

Special Article

Consensus Building on Access to Controlled Medicines: A Four-Stage Delphi Consensus Procedure

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Abstract

Context. In 2011, the World Health Organization (WHO) published the policy guidelines *Ensuring Balance in National Controlled Substances Policies—Guidance for Availability and Accessibility of Controlled Medicines*, presenting a revised version of the previous guidelines from 2000.

Objectives. To describe the consensus process that guided the revision of the guidelines.

Methods. A four-stage revision process was undertaken with a panel of 29 international experts from palliative care, public health, and harm reduction: 1) a qualitative inventory of required changes by means of a structured checklist, 2) & 3) a two-round online consensus Delphi process about the draft revision of the guidelines, and 4) a WHO advisory meeting for the discussion of remaining controversies and final issues.

Results. The qualitative inventory resulted in a draft revision of the guidelines meeting requirements on different levels, such as a broader focus and more accurate evidence. Operationalization of the guidelines was improved by specifying measures, procedures, and responsibilities. The Delphi procedure provided concrete indications for the rewording of both the guidelines and the associated text. During the advisory meeting, any persistent disagreements were systematically discussed to achieve consensus on the new version of the guidelines.

Conclusion. The four-stage multimethod consensus process resulted in a substantial revision to the WHO guidelines. This takes into account the increase in knowledge about opioid medication since the first edition of the guidelines.

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Key Words

Access to controlled medicines, World Health Organization, policy guidelines, consensus process, Delphi method, pharmaceutical policy, Single Convention on Narcotic Drugs

Introduction

One of the persistent challenges of health policy and pharmaceutical legislation is the adequate balance between the beneficial effects of opioids for medical purposes and the risks related to these substances for the individual and public health.^{1,2} The publication of the revised World Health Organization (WHO) policy guidelines, *Ensuring Balance in National Policies on Controlled Substances—Guidance for Availability and Accessibility of Controlled Medicines*, is an important milestone in the history of addressing this legal and political challenge.^{3,4}

In 1961, the Single Convention on Narcotic Drugs (Single Convention) was adopted by the United Nations with the aim of regulating international drug control policies and providing guidance for policy on a national level. It covers laws, regulations, and measures for the prevention of abuse and diversion of controlled substances—including opioids—and their availability for medical purposes.⁵

In many countries, the Single Convention has been implemented in a one-sided manner that mainly emphasizes control and largely ignores issues related to availability. This has led to overly restrictive regulations and policies for access to controlled substances, such as restrictions in prescribing and dispensing opioids, resulting in severe negative consequences for patients and health care professionals. The implications for patients are that they cannot access the medications they require or do not receive them in an effective dose.^{3,6,7} Health care professionals are confronted with overly burdensome formal procedures and must fear prosecution and punishment, for example, if they prescribe higher doses than the average prescriber of opioids. In addition, *opiophobia* and specifically the persistent fear of causing opioid dependence may pose a barrier to adequate treatment with opioids,⁸ although

there is no convincing scientific evidence for this reservation.^{9,10} Worldwide, these barriers lead to undertreatment of pain, including cancer pain, in many countries.^{1,11} They also result in a lack of treatment with long-acting opioids and other drug treatments for injecting drug users, along with increased health risks such as HIV infection and overdose.¹²

For these reasons, in 2000, the WHO Collaborating Center for Policy and Communications in Cancer Care, in collaboration with the International Narcotics Control Board (INCB) and the WHO Department of Essential Medicines and Health Products, drafted the WHO policy guidelines *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*.¹³ The aim was to encourage governments to achieve better access to opioids by identifying and overcoming the regulatory barriers to opioid availability and to highlight the original principle of balance contained in the Single Convention. The document addressed different levels of legislation and policy (restrictive legislation, authorities, needs estimates and statistical reports, cooperation with health care professionals, procurement, manufacture and distribution, stigmatizing terminology, and prescription) providing in total 16 guidelines. It also contained a self-assessment checklist for completion by representatives of a country's relevant authorities to analyze to what extent the guidelines were met on a national level.

A revision of the original guidelines was planned by the WHO Access to Controlled Medications Programme (ACMP) for two major reasons. First, the perspectives of public health and human rights needed to be emphasized more strongly because they have become increasingly important in the planning of health care.^{14,15} Second, the realm of the guidelines needed to be extended from

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