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REPORT

Ensuring Patient Access to Essential Medicines While Minimizing Harmful Use: A Revised World Health Organization Tool to Improve National Drug Control Policy

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ABSTRACT

In 2011, the World Health Organization (WHO) published a series of 21 guidelines to assist governments in improving their national drug control laws, regulations, and administrative procedures to promote the availability of controlled medicines for pain relief and for a variety of acute and chronic diseases and conditions. These guidelines ultimately are designed to encourage the development of policies designed to fulfill a country's dual obligation concerning these medicines: to prevent their abuse, diversion and trafficking while ensuring access for medical and scientific purposes. This article summarizes each guideline and outlines the constituents who can actively participate in making controlled medicines available to the patients who need them. It is hoped that representatives of governments and medical institutions, as well as health care professionals, will commonly and effectively use the revised WHO guidelines as a policy change tool.

KEYWORDS Balance, controlled substances, policy, World Health Organization

INTRODUCTION

Global health is a changing field, transitioning from a historic focus on infectious diseases to noncommunicable diseases that now account for 60% of the deaths worldwide (1). Despite the availability of medical knowledge and both nonpharmacologic and pharmacological treatment modalities, inadequate management of pain, especially pain due to cancer, continues to be a serious health problem in the world. The incidence of cancer is greatest in developed countries, but will shift to developing countries where most patients do not receive the diagnosis of cancer until the disease is already in the late stage and when pain is prevalent (2, 3). In this scenario, the appropriate medical and humane response is to provide pain relief and palliative care. Educating health care practitioners about these clinical issues can help improve the application of effective treatments, but the inadequate availability and accessibility of opioid analgesics also must be successfully remedied to be able to provide sufficient pain relief. Opioids also can be effective modalities for managing pain other than from cancer, both acute and chronic, as well as for the treatment of other conditions unrelated to pain.

Opioid analgesics are indispensable for the management of pain, and there has been a notable cumulative increase in their consumption in recent years. This increase in medical use, however, has occurred predominantly in developed countries, with approximately 80% of the global population still lacking access to morphine for treating pain (4). When pain

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is moderate to severe, there can be few adequate substitutes for opioids in the class of morphine, which also includes fentanyl, hydromorphone, and oxycodone (5).

The International Narcotics Control Board (INCB), the international body that monitors global movement of narcotic drugs and psychotropic substances, has acknowledged that opioids are not sufficiently available for medical purposes (6). The World Health Organization (WHO) and a number of national governments additionally have recognized this reality (7). There are many reasons why these medications are inadequately available. Such reasons include 1. a country's economic and social development (e.g., life expectancy, level of education, and economic factors); 2. the low priority for pain management in a country's health care system; 3. high prevalence of concerns about the development of iatrogenic dependence syndrome (an international term synonymous with "substance dependence" in the United States); 4. problems in procurement, manufacture, and distribution of opioids; and 5. unduly restrictive national drug control policies.

Some countries' governments and health care practitioners have been collaborating recently to improve legislative and regulatory environments regarding the safe and effective medical use of opioids. Countries that have demonstrated notable progress include Colombia, Georgia, Guatemala, India, Jamaica, Kenya, Nepal, Panama, Serbia, Sierra Leone, the United States, and Vietnam. Many countries, however, have yet to address these policy and systems topics.

In the late 1990s, working with the WHO, the University of Wisconsin Pain & Policy Studies Group (PPSG) initiated development of a set of guidelines for countries to evaluate their policies, which was entitled "Achieving Balance in National Opioids Control Policy (8)." To create these guidelines, PPSG members undertook a systematic process drawing on an analysis of the international drug control conventions, and well as on their experience with and knowledge of countries' policies. This process culminated in a seminal meeting held in 1999 in Madison, Wisconsin, which brought together a group of high-level international experts in drug regulation, palliative care, and pain management to review and finalize the guidelines (9).

The WHO recently updated this valuable tool as a means to support the global imperative to better address pain and suffering. The tool can be used by governments, health care practitioners, and others to determine whether their national drug control system has the legal and administrative framework required to make medications available for pain relief and other purposes, an objective supported by international treaties and recommendations from the INCB and the WHO.

REVISED GUIDELINES FROM THE WHO

Early in 2010, Dr. Willem Scholten, Team Leader of the WHO Access to Controlled Medications Programme, invited the PPSG to participate in a project to revise the WHO guidelines that the PPSG helped author in 1999–2000 (8). Dr. James Cleary, Director of the PPSG, became a member of the working group that developed the inventory of topics for inclusion in the updated guidelines and participated in a three-stage Delphi process through mid- to late-2010 to draft, refine, and finalize the document. In March 2011, WHO published the revised guidelines, entitled "Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines" (*Ensuring Balance*) (10), which have been endorsed by the INCB (as were the previous guidelines from 2000).

The purpose and scope of the revised guidelines, which are meant to assist governments about policy development, are explained in the following introduction statement:

> The **purpose** of these guidelines is to provide authoritative guidance on policies and legislation with regards to *availability, accessibility, affordability* and *control* of medicines made from substances that are controlled under the international drug control conventions. In this document, these medicines will be referred to as "controlled medicines." ... The **scope** of these guidelines is "all controlled medicines." These are medicines made from substances controlled internationally under the Single Convention on Narcotic Drugs (further called "Single Convention") and under the Convention on Psychotropic Substances. It also includes medicines made from precursors regulated under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Furthermore, they could also be other substances controlled under national drug laws and regulations (10). (p. 10)

Although the 2000 guidelines emphasized the need to address pain relief and palliative care issues for patients with the disease of cancer, through the access to and availability of opioids, *Ensuring Balance* promotes the availability of controlled medicines (not solely opioids) for pain relief and for a variety of acute and chronic diseases and conditions. It also applies to the use of opioids (i.e., methadone and buprenorphine) for treatment of dependence syndrome, as well as the use of other controlled medicines for practices such as emergency medicine, obstetrics, and psychiatry.

Critically, these guidelines promote the development of policies that are designed to fulfill a country's dual obligation concerning these medicines, which is conceptualized by an international medicolegal principle known as balance:

> The central principle of "balance" represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower health care professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care. (p. 11) (10)

According to the WHO, the maximum public health benefit can only be attained through balanced policy and related activities (i.e., resulting in enhanced medication access for rational medical use while simultaneously curtailing morbidity or mortality from their harmful use). This dual obligation of countries is based on legal, political, public health, and moral imperatives (10). In addition, in 2008 a United Nations (UN) Special Rapporteur emphasized the human rights aspects of drug control in relation to the principle of balance, as well as the indispensability of narcotic and psychotropic medicines for the relief of pain and suffering and for scientific purposes (11).

Ensuring Balance offers 21 individual guidelines that are grouped into seven mutually exclusive categories that represent the major legislative and regulatory systems issues with which governments should be concerned (enumerated below). Each guideline is explained, and its rationale is supported by relevant authoritative or legal citations, with an emphasis on the roles of those professionals who should be an active part of the chain of distribution for controlled medicines. In addition, a Country Assessment Checklist is provided as a tool for evaluating the extent to which the guidelines are adhered—there are 67 checklist questions for the 21 guidelines, which are categorized by whether they relate to legal or policy issues. Overall, the guidelines are designed for use in assessing national drug control policies to determine if a country's legislation, regulations, and administrative procedures are working to make controlled medicines adequately available for safe and effective medical uses. It is hoped that representatives of governments and medical institutions, and also health professionals, will take advantage of these revised WHO guidelines.

1. Content of Drug Control Legislation and Policy

The first two guidelines recognize the indispensability of controlled medicines, and urge governments to adopt and implement policies that ensure their adequate availability and accessibility:

- National drug control policies should recognize that controlled medicines are absolutely necessary for medical and scientific purposes.
- Governments should comply with their international legal obligations to ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes through national legislation and drug control policies.

2. Authorities and Their Role in the System

The purpose of these guidelines is to encourage governments to assign administrative responsibility to assure that medications are sufficiently available and accessible, and also urge legislative and regulatory authorities to cooperate with one another, health care practitioners, and other relevant organizations regarding this objective. Importantly, there is a call for all government agencies to avoid impeding controlled medicine access and contributing to policy barriers.

- Governments should designate a National Authority for ensuring adequate availability and accessibility of controlled medicines in health care.
- Governments should ensure that all authorities involved in developing and implementing policies on controlled substances cooperate and meet as necessary for the promotion of their availability and accessibility for medical and scientific purposes as well as the prevention of abuse, dependence syndrome, and diversion.
- Governments should ensure that there is a forum where drug control authorities and public health authorities cooperate and meet as necessary with health professional organizations and other stakeholders for the promotion of the availability and accessibility of controlled medicines for medical and scientific purposes, as well as the prevention of abuse, dependence syndrome, and diversion.
- All government agencies, depending on their roles and obligations, should ensure that in the fulfillment of their duties, they do not impede health policies and access to legitimate treatment with controlled medicines. Health authorities should provide relevant information on treatment principles to drug law enforcement and other relevant agencies.

3. Policy Planning for Availability and Accessibility

This guideline category relates ultimately to policy content. Recommendations urge that issues of medication availability and accessibility be central to policy activities, that enhancing medication access co-occur with reducing diversion and nonmedical use, that policy evaluation efforts remove undue restrictions, and that stigmatizing terminology be avoided. Moreover, all patient populations are to receive equitable benefit from the treatment options related to controlled medicines for which the policies provide.

- Governments should include the availability and accessibility of controlled medicines for all relevant medical uses in their national pharmaceutical policy plans. They should also include the relevant controlled medicines and relevant services in specific national disease control programs and other public health policies.
- Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rationale medical use and the prevention of diversion, abuse, and dependence syndrome.
- Governments are encouraged to maximize access of opioids for patients in medical institutions and while living at home throughout the country, while maintaining reasonable controls to prevent diversion.
- Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medications. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions that are ordinarily medical in nature should be taken by health professionals.
- Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse.

4. Health Professionals

These guidelines relate to the authority of health care practitioners to prescribe, administer, or dispense controlled medicines, as well as the need for school curricula and other educational initiatives to increase practitioners' knowledge about the appropriate use of these medicines.

- Appropriately trained and qualified physicians, and, if applicable, nurses and other health professionals, at all levels of health care should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge, and good practice without any further license requirements.
- Appropriately trained and qualified pharmacists at all levels of health care should be allowed to dispense controlled medicines, based on their general professional license, current medical knowledge, and good practice without any further license requirements.
- Governments should promote that medical, pharmaceutical, and nursing schools teach the knowledge and skills for the treatment of pain, substance use disorders in the context of medical use of controlled medicines, and other health conditions that need treatment with controlled medicines.
- In countries where controlled medicines become available and accessible for the first time, governments should organize education initiatives for health care professionals to ensure their rational use.

5. Estimates and Statistics

The guidelines in this section emphasize the need for a government to develop accurate estimates of the medical need for controlled medicines. The estimate must be submitted to the INCB in a timely fashion before the government can lawfully obtain and distribute medications. The government also must be prepared to submit supplementary estimates, if unforeseen needs arise, to avoid interruptions in medication supplies to patients.

- Governments should develop a practical method to estimate realistically the medical and scientific requirements for controlled substances, using all relevant information.
- Governments should furnish to the INCB estimates and assessments of the quantities of controlled substances required for legitimate medical and scientific purposes (estimates annually for narcotic drugs and certain precursors; assessments at least every 3 years for psychotropic substances). Governments should furnish supplementary estimates or modified assessments to the INCB if it appears that the availability of controlled substances for legitimate purposes will fall short because of initial underestimation of regular demand, emergencies, or exceptional demand.
- Governments are required to submit statistical reports to the INCB on narcotic drugs and psychotropic substances in accordance with the respective provisions of the international drug control conventions and relevant resolutions of the Economic and Social Council.

6. Procurement

This section emphasizes the importance of maintaining a national system capable of producing

or importing, and then distributing, controlled medicines to the medical institutions that need them. The guidelines also address other administrative responsibilities for managing the system according to international requirements.

- Governments should ensure, in cooperation with companies and agencies managing distribution, that the procurement, manufacture, and distribution of controlled medicines and accomplished in a timely manner with good geographical coverage so that there are no shortages of supply, and that such medicines are always available when they are needed while maintaining adequate controls to prevent diversion, abuse, or dependence syndrome.
- Governments should minimize the negative impact of control and safety measures on the affordability and availability of controlled medicines.
- Drug control authorities should be aware of the existence of the WHO model guidelines for the international provision of controlled medicines for emergency medical care, which provide a simplified procedure for importation and exportation of controlled medicines into a country where disaster disrupted and functioning of the drug control authorities. They should apply them when necessary.

7. Other

Finally, a single guideline recognizes the need to address the aforementioned legislative and regulatory issues with medicines that are not controlled under the international drug control conventions.

- Governments that decide to bring medicines under national control that are not controlled under the international drug control conventions should apply these guidelines equally to those nationally controlled medicines.

CONCLUSION

According to international standards, national drug control policies are intended not only to reduce drug abuse, but also to ensure availability of controlled medicines for medical and scientific purposes. Indeed, drug abuse prevention efforts should not interfere with the appropriate medical use of controlled medicines, and it is only in this way that positive public health outcomes can be realized. Drug regulators in a country (at the national, state, and provincial levels), medical administrators, and health professionals, as well as members of other relevant government agencies and patients and their families, all have essential roles to play to achieve balanced national policies governing controlled medicines.

These guidelines are a critical tool for health care practitioners, drug regulators, and policy makers to evaluate the policies and systems in their countries to identify barriers and formulate an action plan for addressing potential impediments in a balanced manner. The first edition of the guidelines was used by government representatives and health care experts throughout the world at regional opioid availability workshops and national meetings, and as a training tool for programs such as the PPSG International Pain Policy Fellowship (12). Likewise, the revised edition of these guidelines is designed to serve as an updated, improved, and expansive tool for continued utilization in similar forums. For example, the Access to Opioid Medication in Europe Project, which seeks to improve access to opioids for both pain and opioid substation therapy, is currently using the revised guidelines to evaluate legislation from several Central and Eastern European countries (13).

More than a decade after the first published edition of the WHO guidelines, the revised edition expands the context of the guidelines to make them more broadly relevant in today's clinical environment. Importantly, the revised guidelines also reflect UN authoritative bodies' enduring recommendations about applying the fundamental principle of balance when health care and regulatory stakeholders collaborate to identify and address policy barriers as a means of ensuring adequate access to controlled medicines (6, 14, 15). They also represent a continued call to action from UN health and regulatory organizations reiterating the need for governments to evaluate their national policies working with health care authorities in their countries and begin to address the identified deficits.

Declaration of interest

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