

Original Research

Probing biosimilar-related concerns and practices among community pharmacists

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Abstract

Background: The successful integration of biosimilars into routine clinical practice depends on their acceptance. Given the vital role of community pharmacists in medication management, it is essential to understand their concerns and practices related to biosimilars, which was the objective of the present study. **Methods:** In this cross-sectional study, a research pharmacist distributed in person a validated self-administered survey to community pharmacists across various geographical areas of the UAE. The survey included four sections that evaluated sociodemographic and work-related characteristics, pharmacists' concerns and extent of biosimilar utilization, and the factors facilitating its adoption in the community pharmacy settings. **Results:** Out of 472 pharmacists, 415 (87.9%) were familiar with biosimilar efficacy and safety. Most of the study pharmacists were females (53%), and had a median [interquartile range (IQR)] age of 35 (30-41) years. The median (IQR) score for biosimilar-related concern was 21 (20-24) out of a possible score of 32, demonstrating a room for improvement. Most of the pharmacists expressed moderate-to-high concerns. The perceived acceptance of biosimilars by the patients and the prescribers represented the highest concern among the study pharmacists (30.6%). The median (IQR) of biosimilar-related practice score was 25 (23-27) out of 40, showing a window for practice improvement. More than half of the pharmacists did not often perform the essential biosimilar-related practices. The most frequently reported factors to facilitate biosimilar adoption in clinical practice were providing information on the clinical benefits of the biosimilars for prescribers and patients (48.30%), providing education on biosimilar use (44.70%), and establishing guidance on interchangeability or possibility of switching (43.60%). **Conclusion:** Pharmacists in the present study demonstrated concerns and inadequate adherence to practices concerning biosimilar therapy. Targeted educational interventions highlighting the benefits, effectiveness, safety and proper administration of biosimilar therapy are essential to address these concerns and facilitate the integration of biosimilars into routine clinical care.

Keywords: biosimilar, pharmacist, concerns, practice, facilitator, utilization

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INTRODUCTION

Biopharmaceuticals, or proteins produced using recombinant DNA technology and hybridoma techniques, such as vaccines, biological proteins, and monoclonal antibodies, are an integral part of current pharmacotherapy.¹⁻³ However, the high cost of biological medications places a significant financial burden on the healthcare system.⁴ With many biopharmaceutical patents now expired, there is a pressing need for more affordable protein products.³ This has led to the development of biosimilars, defined as biological medicines that have been shown to have no clinically meaningful differences in quality, safety, or efficacy compared to their originator products.⁵ Biosimilars are recognized as safe and effective treatment options for various conditions, including cancer and immune disorders⁶. They offer the potential for comparable quality and benefits to original biologics while increasing access to life-saving medications at potentially lower costs.⁷

A recent report predicts that the global biosimilars market will grow from \$30 billion in 2020 to over \$60 billion by 2026.⁸ Biosimilar use has already increased in the majority of Middle Eastern and North African (MENA) nations. In Lebanon, for example, biosimilars accounted for more than 40% of the biologics market in 2017. They have also made a name for themselves in two other major biologics markets: Egypt and the United Arab Emirates, where they account for approximately 14% and 5% of the respective biologics markets.⁹ As the



prevalence of long-term conditions in the UAE continues to rise, the demand for effective and affordable treatment options has become increasingly urgent. Biosimilars offer a more affordable alternative to expensive biologics, closely resembling the original drugs while potentially alleviating financial burdens on healthcare systems without compromising therapeutic efficacy.¹⁰ The biosimilar market in the UAE is projected to expand at a compound annual growth rate of 23.2% from \$96 million in 2022 to \$510 million by 2030. The UAE market presently offers a range of biosimilar drugs for rituximab, etanercept, and infliximab that are used to treat multiple diseases such as rheumatoid arthritis, psoriasis, and cancer.¹⁰

Pharmacists are key gatekeepers for patient education and medication management. Their acceptance of biosimilars is essential for fully realizing their benefits and successfully integrating them into clinical practice^{11,12}. However, several factors still limit their application, despite the potential advantages. These include doubts regarding their efficacy, safety, immunogenicity, interchangeability, a lack of knowledge, low rates of acceptance, and the long-term outcomes of biosimilar use^{13,14}. Understanding pharmacists' concerns about biosimilars is pivotal for advancing their expertise in this domain. This study aimed to evaluate pharmacists' familiarity, concerns, practices, and facilitators that aid in dealing with biosimilar therapy in the UAE. The anticipated findings of this study are expected to help the healthcare system in better leveraging the benefits of biosimilar therapy, thereby augmenting patient access to necessary treatments and improving therapeutic outcomes.

MATERIALS AND METHODS

Study design and participants

In this cross-sectional study, a validated self-administered survey was distributed in person by the research pharmacist to community pharmacists across the UAE from February to April 2024, using a convenience-sampling. After verifying eligibility, the research pharmacist outlined the study objectives and ensured that participation would be voluntary, anonymous, and confidential. Participants then completed the study questionnaire via a Google Form. Eligible individuals were licensed community pharmacists in the UAE who had graduated from universities accredited by the Ministry of Higher Education were eligible to participate. On average, it took about ten minutes to complete the questionnaire.

Ethics approval statement

The current research received ethical approval from the research ethics committee at Al Ain University- Abu-Dhabi Campus (Ref #: COP/AREC/AD/28). Pharmacists who agreed to participate were asked to confirm their consent by selecting the statement: "I have read the study information and I agree to participate," before proceeding to the survey questionnaire.

Study instrument

The study questionnaire was developed after review of relevant research studies.¹³⁻¹⁵ A group of specialists,

comprising professors of biotechnology, pharmacology, and pharmacy practice, assessed the survey's comprehensiveness and relevance. Subsequently, the survey's completion time, relevancy, and clarity were evaluated in a pilot study involving ten community pharmacists. The final data analysis did not contain the information that was collected from the pilot test. Data on sociodemographic characteristics, work-related variables, and the sources of drug-related information were collected in the first section of the survey. The next question assessed familiarity with the safety and efficacy of biosimilar therapy. Pharmacists who lacked familiarity with biosimilar therapy did not answer the questions related to biosimilar concerns and practices. In contrast, those who were knowledgeable about biosimilars received a definition before proceeding to the next section of the questionnaire. The next 8-item section addressed the participants' concerns regarding biosimilar therapy using a four-point Likert scale that ranged from "Not a concern" (1 point) to "High concern" (4 points), with a maximum score of 32. The participants' practices of biosimilar therapy were evaluated using nine questions, which assessed how frequently the biosimilar-related tasks were performed on a five-point Likert scale ranging from "Rarely" (1 point) to "Always" (5 points), with a maximum possible score of 45. In the final section of the survey, the participants were asked to identify the facilitators that, in their view, could enhance the use of biosimilars in clinical practice.

Sample Size Calculations

The Krejcie and Morgan formula was used to calculate the minimum required sample size: $S = X^2NP(1 - P) + a^2(N - 1) + X^2P(1 - P)$, where S = required sample size, X^2 = the table value of chi-square for 1 degree of freedom at the desired confidence level (3.841), N = the population size, P = the population proportion (assumed to be 50 to provide the maximum sample size) and d = the degree of accuracy expressed as a proportion (0.5).¹⁶ Krejcie and Morgan developed sample size tables based on the above formula for various population sizes, confidence levels, and margin errors. Assuming an indefinite population to determine the required sample size, the minimum required sample was 384 for a 95% confidence level and a 5% margin of error.

Statistical Analysis

The data analysis was performed using the Statistical Package for the Social Sciences (SPSS, version 28, Illinois, New York, USA). Q-Q plots and the Kolmogorov-Smirnov test revealed non-normal distribution of the continuous variables. Therefore, these variables were presented as medians and 25–75 percentiles. Categorical variables were reported as frequencies and percentages. Additionally, scores for concerns and practice related to biosimilars were calculated for participants. The internal reliability of the concerns and practice questions regarding biosimilars was assessed using Cronbach's alpha, with an acceptable threshold set at greater than 0.7.

RESULTS

The study included 472 pharmacists, of which 12.1% reported that they were not familiar with biosimilars' efficacy and safety.



The median (IQR) age of the study participants was 35 (30-41) years. Most of the study participants were females (53%), completed a bachelor's degree in pharmacy (63.6%), worked in chain pharmacies (55.1%), were pharmacist in-charge/employee pharmacists (80.5%), had 6-10 years of experience (45.6%), worked in Abu Dhabi (62.5%), and dispensed an average number of 10-29 prescriptions per day (50.2%). The

most commonly utilized drug information source was the BNF (33.3%). Socio-demographic and work-related characteristics of the study pharmacists are presented in Table 1.

Table 2 presents pharmacists' responses to items pertaining to concerns about prescribing biosimilar therapy in practice. The median (IQR) concern score was 21 (20-24) out of a maximum possible score of 32, demonstrating a margin for improvement.

Table 1. Socio-demographic and work-related characteristics of the study pharmacists (n=472)

n=415 (87.9%)		Pharmacists who reported being familiar with biosimilar therapy in terms of efficacy and safety	Pharmacists who reported not being familiar with biosimilar therapy in terms of efficacy and safety	All pharmacists
		n=57 (12.1%)	n=472	
Median (25-75) percentiles or frequency (%)				
Age		35 (30-42)	32 (29-36)	35 (30-41)
Gender	Female	219 (52.8%)	31 (54.4%)	250 (53%)
	Male	196 (47.2%)	26 (45.6%)	222 (47%)
Education (Highest degree completed)?	BPharm (Bachelor in pharmacy)	264 (63.6%)	36 (63.2%)	300 (63.6%)
	PharmD (Doctor in Pharmacy)	98 (23.6%)	14 (24.6%)	112 (23.7%)
	Graduate (Master or PhD)	53 (12.8%)	7 (12.3%)	60 (12.7%)
Pharmacy type	chain community pharmacy	228 (54.9%)	32 (56.1%)	260 (55.1%)
	independent community pharmacy	187 (45.1%)	25 (43.9%)	212 (44.9%)
Job Title	Owner pharmacist	85 (20.5%)	7 (12.3%)	92 (19.5%)
	Pharmacist In-charge/Employee pharmacist	330 (79.5%)	50 (87.7%)	380 (80.5%)
How many years of experience do you work as a community pharmacist:	<=5 years	104 (25.1%)	21 (36.8%)	125 (26.5%)
	6-10 years	186 (44.8%)	29 (50.9%)	215 (45.6%)
	>=10 years	125 (30.1%)	7 (12.3%)	132 (28%)
In which emirate do you work?	Abu Dhabi	265 (63.9%)	30 (52.6%)	295 (62.5%)
	Dubai and North Emirates	150 (36.1%)	27 (47.4%)	177 (37.5%)
Average number of prescriptions dispensed per day	<10	94 (22.7%)	21 (36.8%)	115 (24.4%)
	Oct-29	209 (50.4%)	28 (49.1%)	237 (50.2%)
	>=30	112 (27%)	8 (14%)	120 (25.4%)
What is your source for drug information?	BNF	138 (33.3%)	19 (33.3%)	157 (33.3%)
	British pharmacopeia	31 (7.5%)	9 (15.8%)	40 (8.5%)
	Lexicomp	44 (10.6%)	6 (10.5%)	50 (10.6%)
	Micromedex	121 (29.2%)	10 (17.5%)	131 (27.8%)
	US pharmacopeia	81 (19.5%)	13 (22.8%)	94 (19.9%)

Table 2. The reported concerns to use the biosimilar in clinical practice (n=415)

	Not a concern	low concern	Moderate concern	High concern
The efficacy/ long-term efficacy of biosimilars.	43 (10.4%)	127 (30.6%)	180 (43.4%)	65 (15.7%)
The safety of biosimilars particularly the risk of immunogenicity	28 (6.7%)	96 (23.1%)	204 (49.2%)	87 (21%)
Interchangeability between a biosimilar and the reference biologic product	29 (7%)	114 (27.5%)	182 (43.9%)	90 (21.7%)
The administration processes of the biosimilar	59 (14.2%)	118 (28.4%)	178 (42.9%)	60 (14.5%)
The quality of manufacturing of biosimilar	85 (20.5%)	108 (26%)	157 (37.8%)	65 (15.7%)
The testing procedures for biosimilar approval	73 (17.6%)	118 (28.4%)	156 (37.6%)	68 (16.4%)
The level of knowledge about biosimilars.	16 (3.9%)	88 (21.2%)	229 (55.2%)	82 (19.8%)
The perceived acceptance of biosimilars by the patients and the prescribers	14 (3.4%)	84 (20.2%)	190 (45.8%)	127 (30.6%)



In all the concerns' items, the majority of the participants reported a concern towards biosimilar prescribing, among which the majority reported moderate concern for all concern items. The perceived acceptance of biosimilars by the patients and the prescribers represented the highest concern among the participants (30.6%). Cronbach's alpha of the concerns scale=0.7, indicating reliability of the instrument.

As shown in Table 3, the median (IQR) of the practice score related to biosimilar was 25 (23-27) out of a maximum potential score of 40, showing a room for practice improvement. More than half of the pharmacists did not often perform

the essential biosimilar dispensing-related practices. The Cronbach's alpha=0.7 demonstrated the acceptable reliability of the practice scale.

Regarding the facilitators for the use of biosimilars in clinical practice (Figure 1), the most frequently reported facilitator was "Providing information on the clinical benefits of the biosimilars for prescribers and patients" (48.30%), followed by "Providing education on biosimilar use" (44.70%), and "Establishing guidance on interchangeability or possibility of switching" (43.60%). The least frequently reported facilitator was "Providing incentives" (20.10%).

Table 3. The reported biosimilar-related practice among the community pharmacists (n=415).

	Never	Rarely	Sometimes	Usually	Always
Identifying the appropriate candidates for biosimilars.	19 (4.6%)	78 (18.8%)	193 (46.5%)	92 (22.2%)	33 (8%)
Providing biosimilar-related safety and efficacy information	16 (3.9%)	76 (18.3%)	191 (46%)	95 (22.9%)	37 (8.9%)
Providing education about the use of biosimilars and dispelling common misconceptions.	22 (5.3%)	82 (19.8%)	191 (46%)	88 (21.2%)	32 (7.7%)
Educating prescribers and patients about the availability of biosimilars	23 (5.5%)	69 (16.6%)	190 (45.8%)	79 (19%)	54 (13%)
Educating prescribers and patients about the interchangeability and substitution of the biosimilars	26 (6.3%)	79 (19%)	194 (46.7%)	68 (16.4%)	48 (11.6%)
Providing information about the approval process and alleviating any existing concerns.	18 (4.3%)	76 (18.3%)	198 (47.7%)	85 (20.5%)	38 (9.2%)
Providing information about the economic benefits of biosimilars	11 (2.7%)	77 (18.6%)	204 (49.2%)	72 (17.3%)	51 (12.3%)
Empowering patients and prescribers in conversation about biosimilars and addressing any raised concerns.	17 (4.1%)	69 (16.6%)	199 (48%)	93 (22.4%)	37 (8.9%)

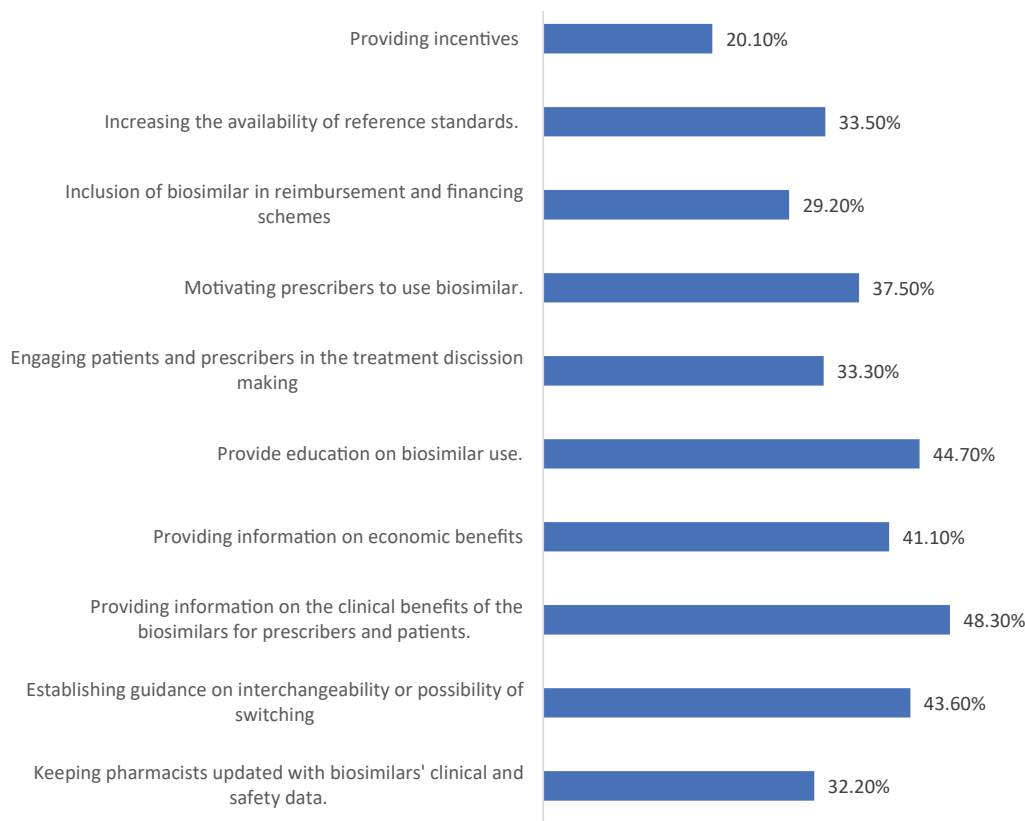


Figure 1. Facilitators for biosimilar utilization in clinical practice



DISCUSSION

In the global pharmaceutical marketplace, the significance of biosimilar medications is increasingly apparent. Despite the promising growth in the market, there are challenges related to healthcare providers' acceptance of biosimilars. Pharmacists play a crucial role in ensuring the safe and cost-effective use of medications, serving as both educators and healthcare providers. This makes their role in the utilization of biosimilars in clinical practice especially important. Therefore, the purpose of this study was to evaluate community pharmacists' familiarity with, concerns about, practices regarding, and facilitators for the use of biosimilar medications.

Consistent with the results reported in previous research,¹⁷ the majority of the current study pharmacists were familiar with biosimilar therapy in terms of efficacy and safety. Despite being familiar, the pharmacists in the current study expressed moderate-to-high concerns regarding several aspects of prescribing biosimilars. The concerns included biosimilar efficacy, safety profile, risk of immunogenicity, interchangeability with reference biologic products, administration, manufacturing quality, approval process, and the overall level of knowledge about biosimilars. Additionally, approximately one-third of the pharmacists reported a high level of concerns regarding the perceived acceptance of biosimilars by both patients and prescribers. A study conducted in New Zealand found that pharmacists' primary concerns about biosimilars included safety, decreased efficacy, a lack of knowledge about the product, and doubts about whether patients and healthcare professionals would accept the treatment.¹⁴ Similarly, more than one-third of pharmacists in a Jordanian study expressed concerns about biosimilar medications.¹⁸ In the UK, 50% of pharmacists expressed concerns about efficacy when switching medications, while 38% expressed concerns about safety when initiating treatment with a biosimilar.¹⁹

Since biosimilars are not identical to their reference biologic products, this can raise concerns among healthcare providers, including pharmacists, about their safety, efficacy, and therapeutic outcomes.²⁰ Moreover, pharmacists may vary in their level of knowledge about biosimilars, which can lead to reluctance or uncertainty if they lack sufficient information. Additionally, the acceptance of biosimilars by patients and other healthcare professionals is essential for their successful utilization. Addressing these concerns can help enhance pharmacists' confidence, reduce their concerns, and promote the adoption of biosimilars in clinical practice. Implementing educational and training programs for pharmacists is essential to deepen their understanding of biosimilars, including their production and approval processes, clinical efficacy, and safety profiles. These educational initiatives will also play a crucial role in increasing acceptance of biosimilars among patients and other healthcare providers. Additionally, developing comprehensive guidelines for biosimilar use that covering aspects such as interchangeability and administration, will help alleviate concerns. Moreover, conducting further investigations into biosimilars, such as side-by-side trials with reference biologics, will provide valuable

data on long-term efficacy and safety, further addressing any lingering concerns.

A study conducted in Pakistan reported that half of the participating pharmacists expressed confidence in their ability to apply biosimilars in a practical context.²¹ However, the current study revealed that biosimilar-related practices were inadequate, indicating significant room for improvement. Most pharmacists reported that they did not frequently engage in essential biosimilar dispensing practices. These practices included identifying appropriate biosimilars' candidates, providing safety and efficacy information, providing education on biosimilars' use, their availability, interchangeability, approval process, the economic benefits of biosimilars, empowering patients and prescribers in conversation about biosimilars, and alleviating any related concerns or misconceptions. Similarly, inadequate biosimilars' practices were reported among clinicians in an Indian study, where less than a third were able to clarify the structural differences between biosimilars and their reference biologics, as well as explain their effectiveness and safety using clinical evidence.²² Inadequate utilization of biosimilars was also observed among both healthcare workers and patients in China.²³ This low level of practice is likely linked to pharmacists' concerns about adopting these treatments in clinical settings, highlighting the urgent need to address these concerns and develop effective strategies to alleviate them and promote the use of biosimilars.

Despite elevated concerns and limited practice, pharmacists in the current study identified several facilitators that could promote the dispensing of biosimilars in clinical practice. The most frequently reported facilitators included providing information on the benefits of biosimilars for prescribers and patients, offering education on biosimilar use, and establishing guidance on interchangeability or the possibility of switching. A study conducted in Spain found that all participants, including physicians and hospital pharmacists, agreed that developing recommendations from professional associations and societies, along with demonstrating the efficacy of interchangeability, were key facilitators for the uptake of biosimilars.²⁴ Financial incentives and real-world data have been identified as facilitators to enhance the use of biosimilars in a study conducted among healthcare professionals in the UK.²⁵ By addressing these facilitators, healthcare systems can enhance biosimilar acceptance and utilization, leading to more affordable treatment options. Providing patients and prescribers with comprehensive information about the benefits of biosimilars can alleviate concerns and increase confidence in their efficacy and safety. Moreover, targeted education on biosimilar use and clear regulations on interchangeability can facilitate their integration into clinical practice. Ultimately, these strategies can improve patient outcomes by increasing access to cost-effective biologic therapies and reducing medical expenses.

Study limitations

The current study has some limitations. First, the cross-sectional design does not allow for establishing cause-and-effect relationships. Second, the use of convenience sampling



may introduce selection bias, affecting the generalizability of the findings. Lastly, reliance on self-reported survey data could lead to social-desirability bias.

CONCLUSION

The current study demonstrated increased concerns and inadequate practices related to biosimilars among community pharmacists in the UAE. To enhance biosimilar utilization in pharmacy practice, it is recommended to implement tailored educational interventions that address these concerns and improve pharmacists' understanding of biosimilar therapy, including its benefits, uses, effectiveness, safety, and proper administration.

AUTHORS' CONTRIBUTION

ASJ conceived and designed the study, conducted research, provided research materials, supervised the project, and wrote initial and final draft of article. WA conceived and designed the study, validated instruments, organized, analysed and

interpreted data and reviewed the manuscript. KHA conceived and designed the study, organized, analysed and interpreted data, and wrote initial and final draft of article. SRA designed the study, collected, organized, analysed and interpreted data, and wrote initial and final draft of the article. TM conceived and designed the study, wrote initial and final draft of article, and provided logistic support. YNA conceived and designed the study, analysed data and reviewed the final draft of the manuscript. RB conceived and designed the study, analysed data and reviewed the final draft of the manuscript. SA conceived the study and research methods, interpreted data, reviewed the final draft of the manuscript and co-supervised the project. All authors have critically reviewed and approved the final draft of the study and agreed to be accountable for all aspects of the work.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest to declare.

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