Medicines in Mexico, 1990-2004: systematic review of research on access and use

Veronika J Wirtz, PhD,[1] Michael R Reich, PhD,[2] René Leyva Flores, PhD,[1] Anahí Dreser, MSc.[1,3]

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Abstract
Objective. To review original research studies published between 1990 and 2004 on the access and use of medicines in Mexico to assess the knowledge base for reforming Mexico's pharmaceutical policy. **Material and Methods.** A literature review using electronic databases was conducted of original studies published in the last 15 years about access and use of medicines in Mexico. In addition, a manual search of six relevant journals was performed. Excluded were publications on herbal, complementary and alternative medicines. **Results.** Were identified 108 original articles as being relevant, out of 2 289 titles reviewed, highlighting four policy-related problems: irrational prescribing, harmful self-medication, inequitable access, and frequent drug stock shortage in public health centers. **Conclusions.** This review identified two priorities for Mexico's pharmaceutical policy and strategies: tackling the irrational use of medicines and the inadequate access of medicines. These are critical priorities for a new national pharmaceutical policy.

Key words: pharmaceutical policy; drug utilization; drug access; Mexico

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Resumen
Objetivo. Revisar estudios de investigaciones originales publicados sobre el acceso y uso de los medicamentos en México de 1990 a 2004, con el fin de evaluar el conocimiento que existe para reformar la política farmacéutica nacional. **Material y métodos**. Se condujo una revisión de la literatura sobre estudios originales publicados entre 1990 y 2004 sobre el acceso y uso de medicamentos en México. Además, se revisaron manualmente seis revistas relevantes. Se excluyeron publicaciones sobre herbolaria, medicamentos tradicionales y alternativos. **Resultados**. Se revisaron 2 289 artículos e identificaron 108 como relevantes que destacan cuatro problemas importantes relacionados con las políticas farmacéuticas: prescripción inadecuada, automedicación dañina, acceso inequitativo y desabasto de medicamentos en servicios públicos de salud. **Conclusiones**. Esta revisión identificó dos prioridades críticas para el desarrollo de una nueva política farmacéutica en México: actuar sobre el uso irracional de medicamentos y sobre el acceso inadecuado a medicamentos.

Palabras clave: política farmacéutica; utilización de medicamentos; acceso a medicamentos; México

(1)   Centro de Investigación en Sistemas de Salud, Instituto Nacional de Salud Pública. México
(2)   Harvard School of Public Health, Harvard University. Boston, USA
(3)   Health Services Research Unit, London School of Hygiene and Tropical Medicine. United Kingdom

This paper provides a systematic review of original research studies of the access to and use of medicines in Mexico published in the last fifteen years. This review is timely, since in October 2005 the Mexican government published a background document for considering a new national pharmaceutical policy.[1] One objective of the government's document is to provide a framework for policy development by various stakeholders. Before designing a new policy, however, it is important to identify the major problems that need to be addressed, and outline possible approaches to tackle them. The purpose of this review is to assess the existing research evidence on two key topics –access and use of medicines in Mexico– and to assist in the design of a new national pharmaceutical policy in Mexico. These two areas were chosen according to the core objectives of a national pharmaceutical policy as defined by the World Health Organization (WHO): availability of medicines at affordable prices and rational use of medicines. [2] The study questions for this review are: Are medicines accessible in public and private institutions and are they affordable? What are the consumption and prescription patterns? If problems have been identified in the past, which corrective strategies have been shown to be effective in the Mexican context? We also discuss the implications of this assessment for the reform of Mexico's pharmaceutical policy.

Material and Methods

A literature review was conducted of original studies published in English or Spanish over 15 years (1990-2004) about aspects concerning the access to and use of medicines in Mexico, using the following databases: PubMed, Excerpta Medica (EMBASE), Ingenta, LILACS (Latin America and Caribbean Health Science), SciElo (Scientific Electronic Library Online), Indice Bibliografico Español en Ciencias de la Salud (IBECS) and INRUD (International Network of Rational Drug Use). Key search words included "Mexico" alone or in combination with the search terms: "drugs", "pharmaceutical preparation", "drug supply", "prescribing", "adherence" and "pharmacy". Additionally, a manual search of six journals of high relevance was performed (*Gaceta Médica de México*, *Salud Pública de México*, *Archives of Medical Research*, *Salud Mental*, *Boletín Fármacos* and *Pharmaceutical Care España*). For this review use of medicines includes the concepts of prescription, dispensing and consumption of medicines as well as adherence. With access we are referring to drug pricing, distribution and marketing. Excluded were publications on herbal, complementary and alternative medicines, clinical trials assessing the benefits and risks of medicines, and

studies on susceptibility and resistance to antibiotics and on drug intoxication. Also excluded were letters to the editor and editorials.

In the review, titles were first checked, and if they were found to be relevant the abstract was retrieved. For all studies included in the review the complete text was obtained for analysis. References of the articles were also searched for titles of other relevant articles.

Our principal aim was to conduct a systematic review –a search and appraisal of the literature under pre-established and explicit criteria. For this we classified the studies according to the following characteristics: topic studied, study site (including the type and level of care), study design, drug group or health condition investigated, and patient group included. This information was used to determine the main strengths and weaknesses of each article and the research base related to access and use of medicines in Mexico. We did not carry out a meta-analysis of the articles identified; that is, we did not synthesize the study results through quantitative analysis. Throughout, we use the terms drugs, medicines and pharmaceutical products interchangeably.

Results

Using the selection methods described above, we found 108 original articles for analysis, out of 2 289 titles reviewed from electronic databases. More were reviewed by hand search.

Tables I and II describe the characteristics of the 108 selected studies. In terms of research topics, 52 of the 108 studies investigated the prescribing patterns of medicines; of these, most were carried out in primary care settings (73.1%) and many focused on physicians working in public health care institutions (48.1%). Antibiotics and drugs for the symptomatic treatment of diarrhea were the most investigated drug groups (22%). Twenty-four of the 108 studies analyzed prescription or consumption in patients suffering from acute respiratory infection (ARI) as well as acute diarrhea. With regard to the study population, around one-fifth of the prescribing and consumption studies focused on children under five years old and only three studies examined people over 60 years old. Regarding the study site, more than one third of the studies (35.2%) were carried out in Mexico City. Regarding study methods, 42.6% used surveys as their main instrument of data collection.

All articles selected were classified in two exclusive categories of use and access. Most research articles addressed use of medicines (95 out of 108 articles). Thirteen studies covered issues of access.

Table I

Characteristics of all studies on access and use of medicines (n=108)

Characteristics of all original studies identified	Number of studies	Percentage (%)
Topic		
Prescription	52	48.1
Recommendation in pharmacies	6	5.5
Consumption	23	21.3
Adherence	14	13.1
Access	13	12.0
Geographical area		
Nation wide	25	23.1
Mexico City	37	34.3
Other Central*	24	22.2
North (including border region)	9	8.3
South	10	9.3
Unknown	3	2.8
Method		
Survey	45	41.7
Document analysis	1	0.9
Interviews	7	6.5
Patients' prescription review	27	25
Observation	9	8.3
Hospital pharmacy data review	2	1.9
Use of other databases	9	8.3
Mixed	8	7.4
Design		
Retrospective	20	18.5
Prospective	12	11.1
Cross-sectional	65	60.2
Interventional	7	6.5
Case-control	3	2.8
Mixed	1	0.9

* One study included Mexico City and another city in the Central region and was classified as central
Literature review, Cuernavaca, Mexico, 2005-6

Use of medicines

We divided the studies related to use into four sub-topics: prescription practice (52 articles), advice by pharmacy personnel (6 articles), consumption of medicines (23 articles) and adherence (14 articles).

Prescription practice (n=52)

Investigating how physicians prescribe is one part of analyzing the use of medicines. The objective of phar-

Table II

Number of prescription practice, consumption and adherence studies investigating specific drug groups or health conditions (n= 90)

Drug use in general	12
Drugs for treatment of diarrhea	12
Antibiotics	12
Symptomatic treatment of diarrhea and ARI	7
Antituberculosis drugs	7
Drugs for treatment of ARI	6
Bronchodilatators and corticosteroids	5
Analgesic/anti-inflammatory drugs	5
Antihypertensive drugs	4
Antidiabetic drugs	3
Antiretroviral drugs	3
Antipsychotic drugs	3
Contraceptives	2
Antihypertensive and antidiabetic drugs	1
Anti-lipedimia drugs	1
Hormone replacement therapy	1
Antipyretics	1
Immunnosuppresants	1
Antigout therapy	1
Premature labor inhibitor	1
Antiulcer drugs	1

Literature review, Cuernavaca, Mexico, 2005-6
ARI: acute respiratory infection

macotherapy is a *rational* utilization of medicines, which means the clinical needs of the patient, individual dose requirements and cost effectiveness are the main criteria for the use of medicines.

All except five studies investigated disease- or drug-specific prescribing practices, most commonly acute respiratory infection (ARI) and/or acute diarrhea (17 out of 52). [3-19] In all of these studies, inappropriate prescribing was identified, mainly due to the use of antibiotics, which is only recommended in a minority of cases of ARI and acute diarrhea. The use of antibiotics was discussed as a risk that could increase the development of bacterial resistance to antibiotics. One study evaluated the use of oral rehydration in the treatment of acute diarrhea.[4] Importantly, half of these studies were developed before 1996.

Studies investigating the prescribing practices of public and private physicians for the treatment of conditions other than acute diarrhea and ARI included the following drug groups: antituberculosis drugs,[20] antipsychotics and tranquillizers,[21,22] bronchodilatators and corticosteroids,[23-26] antihypertensive drugs[27-29] and/or

antidiabetic drugs,[30,31] lipid lowering drugs,[32] antigout therapy,[33] antiretroviral drugs,[34,35] hormone replacement therapy,[36] contraceptives,[37] and antirheumatic drugs.[38] Almost all of these studies concluded that treatment is sub-optimal and sometimes even harmful. Many of the authors attributed this problem to a lack of professional consensus or accepted treatment guidelines. Only one of the studies mentions pharmaceutical promotion as a factor influencing prescribing practice.[28]

The problem of inadequate treatment was also identified in two studies investigating general prescribing practice.[39, 40] These studies detected prescriptions that included harmful medicines, for which the benefits of use were out-weighed by their side effects, and which had already been withdrawn from the pharmaceutical market in some developed countries. In addition to potential harm to individual patients, these medicines contributed to increasing costs to patients.

Three studies investigated prescription costs.[41-43] Two studies used household data obtained by the National Health Survey,[42,43] the other pharmacy customer data.[41] Prescription costs were higher for uninsured individuals, and the use of non-essential drugs was found to impose an economic burden on consumers as it unnecessarily increased costs.

Eleven studies[44–55] were carried out in secondary care. Seven studies evaluated antibiotic use, two analgesic use, one antiulcer medication use, and one pharmacotherapy of respiratory infection. The majority of studies concluded that prescribing patterns in secondary care need to be improved.

Overall, these 52 studies showed that prescribing practices for hospitalized and ambulatory patients are often inappropriate, including problems related to harmful prescription behavior, a lack of implementation and monitoring of evidence-based treatment guidelines, and unnecessary costs to patients.

Advice given by pharmacy personnel (n=6)

According to the six studies in this category, trained pharmacy personnel who are able to provide reliable and unbiased information to the consumer are scarce[56-61] even though one study found about only 9% of pharmacy customers required advice from pharmacy personnel.[56] Three of these studies used undercover researchers posing as customers to investigate the treatment recommendations given by pharmacy clerks mainly regarding treatment of tuberculosis, sexually transmitted infections, contraceptives, acute diarrhea or acute respiratory infections; in more than two-thirds of the cases the advice was either inappropriate or harmful. Three of the five studies did not differentiate between small private and chain pharmacies, and only one compared public and private pharmacies.

Consumption of medicines (n=23)

Consumption is the last stage in the medicines cycle. Twenty-three out of the 108 studies (21.5%) investigated consumption of medicines in the community. The majority of studies used surveys of consumers or patients as their data collection method for investigating the consumption of medicines.

Eleven consumption studies investigated the use of antibiotics[62-66] or the use of medicines including antibiotics in the treatment of acute diarrhea in children under five years of age[67-70] and ARI.[71, 72] All of them reported irrational use of medicines. Four of the studies found that in less than 10% of acute diarrhea cases the use of antibiotics was justified (based on the detection of blood in the stool) and two-thirds of the antibiotics were used for less than five days, which increases the risk of bacterial resistance to antibiotics and unnecessary exposure of patients to side effects.[62-65] Other studies found that between 35 and 65% of children below five years of age suffering from diarrhea received medicines, most commonly contra-indicated antibiotics and drugs against diarrhea.[67-70]

Surveys of either household members or pharmacy customers were used in five studies. These studies found that more than half of the respondents (51 to 61%) bought medicines without a physician's prescription[73-75] and between 43 to 55% self-medicated with prescription-only medicines.[76,77] Most frequently purchased drugs were antibiotics, analgesics, vitamins and cold and cough preparations. One study found that two-thirds of the antibiotics purchased were broad-spectrum, again indicating an increased risk of the development of bacterial resistance.[74]

One study on consumption of medicines in patients with fever found that although only 2% of patients were diagnosed with malaria, 37% took anti-malaria medication.[78] In contrast to the large proportion of the studies focusing on children under 5, only two studies focused on adults over 60 years.[79, 80] They found utilization patterns that are not based on evidence or internationally accepted standard treatment guidelines.[66,67]

Two studies found inadequate use of NSAID,[81,82] one of them concluding that the increasing number of patients presenting with peptic ulcer was potentially related to their increased consumption of these medicines. Using household data from the National Health Survey 2000 it was reported that around half of individuals suffering from hypertension were using medication, but only 20% of them were controlled (<140/90mmHg).[83]

Adherence to pharmacotherapy (n=12)

Twelve studies investigated adherence, with half of them on adherence to tuberculosis treatment.[84-89] The remaining studies examined adherence to diabetes treatment,[90,91] asthma treatment,[92] contraception,[93] antiretroviral therapy,[94] antipsychotic medication,[95] pharmacotherapy of infectious diseases and acute diarrhea[96] and immunotherapy.[97] The majority of these studies investigated factors influencing adherence by using either self-reporting surveys or focus groups. The perception of the disease, education, distance from health centers, living in rural areas, and social support were found to affect treatment adherence. Five studies evaluated the impact of an educational intervention (either patient or physician and patient) on adherence. One study investigated the effect of supervision on adherence. Education and degree of supervision were found to positively influence adherence. In addition to the 12 studies focusing on adherence, one other study examined aspects of adherence to antibiotics along with an analysis of prescribing patterns.[19]

Access to medicines (n=13)

The studies on access to medicines[98-110] show that, first, drug prices in Mexico are higher than in many developed countries when adjusted for income.[88-100] For example, with an average salary, an individual in the United States or France is able to buy more medicines than an individual with an average salary in Mexico. Second, the studies reported that access to medicines is hampered due to stock-outs of essential drugs in public health centers.[101-106] The absence of medicines is the main reason for not returning to use public health care services.[107] Third, there is inequity in access to medicines in Mexico: people from lower income groups spend proportionally more on medicines than individuals with higher income.[43, 105] For example, it has been reported that the region with the highest poverty index received the least amount of drugs free of charge from the government.[43] A recent study found that in the lowest income groups up to 60% of household health care expenditure is spent on medicines and that 66% of catastrophic health expenditure is due to the purchase of medicines.[105]

One study analyzed the legal regulations regarding opioid availability in five Latin American countries including Mexico.[108] Mexico failed to meet the WHO criteria in adequately regulating access to these products. In addition, Mexico ranked as the Latin American country meeting the lowest number of international standards on opioid availability.

Discussion

Overall, the 108 studies in this review reported significant problems in access and use. The research studies on consumption and prescription patterns show that irrational use of drugs is a frequent problem in all therapeutic fields examined in Mexico, mostly documented in antibiotics and drugs for the symptomatic treatment of diarrhea. Studies on the accessibility and affordability of medicines reported frequent stock-outs of drugs in public health centers and inequitable access to medication (people in lower-income groups spend proportionally more on medicines than people with higher incomes). These findings show that Mexico shares many similarities with other low- and middle-income countries where problems of irrational use and inadequate access to medicines are common.[111]

The results also show that the research on medicines in Mexico published in peer-reviewed journals listed in the electronic databases and journals reviewed has significant limitations in terms of health problems and study topics, study methods and study sites (table III). Regarding health problems and study topic, the review identifies four areas where little has been published in the literature: 1) the three major causes of mortality in Mexico (cardiovascular diseases, diabetes, oncology); 2) the causes and consequences of irrational use of medicines (e.g., adverse drug events, their magnitude and the strategies to prevent them, and the beliefs, perceptions and attitudes of consumers related to consumption and adherence patterns); 3) the use of medicines in secondary care and rural areas; and 4) access to medicines.

Regarding study methods, longitudinal studies are scarce, which means that changes of prescribing practice or consumption patterns as well as access to medicines over time are not documented. Only five prescription studies were interventional, all developed during the 1990´s to evaluate the impact of educational interventions to improve prescribing practices for children presenting with acute diarrhea and/or ARI.[11,15-18] An important theoretical limitation is that in these studies irrational prescribing has been addressed largely as an issue of lack of knowledge. The educational interventions carried out in the studies significantly improved prescribing quality. Questions remain about whether these results are transferable to other drug treatments and secondary care and whether they are sustainable in the long term.

Concerning study location, the majority of studies on prescribing practice were carried out in primary health care settings. Only eleven studies analyzing drug prescriptions were carried out in hospitals.[44-55]

Table III

Limitations of the studies on access and use of medicines and areas for further research

Issue	Findings from the review	Areas for further research
Health problems studied	- Majority of studies of consumption and prescribing of medicines investigate acute diarrhoea and ARI, over 70% of them in children - No studies examined the use of medicines in oncology patients, and only five studies reported about hypertension, lipid-lowering or diabetes II treatment	Studies on chronic diseases such as diabetes, malignant tumours and cardiovascular diseases (the top three causes of mortality in Mexico)
Study topics	Majority of studies investigate use of medicines, in particular prescribing	Studies on access to medicines
	Prescriber´s education	Studies on factors apart from knowledge that influence prescribing behaviour (e.g., drug promotion, patient pressure, and financial incentives)
Study methods	Quantification of irrational prescribing and consumption of medicines	- Studies of causes and consequences of irrational drug use; - Interventions to affect the causes of irrational drug use; - Use of internationally recognized drug use indicators to quantify irrational drug use
	Most studies use a cross-sectional design	Longitudinal studies
Study sites	*Urban- rural:* - Study sites in Mexico City dominate - Studies are not representative of settings outside urban areas - Some studies on the differences between urban and rural areas concerning medicine use	Studies in rural areas
	Primary – secondary care: Studies on prescribing pattern focus on public primary care services	Studies on prescribing patterns in secondary care and in the private sector

Literature review, Cuernavaca, Mexico, 2005-6

What do these findings mean for the design and implementation of a new pharmaceutical policy in Mexico? The results indicate three priority areas for a new national pharmaceutical policy to address: a) strategies to combat irrational prescribing and consumption of medicines, b) strategies to improve access to medicines, and c) the promotion of sound nation-wide research on access and use of medicines, in order to inform the development of current and future policies.

Since the results show that irrational use of medicines is widespread among all actors involved in prescribing, dispensing and consumption, strategies to improve rational use need to include all of the actors, in particular medical doctors, pharmacy personnel and consumers. Educational interventions targeted at doctors in public health care institutions have achieved a positive effect on prescribing patterns in Mexico.[11, 15-18] Additional studies are needed to explore how to combine educational interventions with other strategies, such as financial incentives for physicians, to influence prescribing practices.

The studies investigating advice received in pharmacies suggest that behavioral change of pharmacy personnel serving costumers can only be achieved through multiple strategies that discourage selling medicines without prescriptions. As Kroeger *et al.*[56] pointed out, the financial profits from the sale of certain medicines are strong incentives for pharmacies and often of primary interest. Hence, strategies are required that include financial incentives for pharmacies to adhere to regulations and standards, for instance, requiring a medical prescription when dispensing prescription-only medicines. Studies are also needed that explore whether the presence of professional pharmacists would improve the quality of services without negatively affecting affordability of medicines due to higher prices, as some authors have suggested.[112] At present, Mexican regulations do not require the presence of a professional

pharmacist,[113] although various groups have called for this policy.

Strategies to address the irrational use of medicines in Mexico also need to consider the role of consumers. This issue has particular relevance in a country such as Mexico where studies report that 51-61% of the population use self-medication as a response to healthcare needs,[74-75] and up to 55% of consumers who self-medicate purchase prescription-only medicines without a physician's prescription.[77] A public education campaign along with other strategies could help raise awareness among consumers of the potential harmful effects of medicines.

Strategies to improve access must first tackle the root causes of undersupply of medicines in public health care institutions so that individuals can obtain the medicines they require. Addressing the undersupply of drugs in public health care institutions requires a thorough analysis of the current system including financing for an adequate medicine supply. At the same time, health care institutions need to be made more accountable through good governance. Pressure from civil society would be a mechanism to create a more sustainable drug supply. Compared to countries such as Brazil, civil society has played a minor role in shaping health and pharmaceutical policies in Mexico.[114]

It is important to consider strategies that make medicines in the private market more affordable to people from low income groups. This could be achieved through price regulation in the private sector or by stimulating generic use and competition. The government's recent background document for a new national pharmaceutical policy highlights the importance of using generics to lower pharmaceutical expenditure; currently, however, there is no effective price regulation in Mexico.[112] In contrast, in some European countries where the majority of the population have health insurance, price regulation is a central element of national pharmaceutical policy.[115, 116]

Expanding access will also depend on continued implementation of Mexico's new national health insurance program, the Popular Health Insurance Program [*Seguro Popular*], which seeks to provide health care and medicines for all Mexicans without health insurance (over half of the population in 2000).[117] One study of this major policy reform[91] shows that more patients affiliated with Seguro Popular received their prescribed medicines free of charge in comparison to the number of patients covered by other public health insurance schemes. Nonetheless, studies have yet to be published on prescribing patterns within Seguro Popular, consumption of medicines, and effects on health of patients. These are important areas for future policy research.

Conclusions

This first review of published studies on access to and use of medicines in Mexico identified important gaps in the evidence base in four important policy areas, including the use of and access to medicines for chronic diseases and the causes and consequences of irrational use. Research on medicines should be promoted in these areas to help guide the reform of Mexico's pharmaceutical policy. At the same time this review identified two priorities for Mexico's pharmaceutical policy and strategies. The analysis here suggests that tackling the irrational use of medicines and the inadequate access to medicines are critical priorities for a new national pharmaceutical policy. Regulatory changes that only include the government as actor are unlikely to achieve these priorities; instead, multiple strategies and involvement of multiple actors are necessary. Recently, the government launched three new programs, pharmacosurveillance, rational use of medicines, and clinical pharmacists in hospitals of the Ministry of Health; the latter two are specifically intended to improve the quality and cost-effectiveness of pharmacotherapy.[118] It will be important to link these programs with other strategies to improve rational use of medicines, and evaluate their impacts over time.

The government's proposal to introduce a new comprehensive pharmaceutical policy comes at a time of major changes in Mexico's health insurance system, specifically the continuing implementation of Seguro Popular – aimed at providing universal coverage by the year 2010.[117] These health system changes will have a major impact on access and use of medicines in Mexico. So far, there has been no rigorous analysis of what this means for the country's pharmaceutical policy. This review of published research provides important guidance about major gaps in the knowledge base in Mexico, areas where further research is required, and priority objectives for the design of a new national pharmaceutical policy.

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