

Perspectives of consumers or patients on the use of generic medicines

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Abstract

Introduction

Access to medicines constitutes a public health challenge worldwide. Promoting the utilization of generic medicines is one of the strategies that has been proposed to optimize pharmaceutical spending and thus allow greater coverage. However, its use is not yet widespread. This summary seeks to explore the perspectives and acceptability to the use of generic medicines from patients and consumers.

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

Results and conclusions

We identified four systematic reviews including 47 studies overall, of which 1 corresponds to a randomized controlled trial. We concluded that a low rate of consumers have a negative perception regarding generic medicines, including dimensions such as effectiveness, quality, safety, and risk of adverse effects.

Problem

Access to medicines has become a challenge for health systems worldwide, as it represents a significant proportion of out-of-pocket household expenses. Along these lines, the World Health Organization has encouraged states to generate policies pointing to the rational use of medicines and to the increase of generic medicines utilization [1]. The use of generic medicines would enable savings in out-of-pocket consumer spending and result in a more efficient pharmaceutical spending by insurers and health systems, becoming a cost containment strategy [2].

However, although the generic substitution (interchangeability of a brand-name medicine for a generic medicine) is allowed in multiple countries, this practice has not been widely adopted. Potentially, negative perceptions over the quality and safety of generic medicines across different actors could be an explanatory factor for this phenomenon [3]. In this context, it is important to analyze the scientific evidence available in this area, thus the objective of this article is to explore the perception that consumers or patients have regarding generic medicines.

For the purposes of this summary, patients will be understood as the people who attend a healthcare center for any health condition and consumers as those who buy a drug from a pharmacy or may need to buy a drug in the future (general population).

Key messages

- Probably a low proportion of consumers have a negative perception regarding the effectiveness of generic medicines.
- Probably a low proportion of consumers have a negative perception about generic substitution.
- Probably a low proportion of consumers perceive generic medicines as less safe, of lower quality, or with a higher risk of adverse effects.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We identified four systematic reviews [3], [4], [5], [6] including 47 studies overall [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37], [38], [39], [40], [41], [42], [43], [44], [45], [46], [47], [48], [49], [50], [51], [52], [53], of which one was a randomized trial [38].</p> <p>The table and summary are based on the totality of the studies since observational studies provide relevant information for this type of question.</p> <p>It is also worth mentioning that 31 studies conducted surveys [7], [8], [9], [10], [11], [15], [16], [18], [19], [20], [22], [24], [25], [26], [27], [29], [30], [31], [34], [35], [36], [37], [39], [41], [43], [44], [47], [48], [49], [50], [52], 10 interviews [12], [13], [14], [17], [23], [38], [42], [45], [51], [53] and 6 focus groups [21], [28], [32], [33], [40], [46].</p>
<p>What kind of population included the studies?</p>	<p>All the studies included patients or consumers older than 18 years of age except for two studies which included consumers over 15 years [18], [27].</p> <p>According to the World Bank's country classification by income for the period 2018-2019 [54], ten studies (21.3%) were conducted in upper-middle income countries [8], [19], [23], [25], [27], [32], [33], [42], [47], [48] and 37 (78.7%) in high-income countries [7], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [20], [21], [22], [24], [26], [28], [29], [30], [31], [34], [35], [36], [37], [38], [39], [40], [41], [43], [44], [45], [46], [49], [50], [51], [52], [53].</p> <p>Twenty-six studies focused in people with a specific condition [9], [13], [14], [17], [21], [22], [26], [28], [29], [31], [34], [36], [37], [38], [40], [41], [43], [44], [45], [46], [47], [49], [50], [51], [52], [53], and the remaining 21 included</p>

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

	consumers in general [7], [8], [10], [11], [12], [15], [16], [18], [19], [20], [23], [24], [25], [27], [30], [32], [33], [35], [39], [42], [48]. Within the latter, 10 studies were sampled from the general population [7], [8], [15], [16], [18], [19], [20], [23], [27], [35].
What types of outcomes were measured ?	<p>The studies evaluated multiple outcomes, which were grouped by systematic reviews as negative perception of:</p> <ul style="list-style-type: none"> ● Effectiveness ● Quality ● Adverse effects ● Safety ● Interchangeability of generic substitution.

* Information about primary studies was primarily extracted from the systematic reviews identified and was completed with data extracted directly from primary studies.

summary of findings

The information on the perception of the use of generic medicines is based on the information reported by 46 observational studies [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37], [39], [40], [41], [42], [43], [44], [45], [46], [47], [48], [49], [50], [51], [52], [53] and one randomized trial [38], varying the total number of the sample, according to each outcome measured.

The quantitative results of the negative perception of effectiveness are based on 23 studies (18 105 participants) [7], [8], [10], [11], [15], [17], [18], [19], [24], [25], [27], [29], [30], [31], [34], [35], [36], [39], [47], [48], [49], [51], [52], those of the negative perception of quality are based on 17 studies (10 184 participants) [7], [8], [9], [17], [18], [19], [23], [25], [26], [29], [30], [31], [35], [39], [45], [47], [52], the negative perception of adverse effects are based on 15 studies (9 323 participants) [15], [18], [24], [25], [29], [39], [43], [44], [45], [47], [48], [49], [50], [51], [52], the negative perception of safety on 12 studies (6 035 participants) [10], [11], [17], [19], [29], [30], [34], [35], [36], [39], [51], [52] and the results of the negative perception on generic substitution on 9 studies (12 671 participants) [10], [16], [20], [22], [37], [41], [43], [48], [50].

The qualitative results of the negative perception of effectiveness and quality are based on 10 studies (757 participants) [13], [14], [17], [21], [28], [32], [33], [38], [40], [46], those of the negative perception of adverse effects are based on 5 studies (325 participants) [12], [13], [14], [40], [46], the negative perception of safety on 1 study (16 participants) [12] and those of the negative perception on generic substitution on 6 studies (459 participants) [13], [14], [17], [32], [33], [42].

The summary of findings is the following:

- A low proportion of consumers or patients have a negative perception regarding the effectiveness of generic medicines (moderate certainty of the evidence).
- A low proportion of consumers or patients have a negative perception regarding the quality of generic medicines (moderate certainty of the evidence).
- A low proportion of consumers or patients perceive generic medicines increase the risk of adverse effects (moderate certainty of the evidence).
- A low proportion of consumers or patients have a negative perception of the safety of generic medicines (moderate certainty of the evidence).
- A low proportion of consumers or patients have a negative perception about generic substitution (moderate certainty of the evidence).

Perspectives of consumers on the use of generic medicines: quantitative results			
Population	Patients and medicine consumers over 15 years of age from upper-middle and high-income countries		
Outcome	Median (interquartile range)	Nº of participants (studies)	Certainty of the evidence (GRADE)
Negative perception of effectiveness ¹	18.8% (14.3% to 27.1%)	18,105 (23 studies)	⊕⊕⊕○ ² Moderate
Negative perception of quality	23.3% (14.4% to 30.0%)	10,184 (17 studies)	⊕⊕⊕○ ² Moderate
Negative perception of adverse effects	13.4% (6.0% to 3.4%)	9,323 (15 studies)	⊕⊕⊕○ ² Moderate
Negative perception of safety	14.8% (6.5% to 17.9%)	6,035 (12 studies)	⊕⊕⊕○ ² Moderate
Negative perception on generic substitution	29% (14.5% to 43.9%)	12,671 (9 studies)	⊕⊕⊕○ ² Moderate

¹For this outcome it is assumed that in Heikkila (2007) 'cheaper medicines' is equivalent to 'generic drug'.
² The certainty of the evidence was downgraded in one level because there is risk of publication bias, since data was retrieved exclusively from English-language, published studies.

Perspectives of patients and consumers on the use of generic medicines: qualitative results			
Population	Patients and medicine consumers over 18 years of age from upper-middle and high-income economies		
Outcome	Effect	Nº of participants (studies)	Confidence of the evidence (GRADE-CERQual)
Negative perception of effectiveness ¹ and quality	<p>A large number of studies reported qualitative information showing that consumers believe generic medicines are not as effective as brand-name medicines and have inferior quality [13], [14], [33], [38], [40], [46].</p> <p>In relation to quality, three studies reported that participants associated the lower price of generic medicines to lower quality [17], [32], [33] and effectiveness [32], [33].</p> <p>One study reported the majority of participants did not perceive differences in benefits between generic and brand-name medicines [28] and other study showed that some consumers have a positive perception about generic medicines and they do not consider them inferior, less safe or less effective [21].</p>	757 (10 studies)	Moderate confidence ²
Negative perception of adverse effects	<p>Consumers experienced or believed generics lead to more adverse effects [12], [13], [14] or reported increased or different adverse effects [12], [46].</p> <p>One study reported that some consumers thought generic medicines have low potency, so they should be strengthened in order to be as effective as brand-name medicines, which led to more side effects [40].</p>	325 (5 studies)	Moderate confidence ²
Negative security perception	Only one study reported consumers felt insecure about the use of generic medicine [12].	16 (1 study)	Moderate confidence ²

<p>Negative perception about interchangeability</p>	<p>Many consumers reported they would accept generic substitution if recommended by their physician, pharmacist or other health professional [13], [14], [17], [32], [33], [42].</p> <p>One study identified that other factors that facilitate interchangeability are: whether the dispenser provided enough information; if there was previous positive experience with the use of generic; and if there were few or no side effects [33].</p>	<p>459 (6 studies)</p>	<p>Moderate confidence²</p>
<p>² The result is likely to be a reasonable representation of the phenomenon of interest. Confidence in the evidence has been lowered in one level because the reviews mention the report of the methods in the studies was insufficient, without assessing the risk of bias. However, the concordance of the findings with the data from quantitative studies gives credibility to the results.</p>			

About the certainty of the evidence (GRADE)*

●●●●

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

●●●○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

●●○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

●○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision

Other considerations for decision-making

Context analysis

In 1985, the World Health Organization defined the rational use of medicines as the situation in which “patients receive medications appropriate to their clinical needs, in doses corresponding to their individual requirements, over a period of adequate time and at the lowest possible cost for them and for the community” [1].

Likewise, greater access to drugs by citizens has become a public health issue to be addressed worldwide.

The use of generic medicines has increased and became common practice since their approval by the Food and Drug Administration in 1984, based on studies that proved their equivalence to brand-name medicines [55], [56], while representing a less expensive alternative that can also enter the market once the patent expire [69]. They would improve adherence to medication and at the same time reduce health expenditure [55], [57].

To whom this evidence does and does not apply

This evidence applies to consumers, mostly adults, from upper-middle and high-income countries, who have systems that demonstrate the quality of generic medicines.

This evidence does not necessarily apply to low-income countries.

About the outcomes included in this summary

The main outcomes reported by the systematic reviews were included. In addition, the variables that determine perception towards use of generic drugs were also included, such as barriers and facilitators for the implementation of a policy of generic use.

Given the approach of the question, clinical outcomes regarding the use of this type of medicine are not included.

Certainty and confidence of the evidence

According to the nature of the question of this summary, observational studies are possible to qualify as the best evidence available for its answer. Along these lines, outcomes from quantitative and qualitative studies were initially assessed from the highest level of evidence.

It is essential to highlight that a low proportion of consumers or patients have a negative perception regarding generic drugs, either regarding the quality, effectiveness, risk of adverse effects, safety or the exchange of brand-name drugs for a generic one, with a moderate certainty of evidence.

However, this lower proportion of the population is mediated by other factors. For instance, the intervention of doctors, pharmacists or another clinician in the indication of the generic drug, delivery of sufficient information to patients and consumers about the new prescription, previous experience respects its use and price of the medicine, among others.

Resource considerations

Generic medicines are between 20 and 90% cheaper than brand-name medicines [59], so a better perception of them could lead to lower out-of-pocket costs for consumers, and lower costs for the health system.

Incentives or strategies to promote the prescription of generic medicines are further required.

Differences between this summary and others sources

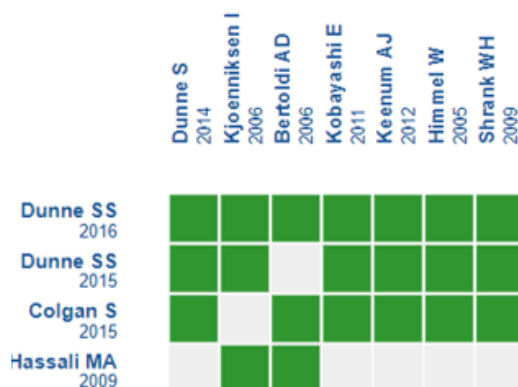
The conclusions of the systematic reviews identified are consistent with each other and coincide with the qualitative and quantitative conclusions of this summary.

Could this evidence change in the future?

The probability of future evidence changing the conclusions of this summary is low because there is a moderate certainty in the findings. However, the evidence could vary for medium and low-income countries where there is still little evidence.

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



An evidence matrix is a table that compares systematic reviews that answer the same question. Rows represent systematic reviews, and columns show primary studies. The boxes in green correspond to studies included in the respective revisions. The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the [interactive version Perspectives of patients and consumers on the use of generic medicines.](#)

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Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (<http://dx.doi.org/10.5867/medwave.2014.06.5997>)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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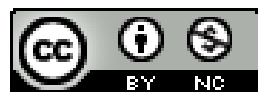
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