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Research Articles

Does the International Narcotics Control Board (INCB) sufficiently prioritise enablement of access to therapeutic opioids? A systematic critical analysis of six INCB annual reports, 1968-2018

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Background
The International Narcotics Control Board (INCB) has overseen international drug control since 1968 with the dual remit of restricting illicit production and use of controlled substances, whilst enabling access for clinical purposes. Two opioid crises are present under its jurisdiction: i) abuse, dependence and premature mortality in high-income countries; and ii) inadequate supply of opioids for clinical purposes for most of the world represented almost exclusively by low- and middle-income countries.

Methods
Systematic critical analysis using corpus linguistics as a method of document analysis to investigate the regulatory climate promoted by the INCB, through language used regarding opioids in a representative sample of annual Reports, 1968-2018. Instances of key terms (narcotics, opiates, opioids, analgesia) were retrieved, with surrounding text for context. Two systematic coding phases were undertaken by two researchers, adjudicated by a third, to develop themes. We report frequencies per-1000 words of themes and key terms, aggregated and by decade.

Results
Five themes were developed within three domains: abuse and dependency, illegal trade (domain 1: illicit uses); policy, enforcement and context (domain 2: illicit and therapeutic uses), and access for therapeutic use, estimates of need (domain 3: therapeutic uses). For fifty years, the INCB has focussed predominantly upon domain 1: illicit uses, with little attention to domain 3: therapeutic Uses. Decreasing attention is provided to the estimates of annual requirements system, under which global opioid access to opioids is documented as inadequate.

Conclusions
The INCB must consider how improving availability of therapeutic opioids could reduce widespread suffering safely and effectively. Urgent international and national action is required to improve methods of accurately estimating population-level needs for opioids for all therapeutic requirements. Fears of illicit production or use should not limit the prospects of accessing appropriate therapeutic opioids where the majority of the world, today, have no realistic access.

Therapeutic opioids (eg, morphine) are listed as Essential Medicines by the World Health Organization (WHO) for a wide range of clinical problems.[1] Opioids are a key aspect of the WHO's widely-used three-step pain ladder and are a primary treatment for acute pain and for cancer pain.[2] Opioids also are indicated in common clinical scenarios such as childbirth,[3] acute musculoskeletal pain,[4] trauma,[5] peri-operative care[6] and, in low doses for chronic breathlessness.[7] Additional to physical suffering caused by lack of pain relief, clinical outcomes are worsened (e.g. heightened risk of post-operative pneumonia[8]) and socio-economic prospects of individuals and families are jeopardised (e.g. risk of poverty due to inability to work due to uncontrolled pain[9]). These circumstances have led to calls for access to pain relief as a basic human right.[10]

Additional to clinical benefits, therapeutic opioids are formulations with addictive properties and the potential to cause harm.[11] Inappropriate prescribing of therapeutic opioids can lead to dependence and addiction, making use of evidence-based clinical guidelines, extremely important for safe prescribing and use. Due to potential risks of inappropriate use, opioids are controlled substances, subject to international and national regulation and there is ongoing debate regarding how to ensure balanced policies for access and safe use of controlled medicines.[12]

The International Narcotics Control Board (INCB) has overseen international drug control since 1968 with the dual remit of restricting illicit production or use of controlled substances, whilst enabling access for clinical purposes.[13] It is a quasi-judicial organization and the only United Nations (UN) agency with powers of enforcement.[14] The INCB aims to oversee the implementation of international drug conventions, ratified by UN member states.[15] International drug laws aim to restrict illicit production and use of harmful opioid substances and ensure appropriate access to opioid formulations for clinical and scientific purposes.[13]

Two dichotomised global public health crises are present

under the stewardship of the INCB.

First, there is a continuing crisis relating to addiction and misuse of opioids, primarily in North America and Western Europe.[16] In the United States, drug overdose is now the leading cause of injury death.[17] A complex array of factors have led to this situation.[18] The United States government attributes the rise in prescription opioid misuse to factors including: lower prices, aggressive marketing by opioid manufacturers, changing prescription practices and inadequate controls.[19] Pharmaceutical companies and even physicians now face criminal lawsuits for advertising and prescribing practices related to opioids.[20] Despite the emphasis in the public discourse on prescription opioids, most opioid-related deaths are still caused by illicitly-obtained, not prescribed, opioids.[21]

Second, and the primary concern of this paper, is the larger public health crisis relating to the billions of people globally who do or will suffer unnecessarily due to lack of *any* access to *any* opioid analgesia, despite their relatively low costs.[22]

In terms of ensuring access to controlled substances for clinical purposes, the INCB uses the 'Estimated Requirements for Substances under International Control' system to oversee implementation of international drug laws. Each year, countries estimate their national requirements for therapeutic opioid use, which places an upper limit on stocks and trade.[23] Should countries fail to comply with the Estimates system, the INCB may call on governments to take remedial actions, or even "*recommend to Parties that they stop importing drugs from a defaulting country, exporting drugs to it or both.*"[24] The consequence of governments failing to comply with the Estimates system may therefore be INCB-endorsed further restriction of access to Essential Medicines.

Under the estimates system, there are huge inequities in access to opioids between countries and most people who may benefit from their use do not have any access.[25] The INCB reports that:

> *"In 2018, 79 per cent of the world's population, living mainly in low- and middle-income countries, consumed only 13 per cent of the total amount of morphine used for the management of pain and suffering, that is, 1 per cent of the morphine manufactured worldwide"* [INCB, 2019[26]].

In the lifetime of the INCB, illicit opioids have become a security issue in many parts of the world, rather than a political or social issue, with a consequent global increase in incarceration rates for misuse of drugs.[27] This is relevant to the present paper as key barriers remain which continue to limit legitimate access to those in need. Barriers include: over-regulation, lack of prescribing knowledge of physicians and 'opiophobia,' or fear of opioids due to the threat of legal action for mis-prescribing.[28,29]

After sixty years of the regulation of opioids by the INCB, a complex situation prevails of two 'opioid crises', where licitly produced and illicitly produced opioids may be accessed for both licit and illicit purposes. Few nations worldwide have been able to successfully implement international drug conventions with national policies that achieve the appropriate balance between restricting inappropriate access and ensuring appropriate access to therapeutic opioids. It is therefore timely to review the role played by the INCB in limiting illicit production and use while promoting safe and systemic access to opioids for medical, scientific and research purposes. We investigate the regulatory climate promoted by the INCB as represented through the language used about opioids in a representative sample of six Annual Reports each one a decade apart, from 1968-2018.

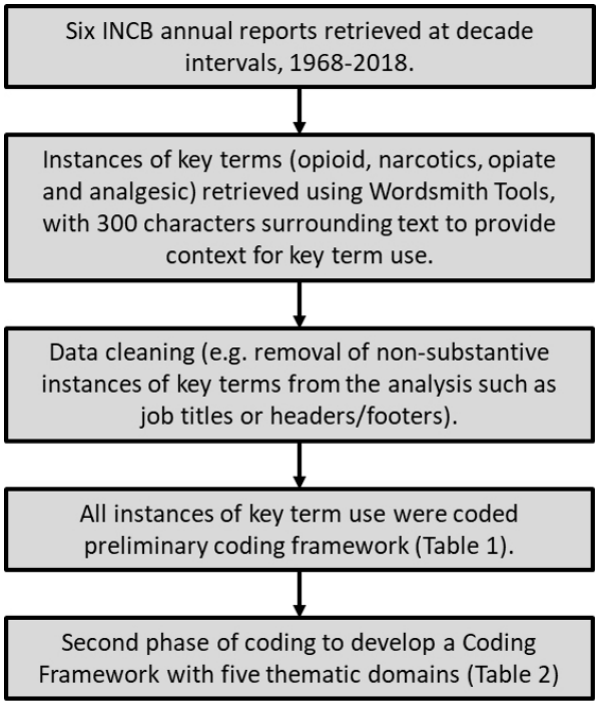

Figure 1: Study flow chart.

METHODS

We conducted a systematic critical analysis of a representative sample of INCB annual reports using corpus linguistics as a method of document analysis.[30] Use of quantitative and qualitative methods allowed investigation of our primary interest in how language is used by the INCB in relation to opioids, seeking to identify the relative emphasis on licit and illicit issues, and whether this has changed over time. The study:

- Identifies key terms used by the INCB relating to therapeutic opioids;
- Quantifies the proportional prevalence of key terms within annual reports and how this has changed over time;
- Describes key discourses of the INCB relating to opioids; and
- Quantifies the proportional prevalence of key discourses within annual reports and how this has changed over time.

DOCUMENT SAMPLING

The INCB is required to publish an annual report which provides a comprehensive account of the global drug situation.[31] Further publications include: '*Precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances'* and technical reports on narcotic drug use/production and estimates of legitimate requirements of each country. Although such reports are relevant to opioid analgesia, the INCB lists the production of an annual report as part of its *Mandate and Function* and may be considered as the key vehicle to connect the organisation with policy makers, law makers and the public in relation to accountability. We therefore selected INCB annual

Table 1. Preliminary coding framework

Code	Example quote
Intent to appropriately restrict access to narcotics for illicit use	"In response to the opioid crisis, the Minister of Health of Canada announced a series of measures to address the pharmaceutical industry's opioid marketing practices, including severely restricting most forms of prescription opioid marketing [INCB, p60, 2018]".[35]
Intent to appropriately enable access to narcotics for a therapeutic use	"In its annual report, the Board has consistently addressed the issue of making opiates available for medical needs, urging Governments to critically examine their methods of assessing domestic medical needs for opiates and to take the steps necessary to remove impediments to the adequate availability of those drugs for medical and scientific purposes [INCB, p15, 2008]."[36]
Intent to appropriately enable and restrict access to narcotics	"It's (The Single Convention on Narcotics 1961) aim, as with the previous treaties, was to ensure the provision of adequate supplies of narcotic drugs to be used for medical and scientific purposes, to prohibit all non-medical consumption of such drugs and to prevent the diversion of such drugs into the illicit market [INCB, p2, 2008]."[36]
Descriptive illicit	"Although the illicit traffic in opiates constitutes the most serious threat, the situation in regard to coca leaf and cannabis continues to be grave [INCB, p14, 1968]."[37]
Descriptive medical	"Narcotic drugs and psychotropic substances should be used in conformity with sound medical practices [INCB, p5, 1998]."[38]
Descriptive making no distinction between illicit and clinical use	"For the purposes of this study, the word "opiates" means opium alkaloids and poppy straw and their derivatives which are subject to international narcotics control [INCB, p3, 1978]."[39]

reports as the most appropriate lens through which to investigate the INCB's organisational priorities.[32]

The first INCB annual report was published in 1968. We included annual reports at decade intervals (1968-2018) as a means of tracking representative changes and developments in the discourse of the INCB since its inception.[33]

KEY TERMS

We consulted the US National Library of Medicine website to extract historic Medical Subject Headings (MeSH) of words related to opioid analgesia. All relevant terms (opioid, narcotics, opiate and analgesic) identified were included as key terms.

DATA CLEANING

INCB reports are publicly available. Annual Reports were 'cleaned' by removing non-substantive instances of key terms from the analysis such as job titles or headers/footers. Appendices, explanatory notes and glossaries were also excluded. We imported six Annual Reports into Wordsmith Tools v6.0 (Scott, 2012, United Kingdom) for data analysis.[34]

ANALYSIS

Using Wordsmith Tools, frequencies of key word usage were retrieved as Wordlists. Wordlists incorporated use of plurals (e.g. opioid/opioids) and relevant synonyms (eg, analgesia/analgesic). Frequency of key term use and overall Annual Report word counts were extracted. Frequencies of keywords per 1000 words were calculated to identify the relative prevalence of our key terms.

A PRIORI CODING FRAMEWORK

An *a priori* coding framework was developed by preliminary coding using an iterative approach (**Table 1**). Key terms are used interchangeably by the INCB and were coded as either a description of clinical (therapeutic) use, illicit use, or both.

All instances of key term use were coded independently by two researchers (JC, BF). Three hundred characters surrounding key terms (opioids, opiates, analgesics, narcotics) were retrieved to allow coding in context using an iterative approach to develop themes.

Agreement between reviewers was 85% and conflicts were resolved with discussion between the study team. Further independent 'free coding' by two researchers (JC, BF) of keywords in context took place to develop a preliminary seven-issue coding framework. After initial codes were assigned, the framework was refined through discussion as a study team in to a five-issue / three domain framework, ahead of further piloting and finalisation of the coding framework (**Table 2**).

Our coding framework reveals the key thematic discourses of the INCB and the relative attention given to each. We report frequencies per-1000 words of themes and key terms, aggregated and by decade.

RESULTS

Five themes were developed within three domains (**Table 2**).

The developed thematic categories account for key term use in the context of illicit and licit production, distribution, supply and demand for opioids, as well as discourse around national and international drug policies and enforcement agencies.

Quantitative analysis of word frequency within our sample, showed that key terms appeared in the six Annual Reports a total of 1376 times. Proportionately, key terms appeared in INCB Annual Reports most commonly in relation to the *Illegal Drug Trade* (0·14 per 1000 words), followed by *Policy, Enforcement, Definitions and Context* (0·11/1000 words) and, *Estimates of licit need, use and related topics*

Table 2. Coding framework for key issues relating to opioids from six reports each one decade apart from the International Narcotics Control Board (INCB) 1968-2018 inclusive

Domain	Theme	Examples of the issue in reports include:
Domain 1. Issues related to illicit uses	Abuse and Dependency	- all use of key terms in reference to illicit use from licit or illicit narcotic formulations; - dependency treatments (eg, opioid substitution therapy); - recreational/criminal use of narcotics; and - 'overuse' of pharmaceutical formulations.
	Illegal Drug Trade	- references to illicit production and trade of narcotics; and - diversion of narcotics from licit channels to illicit.
Domain 2. Issues related to both illicit and therapeutic uses	Policy, Enforcement, Definitions and Context	- all references to international and national drug control agencies; - policies and mechanisms of enforcement; - definitions of narcotics, eg, cannabis defined as a 'narcotic'; and - any relevant historical context.
Domain 3. Issues related to therapeutic uses	Access to opioids for a therapeutic use	- all usage of keywords relevant to access, barriers, patterns of use of therapeutic opioids; - lack of availability of opioids for clinical purposes; and - any non-specific references to unmet clinical need. - all references to clinical need and treatments for specific clinical problems such as pain.
	Estimates of licit need, use and related topics	- all references to keywords in relations to the system of the 'Estimates System', whereby governments must submit estimated annual requirements for opioids for clinical purposes to the INCB; and - licit manufacture and distribution of opioids.

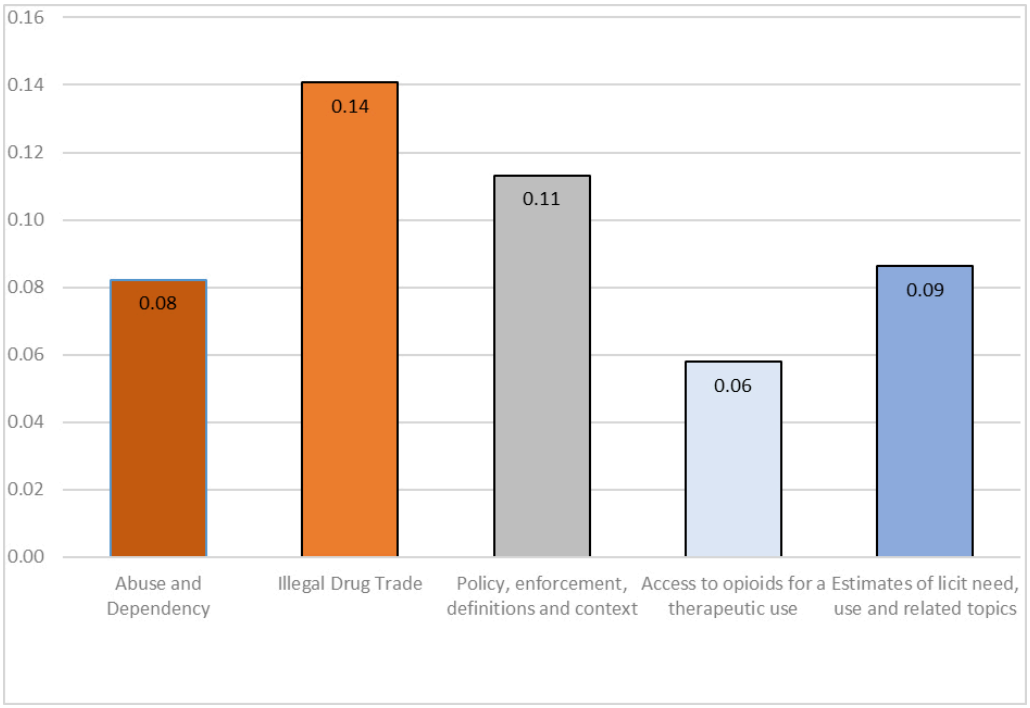

Figure 2. Frequency per 1000 words of themes coded in six annual reports of the International Narcotic Control Board, 1968-2018.

(0·09 per 1000 words) (**Figure 2**).

There are fewer instances of *Access to Opioids for a Therapeutic Use* (0·06 per 1000 words), lower than key term use relating to *Abuse and Dependency* (0·08 per 1000 words).

There has been a sustained emphasis in the discourse relating to *Abuse and Dependency*, *Policy and Enforcement, Definitions and Context* and, the *Illegal Drug Trade* since 1968 (**Figure 3**). In every single year, discourse related to the

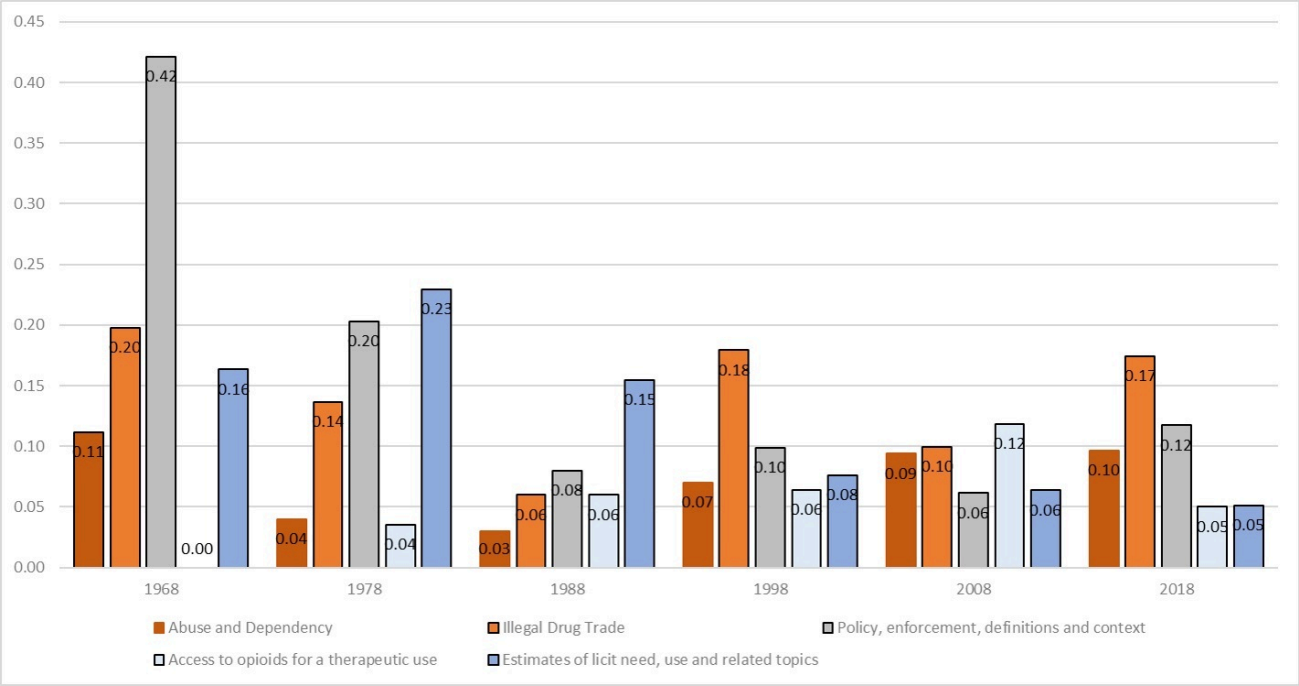

Figure 3. Frequency per 1000 words of key themes coded in six annual reports of the International Narcotic Control Board by decade, 1968-2018.

Illegal Drug Trade is demonstrably more prevalent than *Access to Opioids for Therapeutic Use.*

The spike around *Policy Enforcement, Definitions and Context in 1968* is arguably due to this being the first annual report of the INCB, with much discourse directed towards the stated goals of the INCB to implement the Single Convention on Narcotics.

Discourse in relation to *Estimates of Licit Need* is the only clinical theme in 1968 and has a high point in 1978, after which, overall reference decreases decade on decade. There was noticeably increased attention upon issues in relation to *Access to Opioids for a Therapeutic Use* in 2008, which is otherwise low.

'Narcotics' is the key term most commonly used within all INCB annual reports within the sample (S1 in the **Online Supplementary Document**). The proportional use of 'narcotics' decreased since a high point in 1968, consistent with the focus upon Policy reported in **Figure 3**. From very limited use of 'opiates' in 1968, this increased in 1978 before decreasing and remaining consistent until 2018.

There is almost no mention of 'analgesia / analgesics' until 1998 and limited use at subsequent time points. This is consistent with the minimal discourse relating to symptom management identified within reports regarding *Access to Opioids for Therapeutic Use*. There has been noticeably increased use of 'opioids,' since 2008. Given the increased discourse around *Abuse and Dependency* since 2008, it seems likely that increased use of the term 'opioids' relates to what has been termed the opioid crisis in relation to overuse and abuse of narcotics in a handful of high-income countries.

DISCUSSION

Our systematic critical analysis of INCB Annual Reports using methods of *corpus linguistics* suggests that the INCB prioritises the prohibition of production, trade and, illicit use of opioids over their enablement for clinical purposes. This approach has been in evidence since the first INCB report in 1968 and remains in 2018. Discourse around *The Illegal Drug Trade* and *Abuse and Dependency* is prevalent within all reports in our sample. By contrast, little attention has been paid to *Access to Opioids for a Therapeutic use.* Of concern, discourse relating to *Estimates of Licit Need, Use and Related Topics* has also decreased over time.

Under the Estimates system, millions of people with present clinical need, predominantly in low- and middle-income countries continue to lack any access at all to essential opioid medications. Key components of the Estimates system are shown in S2 in the **Online Supplementary Document**. Importantly, the INCB draws a distinction between 'need' and 'requirements' for controlled substances. 'Need' relates to an estimate based on the size of the population, whereas 'requirements' relate to quantities that health and law enforcement systems are perceived to be able to manage safely in the context of existing health infrastructure. The INCB places the obligation upon nations to devise their method of estimating need based upon one of three approaches reported in **Box 1**.

There is no evidence base cited for any of these three approaches to estimating the annual needs or requirements for opioids at the national population level. Each approach is based upon historic data and practices (which most commonly have guaranteed inadequate access to therapeutic opioids for licit purposes. Method A appears to encourage a path towards ongoing inadequate access, whereby consumption estimates cannot exceed usage in previous years. Method B is reliant upon there being *any* examples of appropriate therapeutic opioid availability in standard healthcare facilities. Method C is reliant upon morbidity estimates from countries facing serious challenges in accurate disease surveillance. None of these processes appears responsive to changing clinical guidelines or future needs.

In the absence of validated guidelines, academics have adopted alternative measures for opioid consumption. For

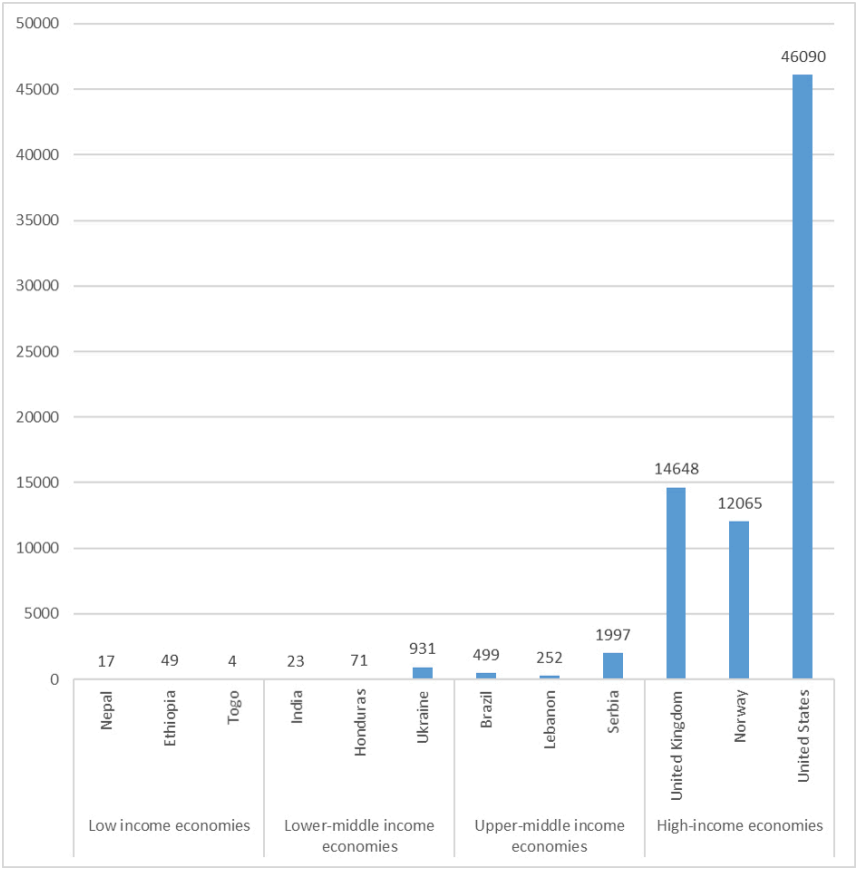

Figure 4. Levels of consumption of narcotic drugs, in defined daily doses for statistical purposes per million inhabitants per day, for selected countries using World Bank income-group classifications 2014-2016.

*Average consumption of narcotic drugs (excluding preparations in Schedule III) and calculated consumption of buprenorphine 2014-2016
Source: International Narcotics Control Board, Narcotic Drugs 2017, Estimated World Requirements for 2018 Statistics for 2016 (42)

example, the Lancet Commission used the Distributed Opioid Morphine Equivalent (DOME), an approach which assess the quantity of opioids available for prescription in countries, though the document still offers no method of assessing total need. Statistical approaches consider the adequacy of therapeutic opioid consumption by measuring adequacy of nations' consumption in relation to that of twenty countries with high Human Development indices which are used as comparators.[40] Whilst such efforts further the conversation, none of these approaches have been evaluated and do not inform governments submitting their estimates of requirements to the INCB.

INCB reports contain detailed country reports, including data on 'seizures of opioids' from illicit channels. However, no data are published by the INCB relating to estimated '*needs'* for therapeutic opioids. Only quantities for '*requirements*' are published. This is in spite of huge variation between countries with similar populations in terms of estimated *requirements*.[41] What then is the gap between needs and requirements for countries around the world?

Globally, huge inequities in access to therapeutic opioids are apparent between countries (**Figure 4**). Whilst the high average consumption in the United States is problematic, the lack of *any* consumption in some low, lower-middle and upper middle-income countries is alarming. Even in countries where there is some access to therapeutic opioids, availability is inadequate and average consumption far below levels seen in high-income countries. [42,43]

Focussing upon availability of opioids for therapeutic use will reduce avoidable suffering globally *and* decrease illicit demand for opioids for legitimate clinical purposes. Global facilitatory leadership from the INCB is required to reframe discourse around therapeutic opioids and increase appropriate access around the world, whilst preventing a repetition of the circumstances which have led to a crisis relating to *over* access in some high income countries.[44] In some high use countries where there has not been an explosion of addiction, there are lessons for countries and regions seeking to promote safe and appropriate access to therapeutic opioids for patients.[45]

After fifty years of regulation by the INCB, appropriate access to opioids around the world remains a global public health crisis. Severe levels of suffering are endured by patients around the world daily, which could be safely reversed with low-cost therapeutic opioids. The INCB must consider urgently how to address the imbalance of attention they provide to improving therapeutic access as a humanitarian emergency. The *status quo* is a situation where millions suffer seriously each day due to lack of appropriate access to therapeutic opioids for severe pain from acute trauma or surgery.[46]

Our analysis has strengths and limitations. A key strength of this analysis is the inclusion of *all* key terms relevant to therapeutic opioids, as defined by MeSH codes within a representative sample of INCB annual reports. Systematic coding of all keywords by two separate researchers, with a third as adjudicator is a robust process. In terms of limitations, we acknowledge that each INCB Annual Report has a specific 'thematic chapter' of one specific issue each year. In terms of keywords use, each Report therefore may

be biased towards the thematic chapter. The INCB also publishes separate reports with different thematic foci. However, because of separate subject-focussed reports, it is most appropriate to review Annual Reports, for a measured assessment of the overall discourse of the INCB in relation to therapeutic opioids over time. Future research may include a sample of more recent reports to focus specifically on current activity of the INCB as opposed to a historic time-point analysis. This analysis has not sought to address debates regarding opioid-substitution therapy for dependents but notes that an alternative analysis from such a perspective could be fruitful. Finally, in spite of using a systematic approach, there is likely to be some variation in applied codes. However, small variations in coding are unlikely alter composite findings materially.

CONCLUSIONS

In INCB Annual Reports since 1968, prioritisation has been given to the restriction of production, trade and use of controlled substances for illicit use over promoting therapeutic opioids. Urgent international and national action is required to improve methods of accurately estimating population-level needs for therapeutic opioids for all clinical requirements. From there, health systems will have accurate assessments of the extent to which reform is needed to ensure that *'needs'* and *'requirements'* for therapeutic opioids become equivalent. Fears of illicit production or use should not limit the prospects of accessing appropriate therapeutic opioids where the majority of the world, today, have no realistic access. Patients the world over and their families deserve better.

Box 1. Methods recommended by the INCB for the quantification of requirements for controlled substances

Method A. Consumption-based methods and variants

The consumption-based method and its variants are based on past health-care demands for controlled substances. Where past use of controlled substances is stable, future requirements can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. A variant of this method may also be applied when patterns of past use of controlled substances show a clear upward or downward trend and when known explanations for such trends allow for the prediction of future changes in use.

Method B. Service-based method

The service-based method starts by taking the quantities of controlled substances currently in use in standard health-care facilities and extrapolating those findings to similar facilities throughout the country. For each type of health-care facility, a number of standard facilities with a representative workload, acceptable controlled substance supply and rational prescribing and use need to be identified. For the last step of the calculation, the adjusted quantities of controlled substances used per standard facility are converted into quantities per 1,000 treatment episodes, and the results are then used to estimate the quantities required for all other facilities of the same type.

Method C. Morbidity-based method

The morbidity-based method uses data on the frequency of health problems (morbidity) and an assumption of how those health problems will be treated (average standard treatment schedules) to calculate the requirements for controlled substances. The quantity of controlled substances recommended as the standard treatment for each health problem multiplied by the number of treatment episodes for that health problem provides the quantity required. The sum of the requirements calculated for each health problem treated with that substance provides the total requirement for each controlled substance.

Source: International Narcotics Control Board. Guide on Estimating Requirements for Substances Under International Control, 2012. Available from: www.incb.org (23)

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ICMJE criteria. Concept; JC, DC, MJ; design MF, JC, DC, MJ: data analysis BF, JC, MJ, DC; data interpretation All; first draft manuscript JC; All authors contributed to manuscript drafts and agreed the final manuscript.

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FIGURES, TABLES, AND SUPPLEMENTARY MATERIALS

Online Supplementary Document

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