Perceptions of Biosimilars Among Healthcare Providers in Saudi Arabia

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Abstract
Background: Biosimilars are safe and effective treatments for chronic diseases, including cancer and rheumatoid arthritis. The Saudi Food and Drug Authority (SFDA) oversees the quality and registration of biosimilars in Saudi Arabia. However, disparities among regulatory authorities such as the lack of guidelines for biosimilars in rheumatology affect healthcare providers' perceptions, leading to hesitancy in switching from reference products to biosimilars. This study aimed to explore the perceptions of Saudi healthcare professionals regarding biosimilars. *Methods:* A convenience sample of 87 participants (75 pharmacists and 12 physicians) was analyzed. The data were collected between December 2022 and February 2023. A logistic regression model was used to predict the intention toward biosimilars. *Results:* Years of practice among physicians significantly influenced their intention to prescribe biosimilars. Positive correlations were also observed between intentions towards prescription and beliefs regarding the safety and efficacy of biosimilars. Pharmacists' authority and knowledge of biosimilars correlated with their intention to substitute or dispense them. However, the logistic regression analysis indicated that behavioral, normative, and control beliefs were not significant predictors of the intention to prescribe or substitute biosimilars in either group. *Conclusions:* Highlighting the significance of continuing education and coordinating efforts in the international harmonization of biosimilar guidelines, as well as education for healthcare professionals, is required for addressing clinical concerns and enhancing confidence in biosimilars.

Keywords: TPB; beliefs; biosimilars; healthcare intention; perceptions; interchangeability.

Introduction

Biosimilars are biological products derived from living organisms, including humans, animals, and microorganisms, used to treat life-threatening diseases such as cancer and rheumatoid arthritis (Chong et al., 2022). In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) is the regulatory body responsible for ensuring biosimilar quality and overseeing registration requirements.

Disparities among regulatory authorities have significantly influenced healthcare providers' perceptions (Renwick et al., 2016). As a result, healthcare providers may hesitate to switch patients from reference products to biosimilars due to clinical concerns (Gibofsky et al., 2019). For example, Saudi rheumatologists lack specific guidelines on the clinical use of biosimilars (Halabi et al., 2018).

Additionally, the nocebo effect can negatively impact patients' perceptions when prescribers fail to provide clear information during the transition from reference biological products to biosimilars (Cantini et al., 2020). These factors all contribute to shaping healthcare providers' attitudes toward biosimilar adoption.

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Investigating biosimilars is essential for understanding healthcare professionals' perspectives on these biopharmaceuticals. This will help identify the factors influencing their adoption in the Kingdom of Saudi Arabia (Aladul et al., 2018). Previous research has investigated healthcare professionals' attitudes (Aladul et al., 2018), still, no prior study has utilized the Theory of Planned Behavior (TPB) to explore healthcare providers' beliefs and attitudes regarding biosimilars comprehensively. Therefore, this study adopts the TPB framework to understand the perspectives of healthcare providers, such as pharmacists and physicians, regarding biosimilars across various domains. By employing the TPB, the research aims to assess its effectiveness in predicting healthcare providers' perceptions of biosimilar use, focusing on examining the beliefs and attitudes of healthcare professionals in the Kingdom of Saudi Arabia.

Methods

This study utilized a correlational survey design to investigate predictors of intentions toward biosimilars. Data were collected from December 2022 to February 2023 via the REDCap platform, targeting licensed physicians and pharmacists in Saudi Arabia (KSA).

Hypotheses

1. There is no significant difference between KSA healthcare professionals' behavioral beliefs toward biosimilars.
2. There is no significant difference in KSA healthcare professionals' normative beliefs toward biosimilars.

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3. There is no significant difference in KSA healthcare professionals' control beliefs toward biosimilars.
4. There is no significant difference in KSA healthcare professionals' behavioral, normative, and control beliefs in predicting the intention to prescribe biosimilars.

Aims

Aim 1: Examine the correlation between sociodemographic variables and KSA healthcare professionals' intentions.

Aim 2: Investigate the beliefs and intentions of KSA physicians and pharmacists toward prescribing or dispensing biosimilars.

Research Questions

1. Is there a positive association between the level of behavioral beliefs (attitude) among KSA physicians or pharmacists toward the intention to prescribe or dispense biosimilars?
2. What is the correlation between the normative beliefs of the KSA physician or pharmacist toward the intention to prescribe or dispense biosimilars?
3. Are the control beliefs of KSA physicians or pharmacists positively associated with prescribing or dispensing biosimilars?
4. Are any factors, such as attitude, subjective norms, or perceived behavioral control, significant predictors of the intention toward biosimilars?

Instrument

Saudi Arabian healthcare professionals (physicians and pharmacists) participated in surveys via the REDCap platform to evaluate their perceptions of biosimilars. To predict intentions toward biosimilars, the analysis used two survey instruments based on the Theory of Planned Behavior (TPB) and sociodemographic variables. Key variables included behavioral beliefs, normative beliefs, control beliefs, and behavioral intention, following validated methodologies, as shown in **Figure 1** (Lee et al., 2018). The TPB questionnaire consisted of four domains, with three independent variables (behavioral, normative, and control beliefs) and one dependent variable (intention). Responses were measured on a 5-point Likert scale, where higher scores indicated a more positive attitude towards biosimilars. The surveys were designed to capture the distinct perceptions of both physicians and pharmacists **(Table 1 and Table 2).**

Data Collection and Analysis Procedures

Data for the study were collected through cross-sectional online surveys administered via the secure REDCap platform, following approval from the Institutional Review Board (IRB) under Protocol Number 2022-404 at NSU. Participants received reminder emails after two weeks. Data were analyzed using SPSS Statistics version 27. Descriptive statistics categorized demographics into eight groups, and logistic regression was employed with behavioral intentions as the dependent variable and behavioral, normative, and control beliefs as independent variables. Pearson's correlation coefficient and Cronbach's alpha coefficient (α) were calculated, with alpha values below 0.05 considered statistically significant.

Results

A convenience sampling approach was used to gather beliefs from KSA healthcare professionals. After excluding incomplete responses, data from 87 participants (75 pharmacists and 12 physicians) were suitable for analysis.

Physicians: Descriptive Statistics

The demographic characteristics and intentions of 12 physicians in Saudi Arabia (KSA). The sample comprised 83.3% males and 16.7% females, with the largest age group being 36-41 years (33.3%). Half of the participants were consultants, and the majority (91.7%) were employed by the government. All participants were Saudi nationals, with 75% having over 11 years of practice. The central region had the highest representation at 41.7%. While the analysis showed a significant relationship between years of practice and intention (Chi-Square Value: 0.018), no significant correlation was found between other demographic factors (gender, age, professional rank, sector, nationality, and region) and the KSA physicians' intentions **Table 6.**

Physicians: Research Question (RQ) 1

Are KSA physicians' behavioral beliefs (Bb) levels positively associated with the intention to prescribe or switch biosimilars?

The analysis of correlations and significance (2-tailed) for eleven items assessing behavioral beliefs and the intention to prescribe biosimilars. The strongest correlations with prescribing intentions were found for the awareness of no clinical differences ($r = 0.539$, $p = 0.070$) and the safety and effectiveness of biosimilars ($r = 0.480$, $p = 0.115$). In contrast, the lowest correlations were associated with the awareness of immunogenicity ($r = 0.161$, $p = 0.618$) and clinical concerns about using biosimilars ($r = 0.056$, $p = 0.863$).

Physicians: Research Question (RQ) 2

What is the relationship between KSA physicians' normative beliefs (Nb) and the intention to prescribe or switch biosimilars?

The analysis of five items assessing normative beliefs and the intention to prescribe biosimilars showed that the highest rankings were given to the promotion of biosimilars by health professional associations and the Pharmacy and Therapeutics (P&T) Committee ($r = 0.646$, $p = 0.023$; $r = 0.550$, $p = 0.064$). The lowest rankings were given to beliefs regarding the standing of medical professional associations in government communication and the P&T Committee's recommendation against adding biosimilars to the formulary ($r = -0.114$, $p = 0.724$; $r = -0.162$, $p = 0.616$).

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Physicians: Research Question (RQ) 3

Are the control beliefs (Cb) of the KSA physicians positively associated with the intention to prescribe or switch biosimilars?

The analysis of eight items assessing control beliefs and intentions toward biosimilars showed the highest correlation with awareness of SFDA regulatory guidelines (r = 0.523, p = 0.081) and familiarity with payer policies (r = 0.414, p = 0.181). The lowest correlations were with access to information comparing biosimilars with reference drugs (r = 0.000, p = 1.000) and satisfaction with current knowledge of biosimilars (r = 0.026, p = 0.936). Key control beliefs include the availability of information and familiarity with payer policies regarding biosimilars in the KSA market.

Physicians: Research Question (RQ) 4

Are any of these factors (behavioral beliefs, normative beliefs, and control beliefs) statistically significant in predicting the KSA physicians' level of intention to prescribe or switch biosimilars?

A binary logistic regression model using Bb, Nb, and Cb as independent variables and intention toward behavior as the dependent variable for KSA physicians was analyzed. The model was not a good fit ($\chi2(3) = 3.907$, p = 0.272). Cox & Snell and Nagelkerke R Square values indicated that 27.8% to 38.6% of the variation in intention toward behavior can be explained by Bb, Nb, and Cb **Table 3**.

Pharmacists: Descriptive Statistics

The survey of 75 KSA pharmacists revealed the following demographic characteristics: 68% were male and 32% were female. Age-rang, 16% were between 25-30 years old, 33.3% were between 31-35 years old (the highest percentage), 24% were between 42-50 years old, and 9.3% were between 51-60 years old (the lowest percentage). In terms of professional specialty, 37.3% were clinical pharmacists. Regarding professional rank, 28% were specialists. Employment Sector, 85.3% worked in the government sector, 9.3% in the private sector, and 5.3% in other sectors. For years of experience, 25.3% had less than five years of experience, while 44% had 11 or more years of experience (the highest percentage). Nationality, 81.3% were Saudi and 18.7% were non-Saudi. Of the region, 54.7% worked in the Riyadh region **Table 5.**

Pharmacists

Research Question (RQ)1

Are the KSA pharmacists' level of behavioral beliefs (Bb) positively associated with the intention to substitute or dispense biosimilars?

The rankings of the correlations of the eleven items assessing behavioral beliefs and intention to substitute or dispense biosimilars were analyzed. The items "I have the authority to decide to use a suitable biosimilar for my patients" and "By knowing the safety and effectiveness of biosimilars, I'm willing to dispense or substitute biosimilars to my patients" (r = 0.439, p < 0.001; r = 0.298, p < 0.001) were the most highly correlated with intentions. The lowest-ranking behavioral beliefs were "I am aware there may be a clinical concern regarding biosimilars, such as immunogenicity," "I am aware that biosimilars are less expensive than the reference product in the market," and "I am aware that the Saudi Food & Drug Authority (SFDA) has approved the use of biosimilars" (r = 0.054, p = 0.644; r = 0.098, p = 0.402).

Pharmacists: Research Question (RQ) 2

What is the relationship between normative beliefs (Nb) and the intention to substitute or dispense biosimilars?

The rankings of the correlations of the five items assessing normative beliefs (Nb) and intention to substitute or dispense biosimilars were analyzed. Four out of five items showed positive associations with the intention to dispense or substitute biosimilars. The highest ranking was given to the items "Biosimilars were introduced and discussed in health professional associations, including the Saudi Society of Clinical Pharmacy (SSCP), and the Pharmacy and Therapeutics (P&T) Committee has promoted biosimilars" (r = 0.279, p = 0.015; r = 0.239, p = 0.039). The lowest-ranking normative beliefs were "My institution has a Pharmacy and Therapeutics (P&T) Committee that does not recommend adding biosimilars to the formulary" and "My institution has a particular Pharmacy and Therapeutics (P&T) Committee that continuously communicates with professional associations" (r = -0.030, p = 0.796; r = 0.021, p = 0.857).

Pharmacists: Research Question (RQ) 3

Are the control beliefs (Cb) of the KSA pharmacists positively associated with the intention to substitute or dispense biosimilars?

The analysis of correlations among eight items assessing control beliefs and intentions toward biosimilars revealed that the highest correlations were found for the statements "I am satisfied with the extrapolation indication of biosimilars" (r = 0.225, p = 0.053) and "I am satisfied with my current knowledge of biosimilars' uses; no further information or education is needed" (r = 0.224, p = 0.057). Conversely, the lowest correlations were observed for the statements "I am aware that the Saudi Food & Drug Authority (SFDA) has regulatory guidelines regarding the use or prescribing of biosimilars" (r = 0.048, p = 0.685) and "I have a basic understanding of biosimilars but would like to know more about their efficacy and safety" (r = 0.086, p = 0.462). These findings indicate that beliefs concerning the interchangeability and knowledge of biosimilars are critical control beliefs.

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Pharmacists: Research Question (RQ) 4

Are any of these factors (behavioral beliefs, normative beliefs, control beliefs) significant in predicting the level of intention to substitute or dispense biosimilars?

A binary logistic regression model was developed using Bb, Nb, and Cb as independent variables and intention toward behavior as a binary dependent variable among KSA pharmacists. The omnibus tests for the model were significant, with a Chi-Square Test value of 0.049, indicating the model was a good fit ($\chi^2(3) = 7.841$, $p = 0.049$). The Cox & Snell R Square was 0.101, and the Nagelkerke R Square was 0.136, suggesting that 10.1% to 13.6% of the variation in intention toward behavior could be explained by the independent variables. However, none of the independent variables had a significant impact on the dependent variable, as Bb ($p = 0.077$), Nb ($p = 0.437$), and Cb ($p = 0.338$) all had p-values greater than 0.05. **Table 4.**

Discussion

The study found that the years of experience of healthcare practitioners positively influenced their perception of biosimilars. Many of the pharmacist sample (44%) and physician sample (75%) had more than 11 years of experience, suggesting that practitioners with more practical experience were more likely to be open to prescribing biosimilars (Chen et al., 2019) . Moreover, the study of pharmacists' behavioral beliefs revealed strong correlations, with decision-making ($r = 0.439$) and knowledge of drug efficacy and safety ($r = 0.298$) being the strongest factors influencing pharmacists' intention to dispense biosimilars. Despite the Saudi health system's lack of support for pharmacists transitioning from reference drugs to biosimilars, the significance of these findings remains relevant, though minimal (Almutairi et al., 2023). Several beliefs also exhibited low correlations, such as awareness of the benefits and costs of biosimilars ($r = 0.098$), which is expected, given that the health system provides medicines free of charge to all Saudi citizens (Almutairi et al., 2023). Moreover, there was a positive correlation between physicians' awareness and intentions to prescribe biosimilars if they knew there were no clinical differences between biosimilars and reference biological products. Physicians' beliefs about the safety and efficacy of biosimilars were also positively correlated, though the results were not statistically significant.

In addition, normative beliefs emerged among pharmacists, indicating that the presence and support of professional institutions, such as the Pharmacy and Therapeutics (P&T) Committee and professional organizations like the Saudi Society of Clinical Pharmacy (SSCP), significantly influenced their decision to dispense biosimilars. Similar to pharmacists, physicians' prescribing intentions were substantially influenced by professional societies and the P&T Committee. Previous studies have shown that positive endorsements from these bodies lead to increased biosimilar prescribing (Chen et al., 2019). Moreover, regarding control beliefs for pharmacists, the results showed that those satisfied with their knowledge of biosimilars were more likely to dispense them (Gibofsky et al., 2019). However, knowledge gaps about the Saudi Food & Drug Authority (SFDA) regulatory frameworks, particularly guidelines, had a negative impact on their willingness to substitute or dispense biosimilars. Similarly, physicians, those familiar with SFDA guidelines and payment policies had a stronger intention to prescribe or switch to biosimilars. However, while physicians' satisfaction with their current knowledge was not as strongly correlated with their intentions, this suggests there are knowledge gaps, which may not significantly influence biosimilar prescribing behaviors. Addressing these educational gaps could further encourage the adoption of biosimilars (Grabowski et al., 2015).

All in all, behavioral, normative, and control beliefs hold significant predictive power. The binary logistic regression model revealed that among pharmacists, these beliefs explained between 10.1% and 13.6% of the variation in their intentions to prescribe or substitute biosimilars. Nevertheless, no single belief stood out as statistically significant, indicating that pharmacists' intentions are influenced by a combination of factors, none of which dominate. Among physicians, these three belief types described 27.8% to 38.6% of the variation in prescribing intentions. However, the model was not statistically significant, indicating that other unmeasured factors, such as patient preferences that affect adherence or regulatory policies needed to address variations between countries, could influence their decisions.

Limitations

It is imperative to acknowledge the constraints of this research. While the theory of planned behavior (TPB) is commonly used to determine individuals' behavior towards a particular intention, certain limitations could affect the study's outcomes. Although many factors outlined in the TPB were included, some influences, such as past behavior, were not considered. Additionally, a larger sample size would have increased the statistical power of the analyses. Specifically, the small sample size of Saudi physicians (n=12) limited the generalizability of their results, as the number of participants was relatively low compared to the two cohorts.

Conclusions

This study explored the attitudes of healthcare professionals in Saudi Arabia towards biosimilars. The findings indicated that physicians' beliefs were positively associated with intentions to prescribe or switch to biosimilars. Among pharmacists, clinical pharmacists exhibited the highest intention levels within their group (Table 5). The results underscored the importance of international harmonization of biosimilar guidelines and the adoption of biosimilars as alternatives to biological drugs in terms of safety and efficacy. The study concluded that pharmacists and physicians were confident about switching to biosimilars. Therefore, it is crucial to educate healthcare

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professionals about biosimilar approval pathways, particularly those with less experience, to support policies that ensure biosimilars are approved efficiently, have unrestricted access, and are used appropriately.

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Disclaimer: The statements, opinions, and data contained in all publications are those of the authors.

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Table 1. *The Theory of Planned Behavior (TPB) Construct*

Variables	Subdomain	Items	Possible Total Score
Independent Variables	Behavioral Beliefs	Perceived relative advantage (cost), Perceived risk of use (risk-benefit), Trust in biosimilar pathway, Perceived ease of use	11 to 55 (neutral 33)
	Normative Beliefs	Internal Project Team (P&T committee), Professional Institution	5 to 25 (neutral 15)
	Control Beliefs	Perceived barriers to prescribing	8 to 40 (neutral 24)
Dependent Variable	Intentions	Intention to prescribe/switch biosimilars (pharmacists) and substitute/dispense biosimilars (physicians)	3 to 15 (neutral 9)
		Dichotomized: low intention (3-9); high intention > 9	

Table 2. *Sociodemographic Variables for KSA Physicians and Pharmacists*

Sociodemographic Variables		Items
Gender		Male, Female
Age		25-30, 31-35, 36-41, 42-50, 51-60, 61 or above
Professional Specialty	Physicians	Gastroenterologist, General physician, Family medicine, Medical genetics, Internal medicine, Other
	Pharmacist	Community pharmacist, Clinical pharmacist, Hospital pharmacist, Oncology pharmacist, Toxicology pharmacists, Regulatory affairs, Other
Professional Rank	Physicians	Residency, Fellowship, Specialist, Consultant
	Pharmacist	Pharmacist, Residency, Fellowship, Specialist, Consultant
Employment Sector		Government, Private sector, Other
Nationality		Saudi, non-Saudi
Years of Practice		Less than five years, 5–10 years, 11 years or above
Regions		Western, Eastern, Southern, Central

Note: Western region: Makkah, Medina, Tabuk, and Al Baha. Eastern region, including the Dammam, Al-Hasa, Al-Jubail, Dhahran, Al-Khobar, and Al-Qatif. Southern region: the provinces of Asir, Jizan, and Najran. Central region, including Riyadh, Al Qassim, and Hail provinces.

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Table 3. *Binary Logistic Regression of KSA Physician's Intention Toward Biosimilars*

Independent variable	OR	*p*-value	95% CI
Bb_total	0.951	0.812	[0.630- 1.437]
Nb_total	0.772	0.724	[0.184- 3.238]
Cb_total	1.715	0.378	[0.517- 5.691]

Note. Bb: Behavioral beliefs, Nb: Normative beliefs, Cb: Control beliefs.

Table 4. *Binary Logistic Regression of KSA Pharmacists' Intention Toward Biosimilars*

Independent variable	OR	*p*-value	95% CI
Bb_total	1.095	0.077	[0.990- 1.210]
Nb_total	0.910	0.437	[0.718- 1.154]
Cb_total	1.093	0.338	[0.911- 1.312]

Note. Bb: Behavioral beliefs, Nb: Normative beliefs, Cb: Control beliefs.

Table 5. *Demographic Characteristics of Pharmacists in Saudi Arabia (KSA)*

Characteristic	Details	Percentage (%)
Gender	Male	68%
	Female	32%
Age Range	25-30 years	16%
	31-35 years (Highest percentage)	33.3%
	42-50 years	24%
	51-60 years (Lowest percentage)	9.3%
Professional Specialty	**Clinical Pharmacists**	**37.3%**
Professional Rank	Specialists	28%
Employment Sector	Government Sector	85.3%
	Private Sector	9.3%
	Other Sectors	5.3%
Years of Experience	Less than 5 years	25.3%
	11 or more years (Highest percentage)	44%
Nationality	Saudi	81.3%
	Non-Saudi	18.7%
Region	Riyadh Region	54.7%

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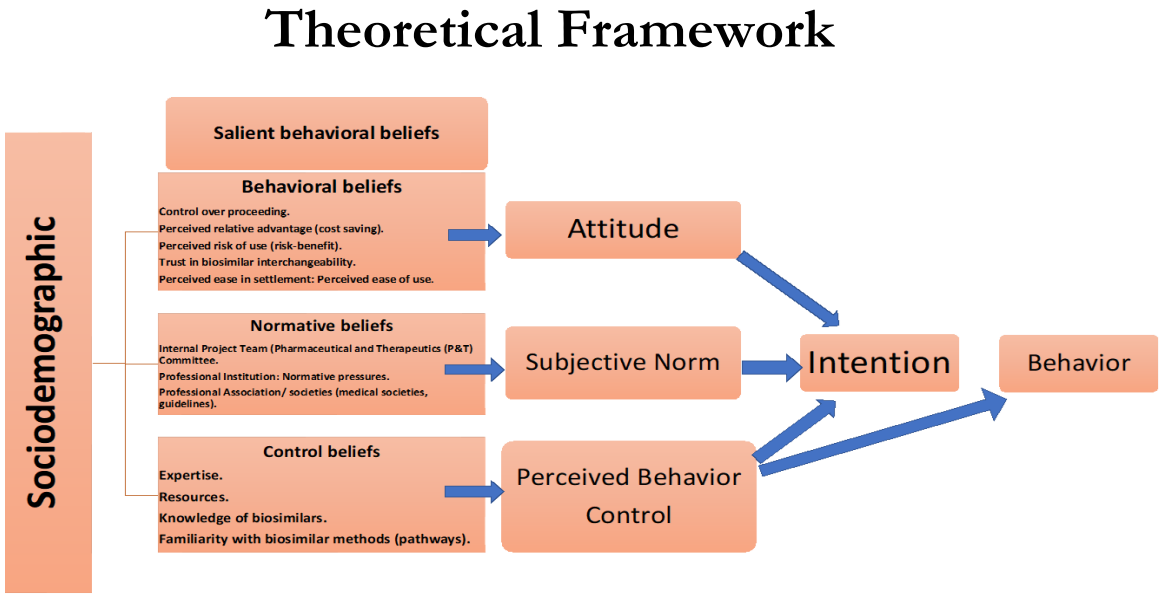
Table 6. *Demographic Characteristics of Physicians in Saudi Arabia (KSA)*

Characteristic	Percentage
Gender	
Male	83.3%
Female	16.7%
Age Range	
36-41 years	33.3%
Professional Rank	
Consultants	50.0%
Employment Sector	
Government	91.7%
Years of Practice	
Over 11 years	75.0%
Nationality	
Saudi Nationals	100.0%
Region	
Central Region	41.7%

Figure 1. *Theory of Planned Behavior Model for Predicting Intention Toward Biosimilar Use - Adapted From (Ajzen, 1991).*



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