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Review

Policies to promote use of generic medicines in low and middle income countries: A review of published literature, 2000–2010

Warren A. Kaplan[a], Lindsay Sarah Ritz[b], Marie Vitello[c], Veronika J. Wirtz[d,*]

[a] Center for Global Health & Development/Department of International Health, Boston University School of Public Health, Boston, USA
[b] Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital and Harvard Medical School, 1620 Tremont Street, Suite 3030, Boston, MA 02116, USA
[c] Children's Hospital, 300 Longwood Avenue, Pavilion 269, Boston, MA 02116, USA
[d] Center for Health Systems Research, National Institute of Public Health, Av. Universidad 655, Cuernavaca, C.P. 62100, Morelos, Mexico

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ABSTRACT

Objective: Review the literature on the impact of policies designed to enhance uptake of generic medicines in low and middle income countries (LMICs).
Methods: We searched for publications related to generic medicines policies (January 2000–March 2010) and did a bibliometric, descriptive analysis of the dataset in addition to an analysis of studies evaluating the impact of pro-generic policies. We repeated a subset of this larger search in January 2012.
Results: Of the 4994 articles screened, 315 (6.3%) full-text publications were related to generic medicines policies. Of these 315, 236 (75%) dealt with generic medicine policies in high-income countries, and 79 (25%) with policies in LMICs. In total, we found only 10 evaluation studies looking at the impact of competition, trade, pricing and prescribing policies on generic medicine price and/or volume. Key barriers to implementing generic medicine policies in LMICs are negative perceptions of stakeholders (e.g., generics are of lower quality) plus perverse private sector financial incentives to sell products with the highest profit margin. Other relevant barriers are legal/regulatory, such as the absence of generic substitution regulations. There also exists a general difficulty in promoting generics due to a lack of transparency in the pharmaceutical supply and distribution system, for example, a lack of price information provided by health care provider organizations to physicians.
Conclusion: There is little policy evaluation to determine which pro-generic policies increase generic medicines utilization in LMICs. Ensuring a functioning medicines regulation authority, creating a reasonably robust market of generic medicines and aligning incentives for physicians, consumers and drug sellers are necessary prerequisites for increasing the uptake and use of generic medicines.

1. Introduction

With the rising costs of healthcare and the uncertain global economic situation, governments and payers in many countries will require the increased usage of generic medicines. Data from price surveys in 36 low and middle-income countries (LMICs) show that in the private sector, prices of the lowest cost generic medicines were on average 2.6 times less expensive than the corresponding originator medicines [1]. By using generic medicines, potential savings can be quite large [2]. For example, in the private sector of 17 countries, the average percentage savings for individual medicines (n = 4–12 medicines) ranged from 9% to 89% if private sector purchasers would switch from originator

* Corresponding author. Tel.: +52 777 329 3040.
E-mail address: veronika.wirtz@insp.mx (V.J. Wirtz).

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brands to the lowest-priced generic equivalents [2]. Savings would not, however, be confined to the private sector. For example, in public hospitals in China, over US$86 million (2008 dollars) could be saved from switching only 4 medicines, saving patients an average of 65% [2].

Given the actual and perceived need for increased usage and promotion of low-price, assured-quality generic medicines, it is important for countries to gather evidence as to what pro-generic medicines policies actually work in their countries' context. There is a large body of research on pro-generic medicine pharmaceutical policies in the United States and Europe, see e.g., [3–6]. In contrast, impact evaluation of pro-generic medicine interventions in LMICs appears much less systematized.

Therefore, the objective of this study was to inquire into the nature, extent and strength of the evidence for successful implementation of pro-generic medicines policies in LMICs. We further attempt to characterize barriers to increasing the uptake of generic medicines in LMICs that are related to "supply side" (e.g., trade, competition, pricing, regulation, intellectual property, reimbursement) and "demand side" (physician, dispenser, consumer) policies. Finally, we attempt to also identify a minimum set of pro-generic medicine "enabling" policies that most LMICs could implement to help policy makers prioritize actions.

2. Materials and methods

2.1. Search strategies

To the extent possible, the literature review followed the PRIMSA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The study protocol is available upon request from the authors. We searched the following databases for publications between 1 January 2000 to 31 March 2010 in English, French, Spanish and Portuguese: PubMed via the US National Library of Medicine, Excerpta Medica Database (EMBASE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Political Science Abstracts of CSA Worldwide (the Public Affairs Information System (PAIS)), Thomson Reuters (formerly ISI) Web of Science, POPLINE (One Source), and the Latin American Literature on Health Sciences (LILACS). For the ISI Web of Science database, we searched for "generic" or "generics" in the title and/or abstract. We searched for topics and keywords using MeSH terms for PubMed. Major subject headings were used for CINAHL, EMBASE, CSA/PAIS, POPLINE and LILACS (i.e., "medicamento" and "generic"). The search strategies were meant to capture high-income countries (e.g., United States, Europe, Canada, Japan, New Zealand, Australia and the like) and "low and middle income" countries. A detailed description of the search terms can be found in Electronic supplementary documents. We defined "policies" as laws, rules, financial and administrative orders made by governments, non-government organizations or private insurers [5]. We tested whether we may have missed literature by using alternate terms for "generic" by just searching PubMed using the terms "interchangeable or interchangeability" plus the term "policy" or "policies". We then compared our results with those from our larger search using "generic" or "generics".

In January 2012, we repeated two broad PubMed searches originally done in March 2010 (i.e., "generic drugs" and "health policy" with, and without, the MeSH designation) as a validity check on the method and to obtain any references after 2010 that might be considered impact evaluation. The results of these two searches (March 2010 and January 2012), were identical between the two dates, aside from new references post-March 2010. The additional references for impact evaluation studies were included in Tables 2 and 4. Other studies from this January PubMed search were not included in the aggregate bibliometric analyses because we only searched PubMed and not any of the other databases.

We created the following policy domains as adopted from the literature [7,8]: regulation (market authorization and labeling), competition (e.g., timing of entry onto the market, balancing interests of originator and generic), trade related aspects/intellectual property right(s) (e.g., Trade-Related aspects of Intellectual Property Rights (TRIPS), free trade agreements, patents), pricing (e.g., reference pricing, tendering and other fiscal policies), reimbursement, prescribing, dispensing and consumer/patient. Publications in the database were classified according to these policy domains for each high-income and LMIC country.

We assumed that a rigorous study of pro-generic policies in LMICs would likely be published in database-indexed journals so our literature review was primarily focused on peer reviewed articles as opposed to the so-called "grey literature" (i.e., written material that is published and/or not widely accessible such as from technical reports from government agencies or scientific research groups, working papers from research groups or committees and so-called "white papers"). We do note, nonetheless, that there is a large amount of "grey" literature on this subject. To capture some of this grey literature, we limited our search to the electronic databases of the following organizations: World Bank, World Health Organization, Health Action International, Pan American Health Organization. If the website of these organizations allowed, the search was done using the same key words as for the database-indexed journals. If the website did not allow searching, or the searches did not result in any hits, we searched the sections (if any) of the website directed to "pharmaceutical policy", "medicines", and/or "pharmaceuticals".

2.2. Data review and exclusion criteria

The original searches from all the databases were combined in an EndNote® library (EndNote® version 8, San Fransisco, CA, USA) and all duplicates removed. References lacking abstracts or studies with ONLY abstracts were excluded. We excluded any study that did not relate to pharmaceuticals (e.g., studies dealing with devices and vaccines) or if it was clearly unrelated to generic medicines (i.e., a study about "generic" administrative policies or "generic" factors related to water purification) or if the reference evaluated the use of generic medicines or was in some way not related to generic medicines policies (e.g., bioequivalency studies). Two independent teams of