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Assessment of community pharmacists' knowledge of the differences between generic drugs and biosimilars: A pilot cross-sectional study

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Abstract

Background: Pharmacists' knowledge of the differences in the characteristics between generic drugs and biosimilars is essential to ensure good practice and lower pharmaceutical bills.

Objectives: This study aimed to evaluate community pharmacists' knowledge and perception of using and substituting biosimilars and generic drugs.

Design: A pilot cross-sectional study was performed over 2 months (August-September 2022) targeting community pharmacists in their work site.

Method: Data were collected using a uniform survey given to 75 pharmacists. Afterward, a knowledge score was generated by summing several individual scores of statements regarding generic drugs and biosimilars.

Results: Overall, pharmacists had moderate to low knowledge scores, namely, with the statements tackling biosimilars. No significance was reported between these scores and their general characteristics. As regards their substitution, most pharmacists agreed to substitute generic drugs if the brand was not available, while the doctor's approval was crucial for biosimilar switching. Most participants perceived equal effectiveness of generic drugs but similar to a lower one for biosimilars compared to the reference medication. Pharmacists highlighted the need to include generic drugs and biosimilars in the continuing education program and workshops.

Conclusion: To promote their use, improving pharmacists' knowledge can help overcome misconceptions about generic drugs and biosimilars. It is recommended that health care stakeholders focus on fostering good understanding among pharmacists to enhance access to medication.

Keywords

Generic drugs, biosimilars, knowledge, pharmacists, medicine access

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Introduction

As part of a general policy to reduce medical expenditures, governments encouraged the prescription and use of generic drugs and biosimilars, known to be cheaper than their reference drug.[1,2] Generic drugs are copies of small chemical molecules identical to the brand drug in dose, form, safety, strength, mode of administration, quality, and indication.[2,3] However, biosimilars are highly similar to large, complex biologic drugs in terms of characteristics, biological activity, safety, and efficacy and require complex and expensive development.[4] Equivalence studies performed on generic

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drugs are insufficient to secure therapeutic equivalence of biosimilars due to differences in their pharmacodynamics, leading to possible batch-to-batch variability.[5] Despite the recent introduction of biosimilars compared to generic drugs, they have a high immunogenic risk and need clinical switching evidence to support their interchangeability.[6]

A different procedure is applied to introduce new biosimilars to the market, and pharmacists have limited substitution ability.[7] The Ministry Of Public Health in Lebanon (MOPH) regulates the introduction and pricing of generic drugs and biosimilars, but no guidelines exist regarding their interchangeability or automatic substitution.[8] Doctors can prescribe and substitute generic drugs in accordance with the characteristics of the reference ones while they base their choice for biosimilars based on clinical evidence.[9] Previous research reported low prescription preferences among doctors,[10] and only older ones with more practice experience accepted pharmacists' substitution.[11] The coronavirus disease of 2019 (COVID-19) pandemic imposed new challenges associated with the limited availability of drugs,[12] which might have induced malpractice among community pharmacists.

The unified medical prescription allowed Lebanese pharmacists to substitute drugs taking into account their price and availability.[13] Good knowledge and practice among pharmacists of the differences in the characteristics between generic drugs and biosimilars are crucial since they play a key role in clinical practice.[14] According to a recent systematic review, pharmacists had limited knowledge of biosimilars and often confused them with generic drugs, particularly their interchangeability, efficacy, and safety.[15] Pharmacists' knowledge should be assessed in order to understand the factors affecting the existing misinformation and lower use. Therefore, the present study aims to evaluate community pharmacists' knowledge and perception of using and substituting biosimilars and generic drugs.

Method

Study design

A pilot cross-sectional study was performed over 2 months (August-September 2022) targeting community pharmacists in their work site.

Study sample

Pharmacists were invited to participate in the study with no preferences based on race or ethnicity. They were included if they were officially registered in the Order of pharmacists of Lebanon (OPL) and working in Lebanon for at least 1 year before the study. Only those refusing to participate in the study were excluded. Sample size calculation was performed using a formula developed by Viechtbauer et al.[16] It yielded a minimum sample of 71 pharmacists with a 95% confidence interval, a precision of 5%, a power of 80%, and a 20% loss to follow-up. The convenience sampling method was used due to limitations related to the pandemic that concurred with the data collection period such as pharmacy limited opening and restricted social contacts. Therefore, subjects more accessible to the data collectors were more likely to be included. Moreover, a parent study with a larger sample size will be performed after the initial assessment based on the present study. Eighty-three potential participants were approached, of whom 75 (90.4%) answered the survey and comprised the study sample.

Data collection

Pharmacists were visited in pharmacies at any time of the day without predefinition of the selected pharmacies. Recruitment took place until obtaining a sufficient sample. Two fifth-year pharmacy students were responsible for data collection. They explained the study's aims orally and asked the participants to complete a uniform survey developed after an extensive literature review[10,17–21] and considering two experts' opinions. It was initially piloted on 20 pharmacists, and questions without clarity or duplicates were modified or deleted. The assessment of the adequacy of the instrumentation was performed as recommended for pilot studies.[22] Positive inter-item correlations (ranging between .30 and .45), test–retest reliability of .807, and a Cronbach's α of 0.698 were noted, supporting the adequacy of the developed questionnaire. The first page of the questionnaire included the written objectives and a consent form. Data completion took an average of 12 minutes per participant, and the questionnaire was provided in English. The first part of the survey included questions about the participants' general characteristics such as age, sex, working area (urban vs rural), level of education, years of work experience, and whether they received their degrees from a public or a private university.

Knowledge of pharmacists of the differences between biosimilars and generic drugs

Several statements were provided to which pharmacists had to link to one of the following products: generic drugs, biosimilars, and both generic drugs/biosimilars. The assessment of pharmacists' knowledge was retrieved from three domains: (1) the knowledge of the characteristics of generic drugs and biosimilars (6 statements), (2) the knowledge of their development and production requirements (9 statements), and (3) the knowledge of their interchangeability (5 statements). Pharmacists had total scores if they linked the statement to the correct answer (Table 1).

Pharmacists' perception of the use and substitution of generic drugs and biosimilars

In this section, participants were asked seven questions, out of which two tackled their perception concerning substituting a brand (chemical or biological) for a generic drug or a

Table 1. Full score answers to the different knowledge statements.

Characteristics of generic drugs and biosimilars	
Statement	Full score
Generic drugs are copies of chemical drugs	1
Generic drugs have the same active pharmaceutical ingredient as the brand	1
Biosimilars are complex and large molecules	1
Generic drugs have stable structures	1
Generic drugs can be administered orally	1
Both generic drugs and biosimilars can be administered parenterally	1
Development and production requirements	
Statement	Full score
Generic drugs require bioequivalence studies	1
Biosimilars require bio-similarity studies	1
Clinical trials (Phase I–III) are required for biosimilars	1
Both generic drugs and biosimilars are cheaper than the reference drug	1
Generic drugs have low development costs and time	1
Both generic drugs and biosimilars need pharmacovigilance studies post-marketing	1
Generic drugs can skip the bioequivalence or bio-similarity studies if found not needed (biowaiver)	1
Studies are performed on patients for biosimilars	1
Studies are performed on volunteers for generic drugs	1
Interchangeability of generic drugs and biosimilars	
Statement	Full score
Biosimilars have limited interchangeability	1
Pharmacists can substitute generic drugs	1
Doctors can substitute both generic drugs and biosimilars	1
Biosimilars need clinical switching studies	1
Biosimilars have an immunogenic risk	1
Total score	20

biosimilar (multiple answers were allowed). Their perceived beliefs in their effectiveness were also requested. Moreover, they were asked whether they received any training or course covering generic drugs or biosimilars and about their needs to improve their knowledge about their differences.

Statistical analysis

Statistical analyses were performed using Statistical Package for Social Sciences (SPSS Inc, Chicago, Illinois) Version 27. Age is presented using means and standard deviations, while categorical variables are presented using frequencies and percentages. The mean of the score of each statement is provided. Scores of the different statements (initially 26 statements) were entered, and 20 items were retained. The index had good reliability (Cronbach's α 0.77) and positive interitem correlations. The scores of the included statements were then summed to generate an overall knowledge score. A bivariate analysis was conducted associating the scores of pharmacists with their general characteristics. The one-way analysis of variance (ANOVA) test was used to compare the means between the associated categorical variables. A p value < 0.05 was considered statistically significant.

Table 2. Distribution of the general characteristics of the patients.

		Total (N = 75)
		Frequency (%)
Sex	Male	30 (40.0%)
	Female	45 (60.0%)
Age (years)	Mean (SD)	26.8 (8.1)
Working area	Urban area	59 (78.7%)
	Rural area	16 (21.3%)
Level of education	Bachelor's degree in pharmacy	41 (54.7%)
	Master's degree	20 (26.7%)
	PharmD/PhD	14 (18.7%)
Years of experience	0–3	53 (70.7%)
	4–7	10 (13.3%)
	>7	12 (16.0%)
University	Public	60 (80.0%)
	Private	15 (20.0%)

Results are given in terms of frequency (percentage) or Mean (Standard Deviation).

Ethical considerations

This study used a survey for data collection without invasive procedures or interventions. The survey and the protocol were reviewed and approved by the institutional review board of the faculty of pharmacy of the Lebanese University (reference: 3/22/D). Anonymity and confidentiality were preserved, and data were stored as the university's general data protection regulation guidelines recommended. The first page of the survey included the written objectives and consent to participate in the study. Pharmacists have not received any financial incentives for their participation.

Results

General characteristics of the pharmacists

Table 2 presents the general characteristics of the study participants. The sample consisted of 40.0% of men and 60.0% of women. The mean age of pharmacists was 26.8 years (SD = 8.1). Most worked in urban areas (78.7%), and only 21.3% worked in rural areas. Around 55.0% of

Table 3. Knowledge scores of pharmacists regarding the differences between generic drugs and biosimilars.

Variables related to the characteristics of generic drugs and biosimilars				
	Generic drugs	Biosimilars	Both	Score/1
Statement	Frequency (%)	Frequency (%)	Frequency (%)	Mean
Are copies of chemical drugs	61 (81.3%)	5 (6.7%)	9 (12.0%)	0.81
Have the same active pharmaceutical ingredient as the brand	53 (70.8%)	1 (1.3%)	21 (27.9%)	0.71
Complex and large molecule	13 (17.3%)	49 (65.4%)	13 (17.3%)	0.65
Stable structure	59 (78.7%)	4 (5.3%)	12 (16.0%)	0.79
It can be administered orally	50 (66.7%)	4 (5.3%)	21 (28.0%)	0.67
It can be administered parenterally	13 (17.3%)	33 (44.0%)	29 (38.7%)	0.39
Variables related to the development and production of generic drugs and biosimilars				
	Generic drugs	Biosimilars	Both	
Statement	Frequency (%)	Frequency (%)	Frequency (%)	Score/1
Require bioequivalence studies	62 (82.7%)	1 (1.3%)	12 (16.0%)	0.83
Require bio-similarity studies	2 (2.7%)	70 (93.3%)	3 (4.0%)	0.93
Clinical trials (Phase I-III) are required for	13 (17.3%)	30 (40.0%)	32 (42.7%)	0.40
Cheaper than the reference drug	46 (61.3%)	4 (5.3%)	25 (33.4%)	0.31
Have low development costs and time	63 (84.0%)	7 (9.3%)	5 (6.7%)	0.84
Need pharmacovigilance studies post-marketing	8 (10.7%)	25 (33.3%)	42 (56.0%)	0.53
Can skip the bioequivalence or bio-similarity studies if found not needed (biowaiver)	38 (50.7%)	14 (18.7%)	23 (30.7%)	0.51
Studies are performed on patients for	8 (10.7%)	15 (20.0%)	52 (69.3%)	0.17
Studies are performed on volunteers for	13 (17.3%)	12 (16.0%)	50 (66.7%)	0.20
Variables related to the interchangeability of generic drugs and biosimilars				
	Generic drugs	Biosimilars	Both	
Statement	Frequency (%)	Frequency (%)	Frequency (%)	Score/1
Have limited interchangeability	8 (10.7%)	62 (82.6%)	5 (6.7%)	0.83
Can be substituted by pharmacists	68 (90.7%)	4 (5.3%)	3 (4.0%)	0.91
Can be substituted by doctors	8 (10.7%)	46 (61.3%)	21 (28.0%)	0.28
Need clinical switching studies	8 (10.7%)	54 (72.0%)	13 (17.3%)	0.72
Have an immunogenic risk	2 (2.7%)	63 (84.0%)	10 (13.3%)	0.84
		Total score/20	Mean (SD)	12.3 (3.1)

Results are given in terms of frequency (percentage) or Mean (Standard Deviation).

the participants had a bachelor's degree in pharmacy, while 26.7% and 18.7% had a master's degree and PharmD/PhD, respectively. Most pharmacists had 3 years of work experience or less (70.7%), and only 16.0% had more than 7 years of experience. Most (80.0%) studied at a public university, and only 20.0% learned at a private one.

Knowledge of pharmacists of the differences between biosimilars and generic drugs

Table 3 presents the means of individual pharmacists' knowledge score for each statement and the corresponding score. Overall, pharmacists had a total score of 12.3 (3.1). Higher scores were noted for statements related to the fact that biosimilars required bio-similarity studies (0.93), generic drugs can be substituted by pharmacists (0.91), and biosimilars have an immunogenic risk (0.84). Nonetheless, lower scores were reported for other statements where most pharmacists said that studies are performed on patients or volunteers for both generic drugs and biosimilars (0.17 and 0.20, respectively). Only 38.7% of pharmacists reported that generic drugs and biosimilars could be administered parenterally (0.39).

When associating pharmacists' knowledge with their general characteristics, no significant differences were noted between their total knowledge scores and their sex,

Table 4. Association between pharmacists' total knowledge scores and their general characteristics.

		Score (N = 75)	p-value
		Mean (SD)	
Sex	Male	12.1 (3.5)	0.756
	Female	12.4 (2.8)	
Working area	Urban area	12.4 (3.2)	0.730
	Rural area	12.1 (3.2)	
Level of education	Bachelor's degree in pharmacy	11.8 (3.1)	
	Master's degree	13.2 (2.4)	0.298
	PharmD/PhD	12.3 (4.1)	
Years of experience	0–3	12.0 (2.8)	
	4–7	14.3 (3.6)	0.097
	>7	11.8 (3.8)	
University	Public	12.2 (2.8)	0.828
	Private	12.5 (4.3)	

Results are given in terms of Mean (Standard Deviation).

working area, level of education, years of experience, or the university attended (Table 4). Nevertheless, compared to others, those with 4 to 7 years of experience had higher knowledge scores.

Pharmacists' perception of the use and substitution of generic drugs and biosimilars

Table 5 presents the perception of pharmacists regarding the use and substitution of generic drugs and biosimilars. Around 45% of pharmacists always agreed to switch to generic drugs compared to only 6.7% for biosimilars. The doctor's approval was needed to change to generic drugs in 26.7% of participants versus a higher percentage (56.0%) for biosimilars. Patients' request for a cheaper option was the driver to switch to generic drugs among 54.7% of pharmacists compared to only 6.7% for biosimilars. Most pharmacists (90.7%) reported that a generic drug has the same effectiveness as the brand, while only 50.7% said the same for biosimilars. Over half of the participants received training or education regarding generic drugs and biosimilars. Most pharmacists reported that programs tackling generic medicines and biosimilars should be included in the curriculum of universities and the continuing education program of the order of pharmacists of Lebanon.

Discussion

This pilot study aimed to assess the knowledge and perception of the characteristics and use of generic drugs and biosimilars in a sample of 75 community pharmacists. Overall, moderate to low knowledge was observed with the statements tackling biosimilars. No significance was reported between the knowledge score and the general characteristics of the pharmacists. As regards their substitution, most pharmacists agreed to substitute generic drugs if the brand was not available, while the prescriber's approval was essential for biosimilar switching. Most participants perceived equal effectiveness of generic drugs but similar to a lower one for biosimilars compared to the reference medication. Around half of the pharmacists received training about generic drugs and biosimilars, and most of them reported the need to include them in the continuing education program and workshops.

The study sample included more women than men, with comparable percentages to the distribution of pharmacists in the registration database of the OPL.[23] Participants were primarily young, which might have limited their knowledge to recent information acquired from universities. Pharmacists had relatively low overall knowledge scores of the differences between generic drugs and biosimilars. This finding was also reported in previous investigations.[15,24] A recent systematic review showed different levels of pharmacists' knowledge ranging between 47% and 86%, with lower scores among participants in settings similar to Lebanon.[15] Distrust and more deficient knowledge were reported among Greek pharmacists during the economic crisis in Greece,[24] which could also reflect the Lebanese scenario. In contrast, a cross-sectional study performed in Pakistan reported relatively higher knowledge among pharmacists,[25] possibly due to the frequent use of biosimilars in clinical settings and the continuous training of medical staff. Good knowledge was also found among pharmacists in Saudi Arabia, with a lower awareness of biosimilars' quality and substitution characteristics.[26] As regards their prices, most pharmacists considered that only generic drugs are cheaper than reference drugs. Although Lebanese pharmacists engaged in continuing education programs, they reported higher preferences for day-to-day workplace experience,[27] which might not be true for biosimilars. Their introduction in Lebanon is new; fewer patients use them than generic

Table 5. Perception of pharmacists regarding the use and substitution of generic drugs and biosimilars.

Question	Frequency (%)
Do you agree to switch from a chemical brand drug to a generic one?	
Always	34 (45.3%)
Only if the doctor approved	20 (26.7%)
If the brand drug is not available	52 (69.3%)
Only if the patients asked for a cheaper option	41 (54.7%)
Never	1 (1.3%)
Do you agree to switch from a biological brand drug to a biosimilar?	
Always	5 (6.7%)
Only if the doctor approved	42 (56.0%)
Only if the brand drug is not available	9 (12.0%)
Only if the patients asked for a cheaper option	5 (6.7%)
Never	26 (34.7%)
The effectiveness of the generic drug compared to its brand is:	
Higher	–
Same	68 (90.7%)
Lower	7 (9.3%)
The effectiveness of the biosimilar compared to its brand is:	
Higher	13 (17.3%)
Same	38 (50.7%)
Lower	24 (32.0%)
The needs to improve the knowledge of generic drugs and biosimilars are:	
Including them in the curriculum of universities	64 (85.3%)
Periodic workshops	60 (80.0%)
Including them in the continuing education program	62 (82.7%)
Have you received any training or education about:	
Generic drugs	18 (24.0%)
Biosimilars	2 (2.6%)
Both generic drugs and biosimilars	41 (54.7%)
Neither generic drugs nor biosimilars	14 (18.7%)

Results are given in terms of frequency (percentage)a.

drugs.[28] Only 20% of patients reported that studies are performed on patients for only biosimilars. Switching to a biosimilar may be assessed in a randomized clinical setting and need evidence on the safety and effectiveness of single transitions,[29] which does not apply to generic drugs. Better knowledge of the characteristics of generic drugs was noted among the study participants, and several misconceptions existed in relationship with biosimilars, in agreement with a report published in 2018.[30] This knowledge was not associated with any of the characteristics of the participants. The novelty of their use in Lebanon induced the need to improve their understanding and adoption,[31] which might have led to a common limited knowledge among health care providers.

Most pharmacists reported substituting for generic drugs if the brands were unavailable or the patients asked for cheaper options. Data were collected during the COVID-19 pandemic and Lebanon's economic crisis, which could explain this behavior. Nonetheless, more than half of pharmacists agreed to change a biological reference drug to its biosimilar only upon the doctor's approval, linking either good knowledge to behavior or a possible lack of knowledge to the referral to other health care professionals. Community pharmacists' knowledge of the differences between generic drugs and biosimilars should be improved, since it was found to be associated with patients' acceptance to buy and substitute for generic drugs.[32] Pharmacists reported the need to include this topic in educational and training programs. It is recommended that the OPL and the MOPH consider that in collaboration with program providers.

This study has limitations. The study participants were relatively young pharmacists that could have different knowledge than older ones. The small sample size may have affected the extrapolation of the findings to all pharmacists or those working in other fields. Despite using a uniform data collection form by trained students, selection bias may have been induced, given that only motivated pharmacists were willing to participate. Statements were given equal weights to generate the overall score, which may reflect something other than the real importance of that knowledge statement. Nevertheless, the present study is the first to assess pharmacists' knowledge of the differences between generic drugs and biosimilars. A longitudinal study is recommended for better external validity and representativeness of pharmacists in Lebanon and other similar settings.

Conclusion

Although overall moderate knowledge was noted among pharmacists, most of them were more familiar with the characteristics of generic drugs than biosimilars. To promote their use, improving pharmacists' knowledge can help overcome misconceptions and misinformation regarding both generic drugs and biosimilars. Further investigation on a bigger sample size is recommended to evaluate the knowledge gaps in assessing the differences between generic drugs and biosimilars.

Declarations

Ethics approval and consent to participate

The study protocol, questionnaire, and consent form were reviewed and approved by the institutional review board of the faculty of pharmacy of the Lebanese University (reference: 3/22/D). Written informed consent was obtained from every participant.

Consent for publication

Not applicable

Author contribution(s)

Sanaa Awada: Conceptualization; Data curation; Investigation; Writing—original draft; Writing—review & editing.
Roudy Sayah: Data curation; Investigation; Methodology; Writing—original draft.
Maribelle Mansour: Data curation; Project administration; Writing—original draft.
Cynthia Nabhane: Data curation; Methodology; Visualization; Writing—original draft.
Georges Hatem: Conceptualization; Data curation; Methodology; Supervision; Writing—original draft.

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Supplemental material

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