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IMPROVING ACCESS TO NARCOTIC ANALGESICS: THE INTERNATIONAL CONTROL SYSTEM AND OPTIONS FOR QUANTIFICATION METHOD

MENINGKATKAN AKSES ANALGETIKA NARKOTIKA: SISTEM PENGAWASAN INTERNASIONAL DAN PILIHAN METODE KUANTIFIKASI KEBUTUHAN¹

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ABSTRAK

Narkotika lebih dikenal masyarakat karena masalah penyalahgunaannya, padahal salah satu kelompok narkotika yang digunakan dalam bidang medis adalah analgetika narkotika, utamanya tablet morfin, yang merupakan obat esensial. Penghitungan kebutuhan yang akurat untuk analgetika narkotika sangat penting untuk memastikan ketersediaannya bagi pelayanan kesehatan pasien. Saat ini data global menunjukkan bahwa penggunaan morfin lebih terkonsentrasi di beberapa negara di Eropa dan Amerika Utara saja, sedangkan di negaranegara lain termasuk Indonesia, konsumsinya sangat minim. Morfin bahkan tak tersedia di 70 negara dan teritori. Penyebabnya bisa karena kurang akuratnya penghitungan kebutuhan, kurang digunakan atau karena kebocoran distribusi. Di lain pihak, ketidakakuratan penghitungan juga bisa menyebabkan surplus persediaan yang bisa menyebabkan kebocoran distribusi dan dapat mengarah ke penyalahgunaan. Oleh karena itu, sangatlah penting untuk memilih metode penghitungan kebutuhan morfin yang paling tepat, agar kebutuhan medis terpenuhi secara optimal. Makalah ini menyajikan sistem pengawasan internasional untuk penyediaan narkotika bagi kebutuhan medis, dan langkah-langkah untuk meningkatkan keakuratan penghitungan kebutuhan analgetika narkotika, dengan tetap memperhatikan langkah-langkah pengamanan distribusinya.

Kata Kunci: sistem pengawasan internasional, analgetika narcotika, morfin, estimasi, metode kuantifikasi

ABSTRACT

Narcotics are popular to public more due to abuse, while people are unaware that narcotic analgesics, particularly morphine tablets, are essential medicines. To ensure the availability of essential medicines, accurate estimation of the requirements of narcotic analgesics is therefore of ultimate importance. Currently, global data show that the use of morphine is more concentrated in some countries in Europe and North America alone, while in other countries, including Indonesia, the consumption is very minimal. Morphine is not even available in 70 countries and territories. The reason could be due to inaccurate estimation of the requirements, underuse, or due to distortion in distribution. On the other hand, inaccurate calculation can also result in surplus, leakage distribution, which in turn leads to abuse. Therefore, it is important to choose the most appropriate calculation method, which best meet the

medical requirement. This paper presents an international monitoring system of narcotics for medical requirements, and steps to improve the accuracy of the estimating the requirements of narcotic analgesic, while considering the control measures.

Keywords: international control system, narcotic analgesics, morphine, estimates, quantification method

INTRODUCTION

The international drug control conventions were elaborated in recognition of the fact that certain substances while being of great benefit to mankind were also liable to cause dependence syndrome. Therefore the conventions established a control system to serve a dual purpose, i.e., ensuring the availability of controlled substances for medical and scientific purposes while preventing the illicit production of trafficking in and abuse of such substances.1 An essential component of this convention is a system under which countries are requested to estimate the quantities of controlled substances required for legitimate purposes and to limit the use and trade of such substances within the calculated estimates. If applied correctly, this system should not hinder but should promote access to adequate levels of controlled substances.

Unfortunately, many countries currently encounter difficulties in calculating their legitimate requirements for controlled substances, including narcotic medicines, which can impede the availability of such substances for medical and scientific purposes.

The accurate estimation of requirements for narcotic medicines is an essential step in ensuring their adequate supply for medical purposes. On the one hand, poor estimation of requirements can contribute to many problems in the use of narcotic

medicines in the health care system, notably shortages, irrational prescribing, and distortion of demand. On the other hand, poor estimation can lead to surpluses, wastage and an increased risk of diversion or abuses. Therefore, it is of utmost importance to assist countries in quantifying the estimates. This paper describes the system of estimates and the recommended methods to use to quantify the requirements of narcotic medicines for medical purposes. It also provides an overview of the major issues that need to be considered to achieve accuracy in applying these methods.

The international drug control system

The international drug control system is based on three international conventions: the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (1961 Convention)², 1971 Convention on Psychotropic Substances (1971 Convention)³, and the 1988 United Nations Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances (1988 Convention).4 The 1961 and 1971 Conventions established control measures over a defined number of narcotic drugs and psychotropic substances, respectively, whereas the 1988 Convention established control measures on 23 precursor chemicals that are used in the illicit manufacture of narcotic drugs and psychotropic substances. By becoming parties to these conventions, Governments have accepted the obligation to translate the provisions of these treaties into their national legislation and to implement them.

The International Narcotics Control Board (INCB) is the body, established by the 1961 Convention, responsible for monitoring the compliance of Governments with the international drug control treaties and for providing support to Governments in this respect. The ability of INCB to monitor the functioning of the international drug control mechanisms established by the Conventions relies, in part, on Governments to provide INCB with the estimated quantities of internationally controlled substances required for legitimate purposes in their countries (known as estimates when referring to narcotic drugs and precursor chemicals and as assessments when referring to psychotropic substances). The estimates and assessments, which are examined and, if applicable, confirmed by INCB, provide guidance for the quantities of controlled substances that countries may manufacture, import and export.

The accurate estimation of requirements for narcotic medicines is an essential step in ensuring their adequate supply for medical purposes. Poor estimation of requirements can contribute to many problems in the use of narcotic medicines in the health care system, notably shortages, irrational prescribing, distortion of demand and low cost-effectiveness. On the other hand, poor estimation can lead to surpluses, wastage and an increased risk of diversion to illicit uses or abuses.

In principle, the process of estimating requirements for controlled substances should be based on effective methods and systematic procedures to collect information about the use of and the need for controlled substances. Unfortunately, a number of factors make it difficult for the competent authorities of many countries to develop and use such methods and procedures. The most common difficulties encountered include a lack of technical knowledge, a general lack of resources, a poorly developed health care infrastructure and the absence of an institutional framework that prioritises access to medicines for all segments of the population. As a result, many Governments furnish to INCB estimates of controlled substances that are not sufficient to meet their requirements or fail to furnish any estimates to INCB.

Problems of narcotic medicine use in the world

As described in the Article 20 of the 1961 Convention, countries must report the statistics of controlled substances that have been used for medical, research, and manufacturing purposes during the previous year. Data are compiled by the INCB and published in the Annual Statistics. The Statistics for 2008 which was recently published in February 2010 shows that the morphine consumption level varies widely among countries (see Figure 1).5 The Figure shows that the consumption was very high in some European and North American countries, but very low in the rest of the world. Seventy countries and territories even reported any consumption. The highest consumption level was reported by Austria, but it should be taken into consideration that Austria uses morphine not only as narcotic analgesics but also for the substitution therapy to heroin addicts.

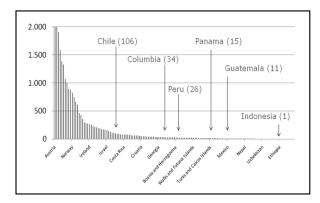


Figure 1. The world morphine consumption in S-DDD, year 2008. One S-DDD is defined as 100 mg daily dose of morphine per day per 1 million

What does the Figure 1 shows? The bars show the consumption level by country in S-DDD unit, and countries are named in order following the level of use. A wide variation can even be seen among countries in the same region such as Latin America. For example, Indonesia consumes 1 S-DDD during the year of 2008. What does it mean? Was it adequate to treat people? One S-DDD is a 100 mg dose of morphine per day per one million people, as recommended by the treatment guideline for palliative care. One S-DDDs were 1 morphine doses per day per one million people. A patient with terminal stage of cancer may need 3-6 month morphine analgesic, so roughly, 1 S-DDD is consumed by 2-4 patients. It means that 1 S-DDD were consumed by 2-4 patients per 1 million people. Did this amount meet the requirement in the country? It should be taken into consideration that there are several clinical condition that need narcotic analgesic as well, such as palliative care in HIV/AIDS, cancer, orthopedic surgery, etc.

It has widely been known that there are impediments to the use of narcotic medicines. In addition to general health system impediments, such as a weak infrastructure for delivering health services and medicines of any kind, there is a subset of impediments that are unique to narcotic medicines given their abuse potential and legal classification as controlled. With regard to opioid analgesics, the INCB surveyed national drug control authorities in 1995,6 and again in 2007 regarding impediments to the availability of opioid analgesics for medical use. The results are summarized in Table 1. Although conducted 12 years apart, it is striking how similar the identified impediments were at each point in time. The impediments are listed in descending order of how many governments identified them, with those

listed first being the most frequently identified by governments.

Table 1. Impediments to availability of opioid analgesics, results of the INCB surveys in 2007 and 1995

2001 4.14 1000	
INCB survey 2007	INCB survey 1995
 Concerns about addiction 	■ Fear of addiction
 Reluctance to 	 Reluctance to
prescribe or stock	prescribe or stock
stemming from fear	stemming from fear of
of legal	legal consequences
consequences	
 Insufficient training 	Lack of training of
of health-care	health care
Professionals	professionals
 Laws or regulations 	 Laws or regulations
that restrict the	that restrict the
manufacture,	manufacture,
distribution,	distribution,
prescribing or dispensing	prescribing or dispensing
 Administrative 	 Overly burdensome
burden of regulatory	administrative
requirements	requirements
	■ Fear of diversion
■ Cost	■ Cost
 Difficulties 	 Inadequate health
encountered in the	care resources, such
distribution system	as facilities and health
-	care professionals
 Insufficient import 	Insufficient amount of
or manufacture	imported or
	manufactured in the
	country
 Lack of national 	 Lack of national policy
policy or guidelines	or guidelines

How the system of estimates works

The system of estimates of narcotic drugs was established by the 1961 Convention (Articles 12 and 19). Estimates should be based on legitimate medical and scientific requirements. The process of calculating these estimates is useful for the following. It allows the competent authorities to obtain accurate and realistic information about the quantities of controlled substances actually required for medical purposes. It provides information that is essential for authorities to ensure that sufficient quantities of controlled substances are available to the health care system. The estimate system informs authorities about the levels required for legitimate use so that they are able to limit their supply to those quantities and to take appropriate measures to prevent their diversion for illicit use.

The estimates furnished by Governments are examined, confirmed if applicable, and published by INCB to provide countries with guidance about quantities of narcotic medicines by each country for

licit purposes. By allowing the manufacture, import and export in quantities that do not exceed the estimates published by INCB, Governments can reduce the risks of diversion of such substances for illicit uses. The estimates of legitimate requirements for narcotic drugs furnished by Governments also allow INCB to promote a balance between their global demand and their supply.

Responsibilities in ensuring the effectiveness of the estimate system controlled substances

The national competent authorities (NCAs) are responsible for calculating the estimates for controlled substances to be furnished to INCB, and developing a method to accurately determine the legitimate requirements for medical purposes in their countries. The NCAs are responsible for informing operators (manufacturers, distributors and health care providers) who provide information for preparing the estimates about their legal obligation to provide the relevant information. Operators should be provided with the knowledge to carry out these responsibilities, and the NCAs should organize the collection of the relevant data from operators and other sources. The NCAs are also responsible for coordinating with other governmental bodies involved in drug supply management and concerned with public health, notably the ministry of health, to ensure that conditions are met for the accurate quantification of requirements for controlled substances.

The International Narcotics Control Board (INCB), as mandated by the international drug control conventions, assists Governments in complying with their treaty obligations. The International Narcotics Control Board (INCB) examines the estimates furnished by Governments to help ensure that controlled substances are available at levels that are adequate to meet medical requirements and that minimize the risk of their diversion. In the case of narcotic drugs, INCB confirms the estimates furnished by Governments, after obtaining additional explanations of the intended usage of quantities furnished if necessary. The International Narcotics Control Board (INCB) publishes the estimates provided by countries to share this public information with all Governments.

There are no set limits on the estimates of controlled substances that Governments should furnish to INCB; it is only required that the quantities furnished reflect the legitimate requirements. Furthermore, INCB encourages increases in the estimates when such increases respond to increasing medical requirements and when appropriate measures are in place to prevent

diversion. When a country fails to meet its treaty-based obligation to furnish the estimates, these are established by INCB to ensure that the country is able to import controlled substances. Under such circumstances, INCB requests the country in question to revise the estimates in such that these reflect more accurately the legitimate requirements.

Estimates for narcotic drugs

These estimates refers to the calculated quantities of a specific narcotic medicines required by a country for medical and scientific purposes for the period of one year. Such estimates are communicated on a yearly basis to INCB, which reviews and confirms them, requesting additional information from the government as needed, and may confirm them. Article 19 of the 1961 Convention says that Governments have the obligation to provide estimates of their legitimate requirements of narcotic drugs to INCB on an annual basis. If the annual estimates furnished by Governments prove inadequate to meet actual requirements in the course of the year to which the estimates apply, Governments may amend their annual estimates by furnishing supplementary estimates to INCB (see Figure 2).

The INCB examines the annual estimates of drug requirements furnished by Governments with a view to ensure that narcotic medicines are available for legitimate purposes only. After examining the estimates provided by Governments and obtaining satisfactory explanations as necessary, INCB confirms the estimates and publishes them. The annual estimates confirmed by INCB are valid for one year. Article 21 of the 1961 Convention says that countries should manufacture, import or utilize narcotic drugs within the limits of the totals of estimates published by INCB. These estimates also serve as a guideline for exporting countries regarding the limits of quantities of narcotic drugs which can be imported by other countries.

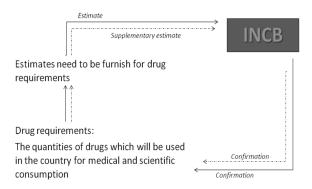


Figure 2. The estimate system for narcotic drugs (simplified)

When a country fails to submit to INCB its estimates for requirements of narcotic drugs, these estimates are established by INCB (see Article 12, para. 3 of the 1961 Convention). In doing so INCB usually relies on previous estimates of the country in question. However, INCB requests the concerned Government to revise the estimates that have been established, to reflect the most recent requirements of its population and to inform INCB of those revisions.

Considerations for the calculation of estimates that accurately reflect medical requirements

One of the main purposes of calculating estimates is to ensure that the quantities of controlled substances made available to the health system in a country accurately reflect the medical requirements. To achieve this objective, the process of quantifying these requirements should not be a purely computational procedure carried out independently, but rather, should be conducted within the framework of the supply management system for controlled substances. The following components form the core of a controlled substance supply management system:7,8 a). Selection: deciding which controlled substances are required for treating the health problems in the country, b). Quantification: estimating how much of each controlled substance is required to meet medical and scientific requirements, c). Procurement: selecting suppliers, placing and monitoring orders, checking delivery quantities and quality, and paying suppliers, d). Distribution: reception, storage, stock control, transportation, and record keeping for monitoring and control, e). Use: prescription, dispensing and use of controlled substances and patients' compliance with prescriptions.

These components are interdependent and form a cycle in which every step builds on the previous one and leads to the next. Weaknesses in any step of the cycle will have an impact on its effectiveness and eventually on the adequate provision of the controlled substances to the health system. Poor quantification will obviously result in an incorrect calculation of medical requirements, thereby limiting the amount of controlled substances available to the country. However, as discussed below, problems in selection, procurement, distribution and irrational use can also affect the accuracy of the quantification process. This is especially important when quantification is based on past consumption patterns, as is the case for many of the countries that report estimates to INCB.6

If the components of the supply management system are managed by different agencies, then coordination and information sharing among the various agencies are essential to ensure that the cycle is not interrupted. Each agency should be aware of their responsibility and of how the components of the system are supposed to work together. Furthermore strategies should be implemented to monitor the effectiveness of each component of the cycle and of the entire system in supplying the required quantities of controlled substances.

In addition to these operational requirements, the effectiveness of the supply management system depends on a well functioning legal and policy framework that is committed to ensuring the availability and rational use of controlled substances for medical purposes. The lack of such a framework can hinder the functioning of the supply management cycle and create impediments to the rational use of narcotic medicines. Fundamental changes to the legal and policy framework are then necessary to eliminate these impediments to use.⁹

Methods for quantifying the requirements for narcotic medicines

Three methods and their variants are commonly used to quantify the requirements for controlled substances: the consumption-based, service-based and morbidity-based methods. The decision to apply any one of the methods is determined by the availability of the data needed for quantification, the resources available and the structure of the controlled substance supply system. However, it should be taken into account that the morbidity-based method will provide the closest figure to the medical need. This method is the most recommended when the morbidity pattern related is well documented and the health care delivery is well-maintained.

This section outlines the optimal circumstances under which each method can be applied to yield accurate results and the main limitations of the methods. In practice, all the conditions that contribute to the accuracy of the methods may not be present. This should however not preclude the application of the methods since achieving accuracy in quantifying requirements for controlled substances is an incremental process. It depends not only on applying the appropriate method but also on many factors external to the quantification process. Efforts to address these factors should be concurrent with a gradual refinement of the estimates of requirements.

Consumption-based method and its variants

The consumption-based method and its variants are based on the use from recent years. If past use of controlled substances is stable, future requirements can be calculated by averaging the amounts used in health facilities in recent years and adding a margin for unforeseeable increases. In variants of this method, calculations are based on data obtained from manufacturers, importers and wholesalers that distribute controlled substances to peripheral health facilities.

Consumption-based method is appropriate in the following situations, in the absence of circumstances that might warrant a change (e.g. emergency health situations), if the demand for health services has reached a relatively steady state, when the demands of the health care system are met by a well-functioning supply management system that ensures an uninterrupted supply of controlled substances, when use of controlled substances is rational, and when reliable data on past use can be collected.

In using this method, it is important to be aware that the consumption-based method and its variants do not provide a detailed and systematic basis for reviewing controlled substance use that could help to improve rational use and the accuracy of the quantification process. For example, if prescribing, dispensing, and administering are poor and not corrected, this method may perpetuate it. In the case of calculations based on quantities requested by trading companies for future sales, the calculated amount may be influenced by limited marketing possibilities or overly optimistic sales expectations, and may therefore not reflect medical requirements. Stock-outs over long periods of time and high loss or wastage of controlled substances may reduce the accuracy of the method. In addition, data collected for the consumption-based method and its variants may be incomplete for the following reasons: poor stock management, inadequate record-keeping, and inadequate reporting to the authorities responsible for data collection.

Service-based method

The service-based method calculates controlled substance requirements based on actual, current levels of use of each controlled substance (for all clinical indications) in a sample of standard facilities. The data collected from the standard facilities can then be extrapolated to calculate the requirements of other similar facilities included in the quantification process. This method targets the health services available and takes into account their current

treatment levels, thereby reflecting the financial and administrative constraints within the existing health care system.

This method is appropriate in the following situations, i.e., when prescribing, administering and dispensing patterns in the standard facilities are considered to be rational; for increased accuracy of the method, strategies should be developed to promote rational use in all facilities, when the pattern of morbidity in the standard facilities is representative of the pattern in the region included in the quantification; if there are large differences in morbidity patterns, other methods may be more appropriate for calculating the requirements of those non-standard facilities, and when detailed data on patient morbidity or standard treatment guidelines are not available.

Authorities should be aware that service based methods may not take into account the medical needs of patients that cannot be met due to cultural or geographical constraints of the existing health system. Any irrational patterns of use (prescribing, administering, dispensing) in the standard facilities, which are not corrected, may be perpetuated throughout the health system as they are carried over into the requirements for controlled substances for other facilities included in the quantification process. In addition, limitations of the health care system (frequent stock-outs, irrational patterns of use, poor record-keeping practices etc) may make it difficult to select valid standard facilities. Servicebased methods may be difficult to apply for controlled substances like benzodiazepines that are prescribed not only in health care facilities but also by doctors with variable prescribing patterns.

Morbidity-based method

The morbidity method calculates the requirements for controlled substances based on an assessment of the frequency of health problems (morbidity) and on accepted treatment norms for the health problems in question. Data on morbidity can be obtained from epidemiological assessments at the regional or national level. When complete data on the population morbidity for a given health problem is available, the method calculates the quantities of controlled substance that would be necessary to treat all the morbidity. However such data are rarely available and may be difficult to collect. In such situations, morbidity profiles of sample health facilities can be used in the calculation and the requirement scaled up to the regional or national level.

This method is appropriate in the following situations, when data on past patterns of use of

controlled substances are not available or are unreliable, health services are new or rapidly changing e.g. for starting an opioid substitution treatment programme, accurate and complete data on morbidity are available, standard treatment schedules have been devised, to promote a change towards more rational prescribing, as defined by standard treatment schedules, or when it is necessary to counter-check the requirements calculated using other methods.

Authorities should be aware that if standard treatments schedules are not followed, the calculated requirements for controlled substances will not match their use. This method will accurately predict requirements only for a limited number of health problems for which complete morbidity data and standard treatment schedules are available. Therefore if a controlled substance is used to treat several health problems, it may be necessary to use other methods to estimate the quantities required to treat those health problems to which the morbidity method could not be applied due to data limitation. The calculated requirement will be more accurate if sample health facilities used in the calculation have a morbidity profile that is representative of the regions included in the quantification.

Stepping the quantification ladder

The quantification process serves to promote the efficient procurement of controlled substances and their rational use. To achieve these goals, regular evaluation of the effectiveness of the quantification process and of the accuracy of the calculated requirements should be conducted. Continuous monitoring of the quantification process is also important to ensure its effectiveness.

Evaluation of the quantification process is useful to assess the effectiveness with which the various steps of the process (e.g. data collection) have been carried out. Problems at each step should be identified and corresponding solutions introduced. It is also useful to determine whether modifications in the method used are warranted. These modifications should respond to changes in prevailing conditions and available information and aim at achieving more accurate quantification. Evaluation is necessary to identify whether adjustments are necessary due to new developments such as population growth and new medicines, programmes and facilities.

The ultimate purpose of the quantification process is to ensure the availability of controlled substances for medical and scientific purposes. However, several other factors and components of the supply management system have an impact on

availability. These should be well understood and accounted for before availability can be used as a criteria to assess the predictive accuracy of the quantification process.

The three methods, namely the consumptionbased, service-based and morbidity-based methods, are commonly used to quantify the requirements for controlled substances:. The decision to apply any one of the methods is determined by the availability of the data needed for quantification, the resources available and the structure of the controlled substance supply system. However, it should be taken into account that the morbidity-based method will provide the closest figure to the medical need. This method is the most recommended when the morbidity pattern related is well documented and the health care delivery is well-maintained. Therefore, countries should gradually step up from consumption-based to morbidity-based method in estimating their requirements of narcotic medicines for medical purposes (Figure 3).

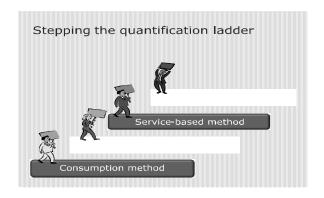


Figure 3. The quantification ladder. To achieve ideal level of narcotic medicine use, every country should step up gradually to using the morbidity-based method

CONCLUSION

The accurate estimation of requirements for narcotic medicines is an essential step in ensuring their adequate supply for medical purposes. Poor estimation of requirements can contribute to many problems in the use of narcotic medicines in the health care system. The world consumption data shows that morphine use is concentrated only in small number of countries in the Europe and North America, while in the rest of the world its consumption level is inadequate to treat pain. Morphine is even not accessible in 70 countries and territories. Therefore, it is of utmost importance to in using the most appropriate quantifying methods to estimate narcotic medicines in order to meet their medical

needs. To improve the access, countries should step up their method of quantification, from consumption-based to morbidity method. However, it should be in a gradual process, taken into account the improvement of measures in preventing the medicines from distortion.

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