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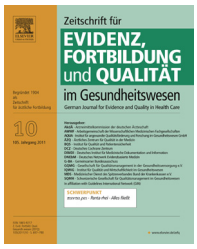

SCHWERPUNKT

# How health economic evaluation (HEE) contributes to decision-making in public health care: the case of Brazil

## *Wie die Kosten-Nutzen-Bewertung zur Entscheidungsfindung im öffentlichen Gesundheitssektor beiträgt: am Beispiel Brasiliens*

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**Summary** The universal access to a health care system for the Brazilian population was established in 1990. Brazil is a country with no tradition in the production and use of health economic evaluation (HEE) to guide decision making in the public health system. It is only within the last two decades that HEEs using a microeconomic approach have appeared in the academic field. On a national level, HEE and Health Technology Assessment (HTA), in a wider sense, were first taken into account in 2003. Two policies deserve to be mentioned — (i) the regulation of medicines in the Brazilian market, and (ii) science, technology and innovation policy. The latter required the fostering of applied research to encourage the application of methods which employ systematic reviews and economic analyses of cost-effectiveness to guide the incorporation of technologies in the Brazilian health care system. The Ministry of Health has initiated the process of incorporating these new technologies on a federal level during the last ten years. In spite of the improvement of HEE methods at Brazilian universities and research institutes, these technologies have not yet reached the governmental bodies. In Brazil, the main challenge lies in the production, interpretation and application of HEE to all technologies within the access scheme(s), and there is limited capacity building. Setting priorities can be the solution for Brazil to be able to perform HEE for relevant technologies within the access scheme(s) while the universal coverage system struggles with a triple burden of disease.

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**SCHLÜSSELWÖRTER**
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**Zusammenfassung** 1990 wurde der Zugang zu einer allgemeinen Gesundheitsversorgung für alle Brasilanerinnen und Brasilianer gesetzlich eingeführt. Dabei hatte Brasilien keine Tradition, auf die es bei der Durchführung und Nutzung von Kosten-Nutzen-Bewertungen in der Entscheidungsfindung im öffentlichen Gesundheitswesen zurückgreifen konnte. Kosten-Nutzen-Bewertungen haben erst in den letzten zwei Jahrzehnten Einzug in den akademischen Bereich gehalten. Im staatlichen Sektor hat man 2003 begonnen, gesundheitsökonomische Evaluation und *Health Technology Assessment* (HTA) im weiteren Sinne zu berücksichtigen. Insbesondere zwei Maßnahmen sind zu erwähnen: 1) Regulierung von Arzneimitteln im brasilianischen Markt und 2) die übergreifende Forschungs- und Technologiepolitik. Letztere hat dazu geführt, dass die Forschung zur Anwendung von systematischen Übersichtsarbeiten und Kosten-Nutzen-Bewertungen intensiviert wurde, um auf deren Grundlage Entscheidungen über die Erstattung im brasilianischen Gesundheitssystem zu fällen. In den letzten 10 Jahren hat auch das Gesundheitsministerium darauf hingewirkt, HTA und insbesondere Kosten-Nutzen-Bewertungen im Erstattungsprozess auf nationaler Ebene zu etablieren. Obwohl man sich an den Universitäten und Forschungsinstituten verstärkt mit den Methoden der Kosten-Nutzen-Bewertung beschäftigt, mangelt es in den Behörden und eigentlichen Zentren der Entscheidungsfindung an Experten auf diesem Gebiet. Daher liegt die große Herausforderung darin, trotz der nicht vorhandenen personellen Ausstattung Kosten-Nutzen-Bewertungen zu erstellen, zu verstehen und für Entscheidungen in der öffentlichen Gesundheitsversorgung anzuwenden. Hilfreich dafür kann es sein, Kosten-Nutzen-Bewertungen für die wirklich im System relevanten Gesundheitstechnologien prioritär durchzuführen, denn angesichts der Krankheitslast kämpft das System mit der finanziellen Nachhaltigkeit.

## Health care in Brazil

In Brazil, the national health legislation was enacted in 1998. According to the Federal Constitution, the country has the duty of guaranteeing the right to health. This goal is to be reached through social and economic policies, actions for the promotion of health, prevention of diseases and delivery of health care. In 1990, with the creation of the Unified Health System (Sistema Único de Saúde, SUS), the universal access to a health care system for the Brazilian population was established.

The SUS structure of administration is characterized by shared financing on the federal level, the 27 states, and the 5.565 municipalities. Financial sources are taxes and social security contributions. This system covers about 90% of the Brazilian population. Public spending amounts to 41.6% of health care expenses; 58.4% comes from private source [1,2]. The share of the health care sector in thefederal budget has remained fixed, withtotal health care spending representing 8.4% ofthe Gross Domestic Product, equaling to 837 dollars per capita in 2008.

Demands on health care systems are increasing as population grows, science advances and public expectations of health care and quality of life increases [3]. These factors are keys to the growth of the industrial sector and the responsibility of offering access to relevant innovations directed to the triple burden of diseases in Brazil [4], characterized by chronic and degenerative diseases (66.3%), communicable disease(23.5%), and injuries (10.2%). While fulfilling the duty of promoting universal and equal health coverage, Brazil, at the same time, is subject to the dilemma of limited financial resources, making rationality inregulatory terms necessary. Brazil, however, is a country without a tradition of production and implementation of health economic evaluation (HEE) to guide decision making in the public health care system.

## Health Technology Assessment and Health Economic Evaluation in Brazil: The Broad Picture

In the government sector, Health Technology Assessment (HTA) and HEE were first officially legislated ten years ago (2003). Two policies deserve to be mentioned — (i) regulation of medicines in the Brazilian market, and (ii) science, technology and innovation policy [5—7].

The first policy, called the pharmaceutical sector economic market regulation, was passed as Brazilian Federal Law number 10.742. This federal law, in which drug prices were fixed and yearly price adjustments were established, was created as a regulation policy for the pharmaceutical sector. It also called for the creation of the Chamber of Medicines Market Regulation (Câmara de Regulação do Mercado de Medicamentos, CMED) by the Government Council. This Chamber is responsible for the price regulation of medicines in the Brazilian market with the goal of settingmaximum reimbursement prices for new drugs after a benefit assessment has taken place. The evaluation is performed by the National Agency of Sanitary Vigilance (Agência Nacional de Vigilância Sanitária, ANVISA), the Brazilian equivalent of the EMA, and is based on a comparison between the efficacy of a new drug and the current gold standard for the therapy. The assessment includes an appraisal of the literature and a price comparison with other countries. If the new chemical entity provides an additional benefit for the treatment, the new drug is classified in Category I, and a premium price is allowed which is limited to the lowest price in developed countries. If there is no added improvement, the drug is classified in Category II, and the price is limited to the price of the comparator used from the Brazilian health system [8].

The second policy required fostering applied research to encourage the application of such methodological tools