

REVIEW

Access to Controlled Medications: Barriers, Measuring Adequacy of Consumption, and Current Developments

Willem Scholten

Willem Scholten Consultancy, NL

Twitter: @WKScholten

Access to controlled medications is problematic in many countries, in spite of the objectives of the international substance control conventions. The review describes barriers for accessing medications and how to assess the adequacy of opioid analgesic consumption globally. As current trends in consumption, it discusses the lack of progress of improving access and the threat of the false narrative that people who suffer moderate to severe pain are the cause of an epidemic of opioid intoxications. Finally, it questions the feasibility of an approach which requires large numbers of anaesthesiologist for treating chronic pain, and wonders what the effect of the COVID-19 pandemic on accessibility to controlled medications will be.

Keywords: Analgesics; Opioids; Pain Management; Health Policy; Needs Assessment

Introduction

Access to controlled medications is problematic in many countries, 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 (United Nations Office on Drugs and Crime 2009a; United Nations Office on Drugs and Crime 2009b).

Psychoactive substances are indicated for a number of conditions and diseases, including pain, anaesthesia, opioid use disorder, dyspnoea, epilepsy, obstetric emergencies, and psychological crises. Moreover, other than many people think, it should be noticed that opioid analgesics are not needed for cancer pain or for palliative care only, but for a wide range of acute and chronic moderate and severe types of pain (Häuser et al. 2015; Moisset and Martinez 2016). The continuing under availability of opioid analgesics is widely documented (International Narcotics Control Board 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). However, many other controlled medications are not readily available. For instance, affordable anti-epileptics are often not available in developing countries, due to their classification as controlled substances (Milani and Scholten 2011).

In 2006, the World Health Organization estimated that in countries with low to non-existent access, each year tens of millions of patients are suffering without adequate pain treatment. These include 1 million end-stage HIV/AIDS patients, 5.5 million terminal cancer patients, 0.8 million patients suffering injuries, caused by accidents and violence, and furthermore, patients with chronic illnesses, patients recovering from surgery, women in labour (110 million births each year), and paediatric patients (World Health Organization 2006).

The Lancet Commission on Palliative Care and Pain Relief estimated that more than 61 million people experienced serious health-related suffering in 2015, including 25.5 million people who died, which is almost half of reported deaths worldwide. More than 80% of these people live in lower- or middle-income countries where access to basic palliative care and medicine-based pain relief is extremely limited or non-existent (Knaul et al. 2018).

The number of people potentially not being treated for pain is much higher: in 2015, 5.7 billion people lived in countries where the per capita consumption of opioid analgesics is very or extremely low, and

another half a billion lived in countries for which no data were available, but which have so many similarities to the former countries, that it is likely that their populations have no access either. This is a constant percentage of the world population and thus, with an increasing world population, the number of people potentially affected is increasing (Scholten et al. 2019; Scholten et al. 2020).

Authorities around the world tend to overemphasise the importance of preventing non-medical use, while not paying attention to the importance of medical use. Non-medical use is perceived as an important problem, but the burden of disease from pain is at least 37 times larger than the burden of disease from substance use disorder (Scholten and Henningfield 2016a).

The World Health Organization published policy guidelines (currently under revision, see below) in order to encourage policies that optimize the balance between the prevention of non-medical use and the accessibility for medical purposes of controlled medications (World Health Organization 2010). The Pompidou Group of the Council of Europe published Guiding Principles focusing especially on access to pharmacological treatment of opioid use disorder (Pompidou Group 2017).

Barriers for Accessing Controlled Medications

Reasons for low consumption levels vary by country. It is possible that opioids are not stocked by the pharmacy (unavailable), that the doctor is not willing to prescribe, the pharmacy not willing to dispense, or the authorities prevent prescribing (inaccessible), or the medication can be too expensive (unaffordable). Regardless whether they are unavailable, inaccessible or unaffordable, in all three cases the patient will not be able to benefit pain relief (Scholten 2013).

Low availability, low accessibility and low affordability can have a variety of causes, which need accurate analysis for improving the situation. Four categories of barriers can be distinguished: legislative and policy barriers, knowledge barriers, attitudes barriers, and economic barriers (World Health Organization 2010).

Legislative and policy barriers consist usually of too strict rules, often not contributing to the prevention of non-medical use, but effectively blocking rational medical use. One study analysed the legislation in 11 countries in Eastern Europe and identified for each country between 22 and 128 rules that were a potential barrier. Between 6 and 76 rules related to prescribing and dispensing of opioid medications, and between 15 and 102 related to access to opioid agonist treatment for treatment of opioid dependence (Vranken et al. 2018). Such rules are often more perceived as a barrier by health-care professionals and other stakeholders, than by civil servants: 55–57% of health-care professionals rated excessive regulation and/or bureaucracy as having a major impact, against 20% of the policy makers (Vranken et al. 2019). The GOPI project identified undue regulation of opioid analgesics worldwide (Cherny et al. 2013).

Although most legislative barriers stem from national regulations, there is also one specific regulatory barrier that originates from the Single Convention on Narcotic Drugs: the estimate system. It was introduced in 1931 in analogy of the Soviet planning economy and later included in the Single Convention (Anonymous 1931; United Nations Office on Drugs and Crime 2009b). The Single Convention requires that all countries submit an annual estimate for the amount of controlled substances they need. Without a sufficient estimate submitted to the International Narcotics Control Board (INCB), other countries will refuse exportation to such a country. In spite of guidance developed by the World Health Organization (WHO) and INCB, many countries do not submit adequate estimates to INCB, leading to supply shortages again and again (International Narcotics Control Board and World Health Organization 2012).

Knowledge among health-care professionals is another problem for the use of controlled medications. Although the prescription of opioid analgesics is not difficult, due to the development of tolerance, there are a few peculiarities that prescribers need to know. The most important is how to safely increase the dosage on initiation of pain therapy (maximum increase 50% per 24 hours), and the other is how to decrease on cessation (taking from a few days after a brief episode of administration up to several months after chronic administration of long-acting opioids). Many prescribers do not know that initiation and cessation are different from most other medications, and many hand and textbooks do not provide this information either (Scholten 2012). This leads to potentially dangerous situations.

Low levels of pain management education were identified by a study in 11 Eastern European countries and another study that covered most of Europe (Radbruch et al. 2014; Briggs et al. 2015). The latter found very low numbers of study hours and even the absence of pain management in the curriculum of many medical schools.

Also attitudes both among professionals and the lay population may lead to avoidance and refusal of therapy that could benefit the patient. Often this has to do with the idea that 'everybody will become dependent upon his/her first dosage', even in situations where the problem of dependence is irrelevant (e.g. terminal disease) (Krakauer et al. 2010). However, two Cochrane reviews showed that there is no evidence that the risk

of developing a substance use disorder is justifying the withholding of opioid analgesics to people with pain (Minozzi, Amato and Davoli 2013) and that less than 1% of people to whom opioid analgesics are prescribed will develop dependence (Noble et al. 2010). Accurate information, therefore, can avoid inappropriate attitudes. Also the use of neutral, precise and respectful (NPR) language may contribute (Scholten et al. 2017).

Economic barriers are not specific for controlled medications, but a more general problem related to pharmaceutical products. Yet some mechanisms may be specific for controlled medications: e.g. (state) monopolies for the distribution of some medications in some countries; and complex procedures to obtain licenses and import permits, making the marketing of a product expensive and commercially unattractive, in particular in smaller countries.

Although access to all classes of controlled medications mentioned above seems to be difficult around the world, research has been conducted almost exclusively on opioid medications, and in particular opioid analgesics. This is not surprising, because of opioid-specific barriers. Their existence can be demonstrated by comparing a study by Health Action International and one by the International Association for Hospice and Palliative Care. Without opioid-specific barriers, availability would be equal for opioid analgesics and non-opioid medications. However, from these studies, which used the same methodology, we may conclude that availability of opioid analgesics is one quarter to half that of non-opioid medications (Cameron et al. 2009; Pastrana et al. 2017). As availability is a condition for accessibility, this shows that access to opioid medications is more difficult in many countries than access to other medications, including other classes of controlled medications such as benzodiazepines (Scholten et al. 2020).

Measuring Consumption and Its Adequacy

Non-benchmarking methods

Traditionally, WHO has considered opioid analgesic consumption as an indicator for access to pain management (Gilson et al. 2013). Usually, morphine equivalents (ME) are used for this purpose. Furthermore, to be able to compare countries, it should be expressed on a per capita basis (Scholten 2013).

Consumption data for narcotic drugs (i.e. those substances regulated under the Single Convention on Narcotic Drugs, e.g. opioid analgesics) are collected already for a long time. They are collected and published by INCB in their most elementary form: the absolute amount by country and by substance. INCB's mandate is based on the Single Convention on Narcotic Drugs. It goes back to the 1930s, long before the Single Convention was enacted. At the time, INCB's predecessor, the Permanent Narcotics Control Board, collected these statistics. All countries being a party to the Single Convention mandatory submit their annual narcotic drugs consumption to INCB and therefore, the INCB is a reliable source for global consumption data. Annually in March each year, INCB publishes statistical data with a two years delay. Thus, in March 2020, statistics for 2018 became available (International Narcotics Control Board 2020).

In addition to the work of INCB, the former Pain and Policy Studies Group (PPSG) at Wisconsin University, Madison, WI, USA, built a global database on opioid analgesic consumption based on INCB data. Since the late 1990s it collected data for the most frequently used opioids, converted them into morphine equivalents per capita and published these on its website (Cleary and Maurer 2018). PPSG's work did not extend to the assessment of adequacy. However, the distribution curve of consumption is typically a logarithmic curve with large differences between the lowest and the highest country and many countries at low levels with a few high developed countries at the higher levels (Seya et al. 2011; Duthey and Scholten 2014; Scholten et al. 2019; Scholten et al. 2020). Therefore, although it did not indicate a right level, the work of PPSG made it self-evident that there is a large number of countries with under consumption.

Benchmarking methods

ACM and AOC Index

If the measurement is intended to assess whether the level is adequate for the purpose of managing pain, a benchmark is essential and how such a benchmark was established should be documented.

Adequacy of consumption has been calculated since 2006, first by WHO as the Access to Controlled Medicines Measure (ACM), then modified into the Adequacy of Opioid Consumption Index (AOC Index). Both ACM and AOC Index are based on the WHO Calculation Method for Drug Utilization Studies (Hogerzeil 1986; Action Programme on Essential Drugs and Vaccines 1988; Seya et al. 2011; Duthey and Scholten 2014; Scholten et al. 2019; Scholten et al. 2020). In this method, the average per capita consumption of a number of well-performing countries (in this case the top 20 of the Human Development Index) is considered to be an adequate level. In the AOC Index, this level is represented by an index ≥ 100 . Lower numbers represent a lower level of adequacy. There are several differences between the ACM and AOC Index methods, the most important being the ACM additionally including morbidity levels for three important conditions combined

with extrapolation to the need for all conditions with pain (Seya et al. 2011; Duthey and Scholten 2014). In the AOC Index, these morbidity statistics were abandoned because of the complexity of the procedures and problems obtaining reliable data (Scholten et al. 2019).

The WHO Calculation Method for Drug Utilization Studies was validated by studies by Hogerzeil (1986). There is also some evidence from the Netherlands that this method applied in the form of the AOC Index is meaningful. A meta-analysis including studies from the Netherlands from 1995 to 2009 found that 43% of chronic non-cancer pain reported not to receive pain treatment and 79% of patients believed their pain is inadequately treated (Bekkering et al. 2011). This leaves 57% receiving pain treatment and 21% of patients considering the pain to be treated adequately, while the ACM for 2006 was 51% adequacy for the Netherlands (Seya et al. 2011). Thus, figures found by Bekkering (2001) and by Seya et al. (2011) correspond quite accurately.

When testing quality indicators for pharmaceutical care at the Amsterdam Academic Medical Center from April to June 2009, De Boer et al. (2014) found that only 41% of the patients were treated in compliance with the norm ('IF the pain score is 4 or higher, THEN the pain medication needs to be adapted in order to lower the pain score') while the ACM for 2010 for the Netherlands was 45% adequacy (Duthey and Scholten 2014). These findings correspond very well.

Both examples show support for considering an AOC Index ≥ 100 as a norm for adequate pain treatment. Moreover, it was demonstrated that the adequate level calculated by means of the AOC Index is not very sensitive for disturbances.

The application of the AOC Index is only suitable for use in the general population, because the data on which they are based stem from general populations of countries world wide. It is a coarse measure and therefore suitable to assess adequacy levels in countries with a lower level of adequacy. In case that a country is approaching adequate levels, the authors recommend further finetuning of policies by direct measurement of pain levels, i.e. using pain surveys (Scholten 2020). Such surveys will also enable to identify situations where under treatment and over treatment exist simultaneously.

Global levels of adequacy of consumption for 2015, expressed as the AOC Index, are presented as a world map in **Figure 1**.

The Lancet Commission for Palliative Care and Pain Relief

Another approach to assess adequacy of opioid analgesic consumption is the approach by the Lancet Commission for Palliative Care and Pain Relief. The Lancet Commission compared actual consumption with the need for opioid analgesics for 20 health conditions. Calculations were based on the three year average acquisition of opioids by country over the years 2011–2013. The need for pain treatment from each of these 20 diseases was calculated using the amount of morphine needed per patient per day, the average duration of the disease and the total number of patients. Then it was totalized. The amounts of morphine needed and the average durations were defined by one clinician. For Western European countries the benchmark is established using a different method, selectively leaving out a large number of outliers. The publications by the Lancet Commission do not provide external proof of evidence for this benchmark, and neither do they mention the source of disease prevalence statistics used. More recently, Lancet Commission's approach was endorsed by the International Association on Hospice and Palliative Care (Knaul et al. 2017; Global Data Platform to Calculate SHS and Palliative Care Need 2018).

Comparing the AOC Index to the Lancet Commission's benchmark shows a range of approximately 4.5–36.7 times difference (depending on the country) between the two benchmarks, the latter being the lower. A separate benchmark was established for industrialised countries, using a different methodology. The Lancet Commission stated that consumption in most western European Countries, the USA, Canada, and Australia is at or well above need (Knaul et al. 2018). E.g., for Canada a consumption is reported which is 31 times higher than needed, for the Netherlands it is 9 times and for Germany it is 15 times (Global Data Platform to Calculate SHS and Palliative Care Need 2018).

INCB

A third approach is the INCB approach (which stands separate from its annual statistical reports). INCB used an upper limit of 200 S-DDD (Statistical Defined Daily Doses) per million inhabitants per day for 'inadequate use' and 100 S-DDD per million inhabitants per day¹ for 'very inadequate use' (Berterame et al. 2016;

¹ 200 S-DDD per million inhabitants per day is equivalent to 7.3 mg Morphine equivalent per capita per year.

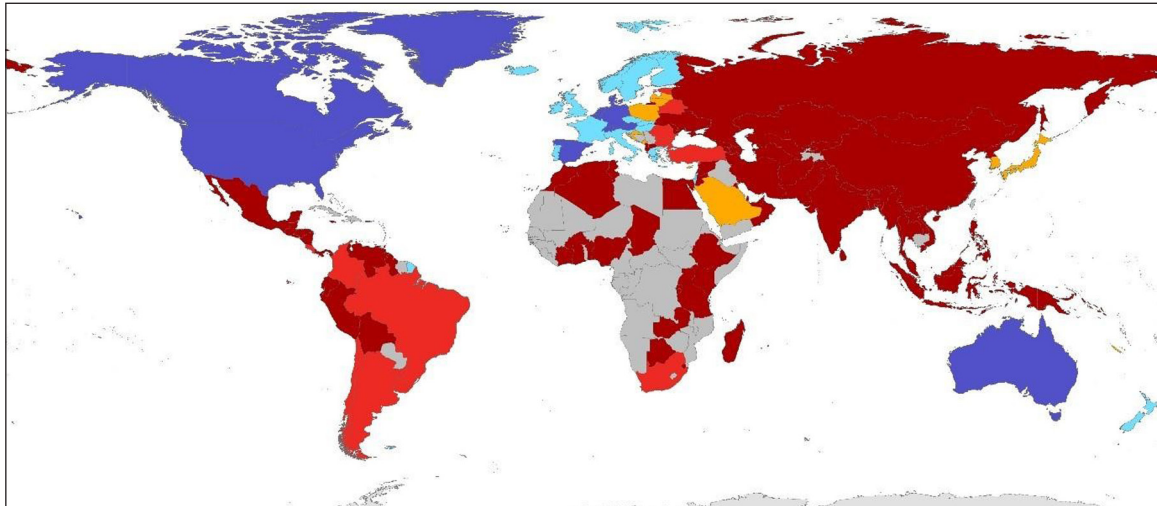


Figure 1: Country levels of adequacy of per capita opioid analgesic consumption, 2015. Levels of adequacy: dark blue: adequate (Adequacy of Opioid Consumption Index ≥ 100); light blue: moderate (AOC Index ≥ 30 and < 100); orange: low (AOC Index ≥ 10 and < 30); light red: very low (AOC Index ≥ 3 and < 10); dark red: extremely low consumption (AOC Index < 3); grey: no data available. (From: Scholten et al. 2019b; <https://www.tandfonline.com/>).

International Narcotics Control Board 2016). This benchmark corresponds to AOC Indices of 1.4 and 2.9, which represent 'extremely low consumption.' It is 34 times lower than the benchmark of the AOC Index. The publication does not provide an explanation why these benchmarks are chosen and how. It is also not explained whether > 200 S-DDD means that consumption is adequate. In newer publications however, the INCB abandoned this approach and reported consumption levels only, without relating these levels to levels of adequacy (International Narcotics Control Board 2019).

Current Trends in Consumption

General

The INCB has been warning for a too low consumption since 1989 (International Narcotics Control Board 1989). Then, over time, the total global consumption increased, mainly caused by the increase of the per capita consumption in many industrialised countries. In many developing countries, there is also improvement, but usually on a too small scale for overcoming under treatment substantially. In the latter countries, improvement did not keep pace with the former. Between 2000 and 2015, the gap between high and low developed countries even widened (Scholten et al. 2020).

The American Crisis of opioid-induced Death

In the United States of America, there is a 'national epidemic' ongoing of high numbers of lethal intoxications from opioids. It is a continuation of the epidemic that started already after the Vietnam War in the early 1970s, when it manifested as heroin use disorder. This epidemic was never gone, but changed to the use of opioid medications (mainly oxycodone) around the year 2000 and became more serious rapidly. Then, it changed to fentanyl derivatives from illicit sources in recent years.

These developments in the USA attracted worldwide attention in the past years and will affect access to opioid medications in many other countries. A few aspects of this epidemic, which are relevant for the international situation, are highlighted here.

For a long time already, it was doubtful that opioids causing accidental death in the United States originated from medications prescribed to pain patients. However, insurance companies, politicians and authorities, including the USA Centers for Disease Control (CDC) and the Drug Enforcement Administration have been blaming pain patients and their prescribers for causing the crisis. They did not distinguish between actually prescribed medications and medications intended for prescription, and also not between the medication fentanyl, illicitly produced fentanyl, and its more potent illicit derivatives ('fentanils'), of which many do not have any medical or veterinary use and which are only available on the illicit markets. Because the mechanisms behind the many lethal opioid intoxications in the United States were not well analysed,

the responses were also not an answer to the problems and therefore, cannot revert these (Scholten and Henningfield 2016a; Scholten and Henningfield 2016b; Dasgupta, Beletsky and Ciccarone 2018).

Because of this, pain patients were gradually denied access to opioid pain relievers. The amount of opioids prescribed in the United States, dropped from 782 mg ME in 2010 to 640 mg ME per capita in 2015 (Guy et al. 2017), but the number of deaths increased with 57% over the same period (National Center on Health Statistics - CDC Wonder no date). In the United States, large numbers of people with pain saw their dosages involuntarily reduced without individual assessment (Weeks 2016; Samet and Kertesz 2018), and as a result many people with pain complain that their pain is not properly addressed any more, even to such an extent that Human Rights Watch announced to investigate the United States for torture with this respect (Anson 2018).

Finally, it was recognized by the CDC that the epidemic is not driven by opioids prescribed to pain patients (O'Donnell et al. 2017). Moreover, the CDC admitted in 2016, that they have historically categorized 'all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids, regardless whether they originate from licit or illicit sources) as "prescription opioid overdoses"' (Rudd et al. 2016). However, a recent study showed that only 1.3% of those who died from an opioid intoxication in Massachusetts had an active prescription for each opioid detected in toxicology reports on the date of death (Walley et al. 2019). An analysis of data from southwest Virginia from between 2011 and 2015 demonstrated that of patients with cancer to whom opioid analgesics were prescribed in this rural and medically underserved area, less than 10 out of 652 experienced opioid use disorder-related hospitalizations. At the same time data suggested under treatment of cancer-related pain among these patients (LeBaron et al. 2019).

Effect on other Countries

The situation in the United States has much been conflated by erroneous data. For instance, the Centers for Disease Control and the anti-opioid organisation Physicians for Responsible Prescribing reported that the US per capita consumption of opioid analgesics is 1.7–4.1 times higher than the actual consumption reported officially by the US Drug Enforcement Administration to the INCB (Scholten and Henningfield 2016a). Such dramatic data did not remain unremarked in other countries. Pressure on the World Health Organization after false allegations from the US side that the content of a treatment guideline and a policy guideline were influenced by the pharmaceutical industry, lead to the withdrawal of these guidelines (Anson 2019).

Gradually, the USA debate has developed a 'spill-over' effect to regulatory authorities in Europe and in developing countries, contributing to restrictions in opioid availability, even though most of these countries do not experience problems with prescribed opioid analgesics.

American authors recommended to limit access to opioid analgesics in other countries, e.g. in the European Union and in Saudi Arabia (Martins and Ghandour 2017), in spite that opioid analgesic usage in Saudi Arabia is already low (AOC Index₂₀₁₅: 16) (Scholten et al. 2020). Moreover, problems reported on opioid use in the European Union are rarely related to pain treatment (Scholten 2017; European Drug Report 2019, Trends and developments 2019). Non-medical use of opioids mainly relates to heroin (around 78%), followed by methadone and buprenorphine (together 14%; usually used in AOT and rarely for pain treatment). Germany has the highest per capita consumption of opioid analgesics in the world, but without serious opioid use problems being reported (Häuser, Schug and Furlan 2017).

Europe has better access to opioid agonist therapy (OAT) which is the first choice treatment for opioid use disorder recommended by WHO (World Health Organization 2009). Therefore, Europe is better prepared for potential substance use problems than the USA is. In 2009, the USA had a coverage for OAT of only 13 out of every 100 people who inject drugs (Mathers et al. 2010). In 2014, nearly 80% of individuals with an opioid use disorder did not receive treatment in the USA (SAMHSA 2017). From the 22 EU countries with data available, the median coverage (calculated as OAT clients/number of high-risk opioid users) is 47% (range 8–86%) (based on data from the European Drug Report 2019 Package, Country reports 2019).

Discussion

Measurement of opioid analgesic consumption is an important tool for defining public-health policies aimed at improving pain management. As shown above, measurement started long ago with the collection of absolute consumption data by the Permanent Narcotics Control Board. Later on, its successor INCB drew attention to the under treatment of pain; the PPSG refined the available data into per capita statistics in an easily accessible online database. However, for adjusting policies, it is better to compare with a standard,

because only this provides an indication of the required direction of change. Scholten and collaborators, the INCB and the Lancet Commission, each developed a benchmark, but in different ways, and with very different outcomes.

When using a benchmark, the method used to establish it should be transparent.

INCB does not provide any explanation for the benchmark it used in the past. It is an extremely low benchmark, and therefore does not effectively contribute to improving access, and rather maintains the status quo. It may provide somewhat help only to those countries where access is almost non-existent. It looks like a compromise was negotiated between INCB members willing to improve access to controlled medications and those who were against. This seems to be less the case with the current composition of INCB, and this may be the reason that in newer publications this benchmark silently disappeared.

The benchmark established by the Lancet Commission on Palliative Care and Pain Relief is a calculated benchmark, using a selection of 20 important conditions that require pain relief, but therefore, also excluding so many other conditions that come with pain. This causes a systematic error leading to under reporting. This comes on top of the known under reporting in any health statistics. A correction for need for pain relief for the missing conditions is not applied. Moreover, using a separate benchmark for industrialised countries, developed through exclusion of many outliers is not scientific. The conclusions by the Lancet Commission that quite a number of countries with well-functioning health systems have over consumption up to 310 times feels awkward and does not contribute to its credibility.

The AOC Index has some indirect evidence that its benchmark lies in the correct order of magnitude, but also this benchmark is not fully validated. All methods need further validation, but validation may be hard. It has no morbidity correction after this correction was abolished when the ACM was replaced by the AOC Index. Reasons were the relative unreliability and limited availability of the statistics used.

Looking at the strengths of the ACM, the AOC Index and the Lancet Commission methods, an ideal method would use a benchmark composed of the need from 20 diseases from the latter method followed by extrapolation to the need for all diseases as applied in the ACM. Simultaneously, this extrapolation could correct for under reporting health statistics. Like for the AOC Index and the Lancet Commission's method, full adequacy could be expressed as '100' or '100%.' Methods, data sources and tables with results should be publicly accessible like in the ACM and the AOC Index, with supplementary graphs and maps.

Access to controlled medications such as opioid analgesics has been problematic for a long time and many influences contribute to the continuation or the return of inadequate access. One such an influence is the false narrative that pain patients are the underlying cause of lethal opioid intoxications in the USA, and the resulting fear that this will spread to European countries. Unfortunately, politicians, health-care insurers and the press hold and promote strong opinions contradictory to scientific evidence. This is not only the case in the USA, but more and more in some European countries too. Today, in many countries, the absolute per capita consumption of opioid analgesics is rather going down than up. This coincides with increasing numbers of people suffering moderate to severe pain, whose pain is not or under treated.

Less informed advocates started lobbying against the use of opioids in several countries, including the author's own country, the Netherlands. Measures for a reduction were announced in the Netherlands. Such unbalanced policy responses may in the long-term lead to under treatment of moderate and severe pain. Globally, opioid analgesics will remain a corner stone of pharmacological pain management, ideally as an element of a multimodal therapeutic approach (using less opioids by combining pharmacological and non-pharmacological pain treatment options, leading to lower opioid consumption). To avoid that prescribed opioids will be used in inappropriate and harmful ways, prescribing them should always be considerate (Fanelli et al. 2016; Scholten and Henningfield 2016a). However, considerate prescribing becomes unethical when it means withholding treatment to people with moderate and severe pain.

Though in modern anaesthesiology a multi-modal approach is considered the ideal approach, we need to realize that pain is omnipresent in both developing and industrialised countries where many suffer chronic pain. It is not realistic to aim at all these people being treated by anaesthesiologists; the large majority will be treated by generalists. However, as long as the current under education on pain treatment persists in the general medical curriculum, it is unlikely that general practitioners will be able to provide much more than just pharmacological treatment.

The question is also what the effect will be of the current COVID-19 pandemic on future access policies related to controlled medications. In recent months, it has become evident that palliative care can provide considerable relief to COVID-19 patients in ICUs, but this will require substances like opioid analgesics and midazolam to be readily available.

The World Health Assembly called on the WHO Member States in a resolution on the response to COVID-19 inter alia to provide access to palliative care (World Health Assembly 2020). We may hope that this will be an occasion for policy makers to realise the importance of controlled medicines for treating large numbers of patients with limited staffing.

Competing Interests

The author provides consulting services as an independent consultant on regulation of and policies related to psychoactive substances. This included work for CannNext, DrugScience, Grünenthal, Jazz Pharmaceuticals, Pinney Associates and Zoetis. He was a member of the Expert Group on Legislations and Regulations for Agonist Medicines Used in Opioid Dependence Treatment of the Pompidou Group. He received honoraria for lecturing from Mundipharma. He received travel support from the German Pain Federation and Grünenthal.

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