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## The Update of the Mexican Health Care Formulary and Supply Catalog in the Context of the Health Technology Assessment

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### ABSTRACT

One of the instruments Mexico has available for the optimization of resources specifically allocated to health technologies is the Health Care Formulary and Supply Catalog (Cuadro Básico y Catálogo de Insumos del Sector Salud [CBCISS]). The aim of the CBCISS is to collaborate in the optimization of public resources through the use of technologies (supplies) that have proven their safety, therapeutic efficacy, and efficiency. The importance of the CBCISS lies in the fact that all public institutions within the National Health System must use only the established technologies it contains. The implementation of strategies that strengthen the CBCISS update process allows it to be thought of as an essential regulatory tool for the introduction of health technologies, with relevant contributions to the proper selection of cost-effective interventions. It ensures that each supply included on the list meets the criteria sufficient and necessary to ensure efficacy, safety, effectiveness, and, of course, efficiency, as evidence supporting the selection of suitable technologies. The General Health Council (Consejo de Salubridad General [CSG]) is a collegial body of constitutional origin that—in accordance with its authority—prepares, updates, publishes, and distributes the CBCISS. To perform these activities, the CSG has the CBCISS Inter-institutional Commission. The CBCISS update is performed through the processes of

inclusion, modification, and exclusion of supplies approved by the Interior Commission. The CBCISS update process consists of three stages: the first stage involves a test that leads to the acceptance or inadmissibility of the requests, and the other two focus on an in-depth evaluation for the ruling. This article describes the experience of health technology assessment in Mexico, presents the achievements and outlines the improvements in the process of submission of new health technologies, and presents a preliminary analysis of the submissions evaluated until December 2012. During the analysis period, 394 submissions were received. After confirming compliance with the requirements, 59.9% of the submissions passed to the next stage of the process, technology assessment. In the third stage, the committee approved 44.9% of the submissions evaluated. The improvements established in the country in terms of health technology assessment allowed choosing the technologies that give more value for money in a context of public health institutions.

**Keywords:** efficiency, health care, health technologies, health technology assessment.

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### Introduction

The search for equity, quality of care, and efficiency has been one of the challenges facing public health systems (PHSs) worldwide. In that context, health technology assessment plays a significant role in gaining greater benefits for the health care field and planning of the rational use of resources.

As a result, recent decades have been characterized by significant progress in the supply and availability of new health technologies (HTs). Many of these technologies have budgetary implications owing to the high costs of their incorporation. Despite the benefits offered by these new technologies as compared with existing ones, their incorporation does not always solve the population's major health issues and they are not effectively accessed by all public sector institutions.

One of the instruments Mexico has available for the optimization of resources for HTs is the Health Care Formulary and Supply Catalog (Cuadro Básico y Catálogo de Insumos del Sector Salud [CBCISS]) [1], and as such, the strategies developed to strengthen it must be favorable in terms of meeting the growing demands for technology and health care services in a difficult economic and social environment.

### The Health Care Formulary and Supply Catalog

The CBCISS is a document that includes, defines, and encodes all medical supplies used by public institutions to provide health services to the population.

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Its origins date to 1846, the year the first Mexican Pharmacopeia [2] was published, and its development over time has set the standards for PHSs. In 1975, a presidential decree [3] was published that established that all public health institutions must have a drug formulary (Cuadro Básico de Medicamentos [CBM]). That same year, the Public Sector Drug Formulary Commission was formed, responsible for the development of the first sectoral-type CBM in 1977 [4]. Later, in 1983, biological products and laboratory reagents, instruments and medical equipment, wound dressing materials, and prosthetics were added to the CBM [5].

In 1996, for the purpose of facilitating information about the supplies used in the support of diagnosis and treatment, the CBM was divided into two parts, on the basis of the type of medical unit: one referred to as formulary for primary care and the other called catalog for secondary and tertiary care [6], just as we know it today.

The aim of the CBCISS is to ensure the optimization of public resources through the use of technologies (supplies) that have proven their safety, therapeutic efficacy, and efficiency. The importance of the CBCISS lies in the fact that all public institutions within the National Health System must use only the established technologies it contains.

To reinforce its compulsory nature, the bylaws of the CBCISS Inter-institutional Commission were published in the Official Gazette of the federation in February 2003, which specify the powers of the Inter-institutional Commission and Specific Technical Committees (Comité Técnico Específico [CTEs]) as well as institutional representatives. In addition, it describes the CBCISS update procedure [7].

## Strategies for Strengthening the Update Process

We know that as a country becomes more developed, the burden and weight of disease increase, especially for noncommunicable diseases that accompany the epidemiological transition. This translates into new health care needs and causes the development of new technologies that revolutionize medical practice and contribute to the challenge facing the PHSs, which is to improve the quality of care and supplies, making them safe, effective, efficacious, and efficient services and supplies.

Against this backdrop, the CBCISS Inter-institutional Commission of the General Health Council, through the Directorate for Prioritization, was given the task of strengthening the CBCISS update process, implementing strategies that contribute to the effective and efficient use of technology in PHSs.

Some of these strategies were as follows:

- The organization of a structure dedicated to the assessment and evaluation of the information contained in the requests, primarily those that include HTs.
- The amendment and approval of the bylaws of the CBCISS Inter-institutional Commission, published in the Official Gazette in June 2011 [8], to have a legal regulatory framework that supports the process. The bylaws contain seven sections, which provide for the activities and responsibilities of the commission, the requirements that CBCISS update requests must meet, and the timing thereof.
- The development of the Guidelines for the Evaluation of Supplies (Guía de Evaluación de Insumos [GEI]) [9] with the application of standardized criteria based on scientific methods to evaluate the clinical, epidemiological, and economic evidence from the studies presented in the update proposals and the process to obtain a ruling.

The strategy consists of three key, interconnected themes for the update process: transparency, scientific evidence, and

efficiency. On the one hand, these strategies help to overcome the inefficient use of limited resources, as one of the main obstacles identified in the health world, and on the other hand, they align the efforts of the institutions and stakeholders involved in the process, avoiding the duplication of effort in the initial evaluation.

The General Health Council (Consejo de Salubridad General [CSG]) is a collegial body of constitutional origin that—in accordance with its authority—prepares, updates, publishes, and distributes the Formulary for the primary health care level and the Supply Catalog for the secondary and tertiary levels. To perform these activities, the CSG has the CBCISS Inter-institutional Commission, which is composed of representatives of the Ministry of Health, the Mexican Social Security Institute, the Government Employees' Social Security and Services Institute, the National System for Integral Family Development, the Ministry of National Defense, the Secretariat of the Navy, Petróleos Mexicanos, and the Federal District's Ministry of Health.

For the purposes of updating the CBCISS, the commission has a Technical Secretariat under the Directorate-General for Prioritization and Specific Technical Committees (CTE) for medicines, wound dressing materials, diagnostic aids, and instruments and medical equipment, in addition to the Technical Committees for herbal remedies, homeopathic medicines, and acupuncture supplies, which were recently formed as part of the strategy to strengthen the upgrade process. Each CTE consists of representatives of the commission's full members and is coordinated by its technical secretary.

## Update Process

The CBCISS update is performed through the processes of inclusion, modification, and exclusion of supplies approved by the Interior Commission.

Update requests are received at the CSG during the first five working days of each period (January–April, May–August, September–December), in accordance with the bylaws, and they are passed to the Directorate General for Prioritization, which, in turn, acts as the Technical Secretariat of the Commission to initiate the review and assessment process.

According to what was instituted by the new bylaws, CBCISS update requests related to supplies may be made by public institutions that serve as health care providers; scientific organizations; academies and specialty boards; government institutions; members of the commission; the secretary and the chairman of the General Health Council; and providers or manufacturers of technology, who, to date, make the majority of requests.

## Stages of the Upgrade Process

The CBCISS update process consists of three stages. The first stage involves a checklist that leads to the acceptance or inadmissibility of the requests, and the other two focus on an in-depth evaluation for the ruling.

The first stage, called review and assessment of update requests, leads to verification of compliance by the Technical Secretariat with the requirements instituted in the bylaws (explicitly expressed, for the most part, in Article 28), to ensure integrity, internal consistency, and accuracy:

- Request indicating generic name, code, and reasons for the update request;
- Current Health Registration issued by the a decentralized organ of the Department of Health with technical,

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