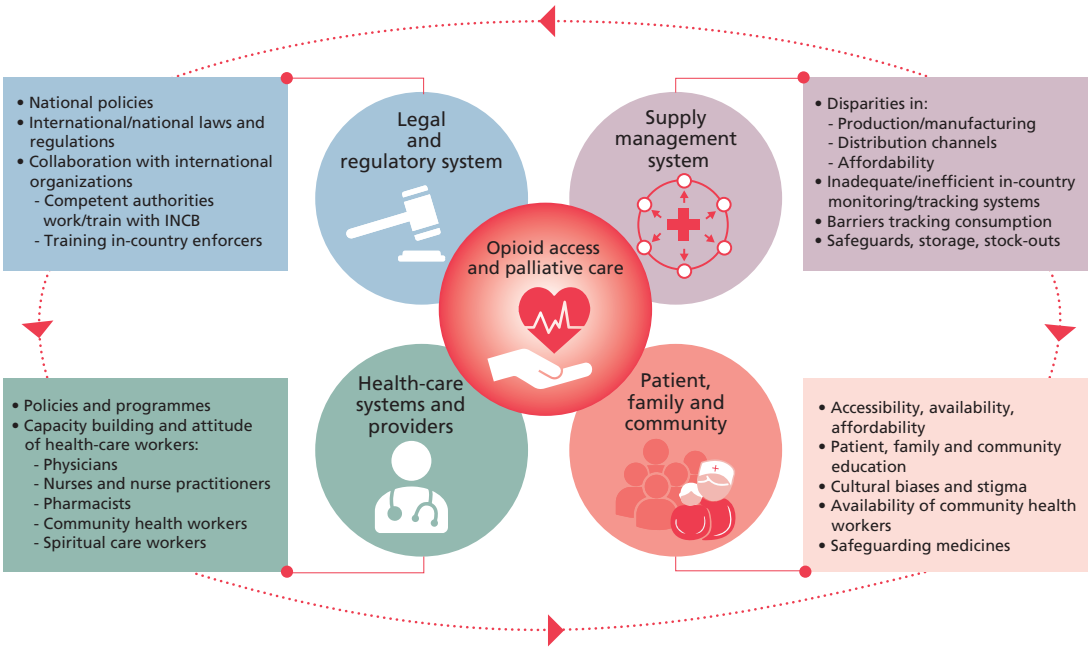
Legislation and regulatory systems

In 2018, INCB conducted a survey[27] of competent national authorities in order to assess the barriers and evaluate progress made at the national level in improving access to and availability of controlled substances for pain management since the previous surveys in 1995, 2010 and 2014. Of the 130 countries (representing 78 per cent of the global population) that responded, 40 per cent indicated that over the previous five years, legislation and/or regulatory systems had been reviewed or changed to affect the availability of controlled medicines. Some countries reported unspecified "general changes," others indicated that changes were made to the status of controlled substances, while some introduced electronic measures to facilitate prescriptions and/or procurement.

Although regulations that have limited the availability of controlled medicine have been reduced in many countries since 1995, challenges remain. In 2018, 26 per cent of the countries that responded to the survey mentioned the existence of legal sanctions for unintentional errors in handling opioid analgesics. The legal threat was reported to be a major factor in the decisions of some doctors not to procure, stock or prescribe opioids, thus limiting their access. Similar challenges affect the number of pharmacies that are willing to dispense opioids.[28] In 2018, the three major impediments to the

23 E/INCB/2019/2.
24 Ibid.
25 E/INCB/2018/Supp. 1.
26 E/INCB/2018/Supp.1.
27 Ibid.
28 Ibid.

Systems and influences affecting access to and availability of controlled medicines



availability of opioids, as reported by the countries responding to the survey, were lack of training and awareness of health-care professionals, fear of addiction, and problems in sourcing opioid medications.[29]

Some evidence of progress in improving access to and availability of controlled medicines for pain management is suggested in a small proportion (16 per cent) of countries that reported that legislation and regulations had been modified to broaden the range of health-care professionals who are allowed to prescribe controlled substances. Overall, 123 countries reported that they allow medical specialists to prescribe controlled substances for pain management and palliative care, while 98 countries also allow general practitioners. Challenges continue to limit the range of health-care providers who can prescribe opioid analgesics, as only nine countries surveyed reported that their legislation allowed nurses, including nurse practitioners, to prescribe those drugs.[30] This legislative and regulatory limitations on who can prescribe controlled substances perpetuates a barrier to access, particularly in low- and middle-income countries without decentralized health-care services and/or where the number of physicians or doctors is limited.

In 2018, INCB also surveyed civil society organizations and received responses from 30 organizations based in 23 countries in Asia, Africa, Europe and the Americas.[31] More than half of the organizations that responded to the questionnaire reported changes to, or reviews of, legislation or regulations aimed at simplifying and streamlining processes and removing unduly restrictive regulations in order to ensure accessibility of controlled substances and maintain adequate control systems in their respective countries. Although this is a limited sample of civil society organizations, it demonstrates a relatively positive perception of some of the actions that countries have taken to change or streamline the laws and regulations that limit access to and availability of controlled medicines.

National supply management systems

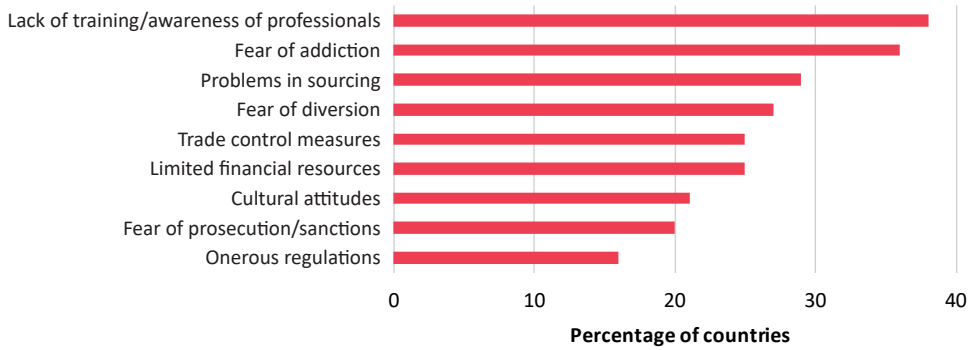
Functional, effective and efficient national supply chain management systems that are guided by the international drug control conventions are critically important to achieving the balance between preventing diversion and ensuring adequate access to and

29 Ibid.

30 Ibid.

31 Ibid.

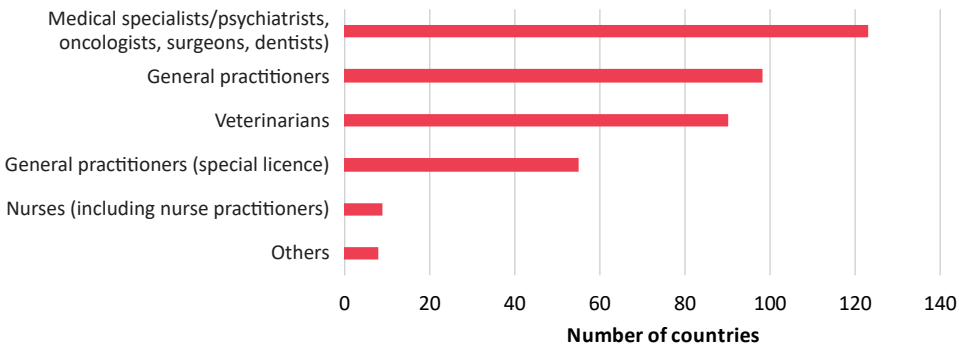
FIG. 8 Reported impediments to the availability of controlled medicines for pain management, 2018



Source: *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes* (E/INCB/2018/Supp.1).

Note: The percentage represents the proportion of responding countries that mentioned each of the factors as an impediment to the availability of pain medications. Multiple responses were possible.

FIG. 9 Health-care providers allowed to prescribe controlled substances, 2018



Source: *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes* (E/INCB/2018/Supp.1).

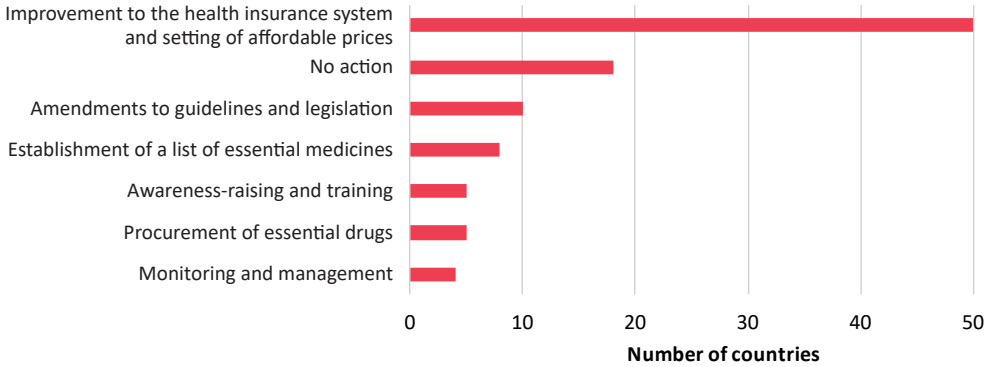
Note: The data represent the number of countries who responded to the survey and indicated the kind of health-care providers who can prescribe controlled substances, including opioids for pain management and palliative care. Multiple responses were possible.

availability of controlled medicines for pain management and palliative care. Within national supply chains and management systems, diverse domains affect export, import, procurement and monitoring of access to and availability of controlled medicines, to name but a few. Within this chain, primary areas that affect the accessibility of controlled substances in a country are: (1) processes to produce national estimates of controlled medicines for pain management and palliative care; (2) assessment of the availability of controlled substances; and (3) developing benchmarks (compared to thresholds for high and low use of controlled substances).

Countries report that import and export control measures or restrictions are among the main impediments to ensuring the availability of controlled substances. To address this, INCB has introduced a number of online and electronic systems to streamline and simplify import and export processes within countries.[32] One improvement over the years has been the gradual establishment of electronic tools for processing import and export authorizations, with competent national authorities in 50 countries reporting the use of such tools in 2018. In addition, with a view to facilitating the production of reliable estimates of the quantities of controlled substances needed nationally, guidelines

32 These include the National Drug Control System and the International Import and Export Authorization System (I2ES).

FIG. 10 Steps taken by countries to improve the accessibility of controlled substances, 2018



Source: *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes* (E/INCB/2018/Supp.1).

Note: The data represent the number of countries that responded to the survey and indicated the steps taken to improve the accessibility of controlled substances, including opioids for pain management and palliative care. Multiple responses were possible.

for estimating the national requirements of controlled substances have also been made available in recent years.[33] Nevertheless, many countries, for a myriad of reasons, continue to report to INCB that they are unable to properly estimate or to monitor consumption of controlled substances and continue to inadequately or insufficiently estimate opioid requirements.

Health systems

Improving the accessibility and availability of controlled substances, including opioids for pain management and palliative care, also requires improving health systems to ensure controlled substances are prescribed and administered in a rational and efficient manner.[34] Overall, the major steps taken by countries that responded to the INCB survey in 2018 included improvements to the health insurance system and the setting of affordable prices to improve the accessibility and availability of controlled substances, including opioids for pain management and palliative care.

Training and capacity-building

The training and capacity-building of health-care professionals in all domains is key to ensuring access to and availability of opioids for pain management. In this regard, 71 countries (or 62 per cent of those that responded to the INCB survey) reported that palliative care was included in the educational curricula in medical schools. Similarly, 76 countries reported that continuing education, training and information on palliative care, including on the rational use and the importance of reducing the misuse of prescription drugs, was provided to health-care professionals. However, 11 countries reported that education on palliative care was provided for only a limited number of medical specialities, such as oncology, and a further 43 countries reported that palliative care was not included as a discipline in their medical education programme. While nine countries reported that they did not have a medical school, four countries noted that they would build palliative care into the medical curriculum from the onset. This demonstrates an awareness, and a concerted effort, on the part of the medical profession of the importance of palliative care training across the life course of wider medical training.

In addition, 41 countries noted that national competent authorities did not have training programmes on the rational use of controlled substances and that this was either due to a lack of resources or because it was "not a priority" for the Government.

Regarding other fields of specialty with interaction with patients and which are an important resource in health-care delivery, especially in low- and middle-income countries where the availability of doctors is limited, the nursing profession has made significant strides in incorporating palliative care and end-of-life care training, not only in the curriculum for

33 INCB and WHO, *Guide on Estimating Requirements for Substances under International Control* (Vienna, 2012).

34 E/INCB/2018/Supp. 1.

nurses but also for them to train other health-care providers within the larger health-care community.[35, 36, 37] For example, many non-governmental organizations in Africa have initiated programmes for training community health-care workers in palliative care, who do not necessarily require licensure and do not undergo extensive formal training in medicine, pharmacy or nursing.[38] In resource-constrained settings, community health-care workers are considered quite instrumental in providing care outside urban areas, in villages and other community settings with limited access to formal health-care services and facilities.[39]

Pharmacy training is gaining attention given the frontline role of pharmacies in making opioids accessible for patients. Palliative care training is not mandatory but many programmes, including by non-governmental organizations and other advocacy organizations, are targeting pharmacy professionals.[40]

Education and awareness-raising

Lack of awareness and "fear of addiction", i.e., the concern that patients who are prescribed strong opioids are likely to develop dependence or iatrogenic addiction,[41] were reported to be among the top impediments to access to controlled substances reported by 130 countries.[42] Fear of addiction seems to be related to a lack of awareness and training, and to cultural attitudes.[43] These barriers influence all systems and the people in them, including national and international policymakers, regulators, health-care professionals, community advocates, patients and the public at large.

Moreover, at the global level, concerns over the non-medical use of pharmaceutical opioids, triggered by the opioid crisis in North America, North Africa, and West and Central Africa has created a challenge for increasing the availability of opioids for pain management and palliative care due to the concomitance of the two opposing needs. As a result, low- and middle-income countries, not only in Africa but also in other regions, some of which have extremely limited access to opioids, are now facing diminished access and have to counter increased fear of addiction – that may result from a lack of knowledge about substance use disorders and the science of prevention and treatment – among policymakers, national authorities, health-care providers and even among the public.[44, 45, 46, 47]

Countries that reported to the 2018 INCB survey mentioned specific initiatives undertaken by national competent authorities to enhance the understanding of, awareness of and education about, and address cultural resistance to and the stigma associated with, the use of opioids and other controlled substances: education for representatives of the pharmaceutical community, professionals and consumer groups; and the promotion of ethical attitudes among medical doctors and pharmaceutical companies, in particular to reduce the excessive marketing of opioids.[48]

35 A leading programme is the End-of-Life Nursing Education Consortium, which is based on a train-the-trainer model and has been implemented in over 100 countries worldwide.

36 Betty Ferrel, Pam Malloy and Rose Virani, "The end of life nursing education nursing consortium project", *Annals of Palliative Medicine*, vol. 4, No. 2 (April 2015), pp. 61–69.

37 Henry Ddungu, "Palliative care: what approaches are suitable in developing countries?", *British Journal of Haematology"*, vol. 154, No. 6 (September 2011), pp. 728–735.

38 The African Palliative Care Association is one leading organization working in this area. See, for instance, *Annual Report: Building Bridges 2017-18* (Kampala, 2019).

39 Katherine Pettus and others, "Ensuring and restoring balance on access to controlled substances for medical and scientific purposes: joint statement from palliative care organizations", *Journal of Pain Palliative Care and Pharmacotherapy*, vol. 32, No. 2–3 (September 2018), pp. 124–128.

40 African Palliative Care Association, *Annual Report: Building Bridges 2017-18*.

41 A structured review of 67 studies found that 3 per cent of chronic non-cancer patients regularly taking opioids developed opioid use disorders. See David A. Fishbain and others, "What percentage of chronic non-malignant pain patients exposed to chronic opioid analgesic therapy develop abuse/addiction and/or aberrant drug related behaviours? A structured evidence-based review", *Pain Medicine*, vol. 9, No. 4 (May 2008), pp. 444-459.

42 E/INCB/2018/Supp.1.

43 *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes – Indispensable, Adequately Available and not Unduly Restricted* (E/INCB/2015/1/Supp.1).

44 Knaul and others, "Alleviating the access abyss in palliative care and pain relief".

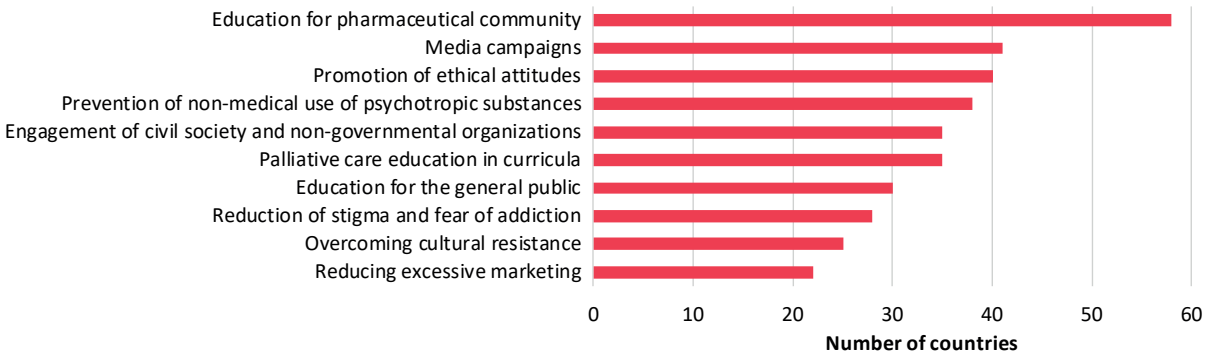
45 African Palliative Care Association, *Guidelines for Ensuring Patient Access to, and Safe Management of, Controlled Medicines* (Kampala, 2013).

46 De Lima and Radbruch, "Palliative care in the Global Health Agenda".

47 Pettus and others, "Ensuring and restoring balance on access to controlled substances for medical and scientific purposes".

48 E/INCB/2018/Supp.1.

FIG. 11 Education and awareness-raising initiatives, 2018



Source: *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes* (E/INCB/2018/Supp.1).

Note: The data represent the number of countries that responded to the survey and indicated the initiatives taken by the competent national authorities for education and awareness to improve the accessibility of controlled substances, including opioids for pain management and palliative care. Multiple responses were possible.

Affordability

The availability of pain medications is determined by factors that include their physical availability and practical accessibility. These in turn depend on the extent to which pain medications are procured and the existence of an appropriate and viable health system. Furthermore, the affordability of those medications is central to all of the elements, especially in the context of universal health coverage. Affordability is addressed, among other ways, by ensuring funding for the purchase of opioid medications as well as developing and improving health insurance and reimbursement schemes that guarantee access to pain medication.[49] In 2018, 50 countries reported to INCB that steps had been taken towards improving their health insurance systems and setting affordable prices for essential medicines, including opioids. However, limited resources can impair even a well-intended Government from procurement or preclude it from providing or subsidizing controlled medicines for pain management. Other issues that may affect the affordability of pain medications include licensing, taxation, poor or inefficient distribution systems, lack of reimbursement and lack of availability of inexpensive formulations. Even in the case of Governments that are strongly committed to addressing challenges and barriers to access, financial resources may not be available to make systemic changes. Moreover, because of the high cost of pain medications, in many high-income countries and in most low- and middle-income countries, where a large number of people are not covered by either health insurance or a national health-care system, many people can encounter difficulties in accessing the pain medications that they need.[50]

International cooperation and coordination

For many years, Governments, academic institutions and non-governmental organizations have worked across and within systems nationally and internationally on the central principle of balance between access to controlled substances for medical and scientific purposes and prevention of their diversion. Over the past 20 years, demonstrable progress has been made in over 30 countries in this regard.[51] Similarly, collaboration between international stakeholders that aim to improve the legislative framework, build capacity of health-care professionals, and work with patients, families and the public in order to improve access to and availability of controlled substances has shown the importance of working across these major domains. Each of them could act as an impediment or serve to enable access to opioids for pain management and palliative care at the country level.

49 Ibid.

50 Ibid.

51 Cleary and Maurer, "Pain and policy studies group".