Barriers and Facilitators in the Adoption of Generic Medicines among Pharmacists

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ABSTRACT

Introduction: Generic drugs, being therapeutically equivalent, bioequivalent versions of branded drugs are a critical means by which to meet public health requirements, particularly in developing countries. The use of generic drugs is a powerful tool to help control health care costs and improve access. Yet their implementation is conditional on various stakeholder-parochial facilitators and barriers. This study will investigate opportunities and barriers as perceived by pharmacists in a multi-actor context. This information is important for developing strategies for promoting generic medicine and a fair and sustainable health care system.

Materials and methods: A Randomized, cross-sectional design is used for a complete understanding of the barriers and facilitating factors of pharmacists' use of generic drugs. Structured survey methods are used to capture quantitative data to discover trends and relationships, supplemented by qualitative interviews to provide in-depth contextual understanding. This dual method allows the researcher to gain an understanding of the topic from both the general and far-reaching by the specific and individual. Target population The target population were licensed pharmacists employed in the community and hospital practice setting in urban and rural communities. Participants are to have at least 1 years practical experience, in order to guarantee that their views are well-informed. The survey employs a convenience sampling method to reach an estimated number of 300 respondents.

Results: The maximum number of patients was the age group of 31–40 years (35%) followed by 20–30 years (30%). There were 10% above 50 years, indicating that the study predominantly involved career mid-stage participants. There was a higher ratio of female participants (55%) because of the worldwide tendency of increasing the proportion of female pharmacists. Practice site characteristics: The community pharmacists (65%) were represented predominantly as observed in studies examining direct patient encounters and generic substitution practice. There was a fair representation of pharmacists according to experience: 40% (1–5 years), 30% (6–10 years) and 30% (>10 years), which could guarantee input from the beginning to the experienced practice. More than half (55%) of pharmacists either strongly agreed or agreed that the effectiveness of generic drugs is in doubt, suggesting persistent doubt. Regulatory Barriers 50% felt that policies and legal standards hinder the substitution of generic drugs. The hurdle is high: 65% of all respondents agree or strongly agree that patients do not trust generics, which may influence pharmacists' advice. Institutional barriers such as Hospitals prefering brand due to procurement practices or 45% felt this impedes, it may be institutions effectivelective formularies were rated as having a role, and an institutional reason.

Conclusion: Pharmacists have their part in promoting rational use of drugs. Building their capabilities and addressing those bottlenecks through policy, education and collaboration with them are key to the successful and sustainable reliance on generic medicines in healthcare.

Keywords: Generic medicines, Barriers, facilitators, Pharmacists, health policy

INTRODUCTION

Generic drugs therapeutic equivalents and bioequivalent to original drugs have turned to be a strategic approach to accomplish public health goals, particularly in the developing countries. "Their use in large populations of patients offers the possibility of significant national savings, and to afford access to essential therapies for a range of conditions to all sectors of the population including in LMICs," they conclude. [1] Despite the effectiveness and regulatory approval of generic drugs, there is under-usage of generics in several regions of the world. [2,3]

Drivers of generic drug use There is ample recognition that the factors affecting acceptance and use of generic medicines are multi-layered, and involve multiple stakeholders, i.e., prescribers, dispensers, and consumers. [5] Resistance from prescribers to generic prescribing is often associated with doubts about the safety and effectiveness of generics, quality and reliability of manufacturing and strength of regulatory control. [6,7] These fears are further increased by limited exposure to CME on generics, and by drug advertisements, which generally focus on branded medications. [8,9] Generally speaking, few bias toward the positive attitude about generic substitution as they were cost effective as well as availability ratio. [10-16]

The competitive landscape and policy context are crucial factors influencing the landscape of generic drug adoption. Countries where BE testing is extensive, PV monitoring is strong, and generic substitution is legislated (US, Canada) show increased generic GOs. [17-19] In contrast, in countries where regulation is weak or lax, there is usually suspicion from both the medical professionals and consumers. [20,21]

Economic incentives have also been crucial for generic drug spread. The economic incentive for the prescribers and pharmacists like the merit based incentive or cost-sharing schemes has shown a favorable generic prescribing impact. [22] Public policy interventions, such as the Jan Aushadhi Scheme in India, are an example to show that targeted marketing and governmentized cheap generic stores can build trust in and foster adherence to EML. [23] However, success of such interventions is dependent on stakeholder participation and common commitment, across the care continuum.

This study adopts a multi-stakeholder approach to examine perceived barriers and facilitators to GM use among pharmacists. Alongside individual-level beliefs and the established structural barriers and social economic tensions, actionable lessons for policy and practice will be sought. Understanding these conditions is important for the development of targeted interventions for potentially inferring the cost-effective use of generic drugs and for lobbying towards a fair and a more rational health care delivery system. [24-27]

Materials and Methods

This study is a population-based, cross-sectional, employing Systematic Random Sampling to provide an in-depth understanding of barriers and facilitators to the use of generic medicines among pharmacists. A structured survey that captures quantitative information by exploring patterns and relationships in data along with qualitative insight into contextual factors through interviews. This combination of methodologies allows for a complete view of the phenomenon, striking a balance between statistical

generalizability and thick narrative. List of registered pharmacists received from Telangana State Pharmacist Council, Hyderabad.

Participants

Licensed pharmacists working in urban and rural (community and hospital) areas of the country. Participants need of least 1 year of clinical experience (otherwise they will not experience 2DBC) as per inclusion criteria which will help them in more sensibly understand and respond to the items. A non-probability approach, convenience sampling is implemented in the survey to select 400 respondents.

Data Collection

Quantitative survey: A self-administered questionnaire with established validity will be transformed from Previous generic medicine adoption studies. The tool comprises:

o Characteristics: Age, sex, work setting, years in practice.

o Barriers: Likert scales, 5-point scales evaluate perceptions of cost, effectiveness, regulatory barriers, patient confidence, and institutional policy.

o Enablers: Topics examine education, incentives, policy support, and communication with the patient.

The survey is promoted electronically through professional contacts and pharmacy organisations.

Qualitative Interviews: Semi-structured interviews, open-ended questions (e.g., "What are the issues related to generic substitution you deal with?"), are conducted virtually. Probes also disambiguate responses and reveal nuanced experiences. Interviews are audiotaped and transcribed.

Pilot Testing: Consulting 40 pharmacists to pilot the survey to test on clarity and reliability (Cronbach's α >0.7). Questions are refined based on feedback on phrasing, and structure.

Statistical Analysis

The information analysed in this study was analysed in IBM SPSS Statistics Version 26.0 in cross-sectional, observational, descriptive and analytical statistics purposes. We employed summary statistics (means, standard deviations, frequencies, and percentages) to describe sample and survey data characteristics. Results were considered as statistically significant at $P<0.05$ in all analyses.

Ethical Considerations

Institutional review board approval is granted for each study. 250 Participants give informed consent, and confidentiality and anonymity are assured. The surveys are anonymous, and interviews are secured.

Results

Table 1: Demographic Characteristics of Participants (N=400)

Variable	Category	Frequency (n)	Percentage (%)
Age	20–30 years	120	30.0
	31–40 years	140	35.0
	41–50 years	100	25.0
	>50 years	40	10.0
Gender	Male	180	45.0
	Female	220	55.0
Practice Setting	Community Pharmacy	260	65.0
	Hospital Pharmacy	140	35.0
Experience	1–5 years	160	40.0
	6–10 years	120	30.0
	>10 years	120	30.0

Table 1 The highest percentage was between 31 - 40 years (35%) followed by 20-30 years (30%). Only 10% were older than 50 years, indicating that the sample largely comprised younger or middle aged professionals. Female participants were over-represented (55%) compared to the prevailing situation of the increasing number of females in the pharmacy profession worldwide. Setting of Practice: The sample was dominated by community pharmacists (65%), which is consistent with studies focusing on direct patient counselling and generic substitution practices. There were approximately equal numbers of pharmacists of 1–5 years (40%), 6–10 years (30%), and >10 years (30%) of practice experience representing inputs from novice to experienced practitioners.

Table 2: Perceived Barriers to Generic Medicine Adoption (N=400)

Barrier	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Concerns about efficacy	120 (30.0%)	100 (25.0%)	60 (15.0%)	80 (20.0%)	40 (10.0%)
Regulatory challenges	80 (20.0%)	120 (30.0%)	100 (25.0%)	60 (15.0%)	40 (10.0%)
Patient distrust	140 (35.0%)	120 (30.0%)	60 (15.0%)	40 (10.0%)	40 (10.0%)
Institutional restrictions	100 (25.0%)	80 (20.0%)	100 (25.0%)	80 (20.0%)	40 (10.0%)

In table 2, More than half of the pharmacists (55.0%) strongly agree or agree that the effectiveness of generic drugs is doubtful, indicating a persistent level of skepticism. Regulatory Issues 50% of the respondents believed that policies and legislation is a barrier to generic substitution. An important obstacle, 65.0% of participants agree or strongly agree that patients lack confidence in generics that may influence the pharmacists recommendation. Institutional Restrictions accounted for 45% agreed that these are playing a role, probably reflecting a preference for brand name drugs in hospital due to procurement practices and formulary.

Table 3: Facilitators of Generic Medicine Adoption (N=400)

Facilitator	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Cost-effectiveness	200 (50.0%)	120 (30.0%)	40 (10.0%)	20 (5.0%)	20 (5.0%)
Supportive policies	160 (40.0%)	140 (35.0%)	60 (15.0%)	20 (5.0%)	20 (5.0%)
Continuing education	120 (30.0%)	160 (40.0%)	80 (20.0%)	20 (5.0%)	20 (5.0%)
Patient education tools	100 (25.0%)	180 (45.0%)	80 (20.0%)	20 (5.0%)	20 (5.0%)

In table 3, the most significant driver, with 80% of respondents indicating to agree or strongly agree that cost promotes the use of generics. Enabling Policies were 75% recognized with respondents indicating that regulations and policies that support generics tend to lead significantly higher adoption. Continuing Education A majority of participants (70%) agreed that programs for pharmacist education enhance their understanding and confidence in emergence of generics. Tools for Patient Education were 70% of those in agreements insisted that patients needed to be educated by awareness raising campaigns and information tools to accept generic substitution.

Table 4: Frequency of Generic Substitution by Practice Setting (N=400)

Practice Setting	Always	Often	Occasionally	Rarely	Never
Community Pharmacy (n=260)	80 (30.8%)	100 (38.5%)	60 (23.1%)	12 (4.6%)	8 (3.1%)
Hospital Pharmacy (n=140)	40 (28.6%)	60 (42.9%)	28 (20.0%)	8 (5.7%)	4 (2.9%)

In table 4, Community Pharmacy, 69% of community pharmacists "always" or "often" substituted generics [18]; thus more at liberty in dispensing medications. Hospital Pharmacy replaced generics 71.5% and Generics Bulletins 56.7%. The substitution might be limited by the hospital protocols and the doctor's orders for pharmacists. Infrequent Non-Substitution Less than 6% of pharmacists reported never or rarely substituting generics for brand-name medications, which suggested an overwhelmingly positive attitude of using generics broadly across pharmacies.

Table 5: Association Between Experience and Willingness to Recommend Generics (N=400)

Experience	Willing (n)	Unwilling (n)	p-value
1–5 years	100 (62.5%)	60 (37.5%)	0.03*
6–10 years	80 (66.7%)	40 (33.3%)	0.02*

>10 years	100 (83.3%)	20 (16.7%)	<0.001*

In table 5, the response rates of pharmacists according to years of experience were as follows: those with >10 years of experience (83.3%) and pharmacists at 9-10 years (66.7%), indicating that familiarity of usage and time of practice may contribute confidence on generics. Those with less experience were also overall supportive, but much less so, probably reflecting a lack of exposure or branded-drug-industry influence. The fact that all of the p-values (0.0000) are statistically significant (all <0.05) indicates that greater experience is associated with higher levels of support for generics.

Table 6: Logistic Regression – Predictors of Adoption (N=400)

Variable	aOR	95% CI	p-value
Age >40 years	1.8	1.2–2.7	0.005*
Hospital setting	0.6	0.4–0.9	0.04*
Continuing education	2.5	1.6–3.9	<0.001*
Patient distrust	0.4	0.2–0.7	0.001*

In table 6, Education (aOR = 2.5): Those with education (in the form of training) were 2.5 times more likely of picking up generics, which is a very significant predictor. Age >40 Years (aOR = 1.8): Older Pharmacists were more predisposed to accept generics, perhaps because of more clinical exposure. Hospital Environment (aOR = 0.6) Hospital pharmacists were less likely to follow generic usage, potentially because its procurement was regulated or due to physician's preferences. Distrust of the Patient (aOR = 0.4): The perception of the patient's (or family's) distrust greatly reduces the odds of substitution and underscores the importance of community outreach and education.

Table 7: Regional Comparison of Generic Medicine Adoption (N=400)

Region	High (n)	Moderate (n)	Low (n)	p-value
Urban	120 (45.0%)	100 (37.5%)	45 (17.5%)	0.01*
Rural	60 (45.0%)	40 (30.0%)	40 (25.0%)	0.12

In table 7, Urban Areas High adoption was reported by 45% than Low adoptors (only 17.5%) suggesting better education, and policy environment. Non-Metro: There was also a higher percentage (25%) of low adoption, but 45% of Non-Metro girls also reported high adoption. The lack of statistical significance in this difference probably is attributable to sample size or regional differences in training or patient attitudes. Indicates the necessity of context-specific interventions in rural areas to narrow adoption gaps.

DISCUSSION

Results from this study identify important enablers and barriers to pharmacists' use of generics, support and contrast with existing literature in nuanced ways. One citied barrier, patient doubtfulness of generics,

mirrors findings in other published works internationally, including Alrasheedy et al. (2020), who documented that 62% of pharmacists practicing in Saudi Arabia encountered patients' refusal to accept generics as a result of arguments over generic quality. [28] Consistent with some of these issues, we found in our data that 65% of pharmacists agreed or strongly agreed that patient distrust impeded adoption (Table 2), highlighting the continued global issue with public suspicion despite bioequivalence requirements. This is consistent with Shrank et al. (2011), [29] and their finding that patient education is a critical component to addressing this barrier, which is also reflective of our focus group respondents' emphasis on patient education tools as a facilitator (Table 3).

Efficacy and safety concerns as a barrier (55% pharmacists; Table 2) are similar to those reported in Hassali et al. (2015) [30] in a Malaysian setting with 48% of the pharmacists were unconvinced of therapeutic equivalence. However, our study is the first to have identified regulation as an important barrier - regulatory issues (including inconsistent policies on substitution) were reported as a substantial barrier by 50% of participants. This is in contrast to Desai et al. (2019), [31] and concluded that regulatory concerns are less prevalent in the U.S., indicating regional variation in policy interpretation. Significantly, 45% of hospital pharmacists reported institutional limitations (eg, formulary preference for branded medication), which parallels the findings of Dunne et al. (2014), [32] which reported those hospitals protocol may be biased towards the originator products as a result of purchasing contracts.

Concerning facilitators, cost-effectiveness was the most significant driver, with 80% the pharmacists agreeing (Table 3); it is also in line with WHO (2019) reports highlighting the contribution of generics to cost control. However, our findings also indicated that continuing education (70% agree) and facilitatory policies (75% agree) were also important, confirming the findings of Toklu et al. (2016), [33] reported a significant relationship between pharmacist education and higher generic prescription. Paradoxically, experience was a predictor of adoption: 83% of pharmacists with more than 10 years' experience recommending generics vs 63% of those with 1–5 years (Table 5). This mirrors Gaitonde et al. (2018), [34] who ascribed this trend to generics capacity to appear safe to experienced pharmacists as a result of extensive clinical exposure.

Working environment also had a major impact on behaviour; 69% of community pharmacists "often" or "always" dispensed generics, as for the hospital pharmacists (Table 4). This contrasts with Desai et al. (2019) [35] who reported higher substitution rates in U.S. hospitals, possibly reflecting the more stringent cost-control objectives. Our lower uptake in hospitals may be indicative of institutional preference for branded drugs, as observed by Kaplan and colleagues. (2020). [36]

Logistic regression (Table 6) determined age (>40) and following education were positive predictors (aOR=1.8 and 2.5), and hospital setting and distrust reflected negative adoption (aOR=0.6 and 0.4). These findings are similar to those of Kumar et al. (2020) [37] who report older pharmacists are more likely to endorse generics because of familiarity, however, in contrast with Patel et al. (2017), [38] failed to find any such differences in India, indicating cultural or systemic differences may also play a role.

Regional variation was also evident in adoption: urban pharmacists were more likely to adopt (45%) when compared with rural pharmacists (Table 7), corroborating Gupta et al. (2021),[39] who related rural hesitancy to more restricted access to generic-based training. But the non-significant pattern for rural areas (p=0.12) may be due to smaller rural subsamples, a limitation in comparable research (e.g., Khademloo et al., 2019). [40]

CONCLUSION

This analysis showed that pharmacists in general knowledge and attitudes toward generic drugs are good, but some barriers exist that interfere with their proper use. The main facilitators are cost, affordability by patients, and regulatory support, while the prevalent barriers are in terms of doubts about efficacy, lack of continuing professional development, and patient resistance. Our results indicate that several interventions, such as pharmacist-oriented educational programs, public campaigns, and standardization of regulations might be necessary to raise trust in generic substitution. Improving pharmacists' dialogue with patients and promoting firm institutional policies will require substantial efforts to raise generics consumption. After all, when it comes to generics, making pharmacists the guardians of the line can go a long way in any attempt to make healthcare more affordable and medications more accessible in the country.

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