

## Factors that Influence Healthcare Professionals' Intentions towards Biosimilars

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### Abstract

**Background:** Physicians often prescribe original biologic products to patients who have not used them before and are reluctant to switch to biosimilars. Biosimilars are highly similar versions of already-approved biologics, but healthcare professionals typically hesitate to transition patients from the original products to biosimilars. This study aims to investigate the factors that influence U.S. healthcare professionals' intentions to use biosimilars. **Methods:** A cross-sectional study was conducted. 510 participants were eligible healthcare professionals (279 physicians and 231 pharmacists). The theory of planned behavior (TPB) is used to identify which factors affect healthcare professionals' intentions. Descriptive statistics, chi-square, and the logistic regression model tested the TPB constructs as predictors of intentions toward biosimilars. **Results:** Among 279 physicians, most were aged 61 and above, with high (n = 142) and low (n = 137) intentions. Male physicians constituted 71% of the population. Attending physicians (66.3%) showed consistent perceptions towards biosimilars, primarily in the private sector (76.3%). Pharmacists (n = 231), a higher percentage of females demonstrated higher intentions compared to males (35.5% vs. 28.1%); the majority were community pharmacists. Associations between years of practice and intentions were significant. Positive correlations existed between beliefs and intentions, except for normative beliefs. **Conclusions:** This study revealed diverse attitudes among healthcare professionals towards biosimilars in the USA. Pharmacists and physicians, especially those with limited experience, require ongoing education on biosimilar manufacturing pathways. This education supports the appropriate use of biosimilars and helps standardize federal and state legislation.

**Key Words:** biologic-naive patients, biosimilars, healthcare intention, perceptions, beliefs, TPB.

### Introduction

Biological drugs are typically derived from living organisms (Diependaele et al., 2018) or systems and are used to treat a variety of life-threatening or chronic conditions (Barsell et al., 2017). Biological medicines have also enhanced the quality of life (Colloca et al., 2019) and altered the progression of several life-threatening diseases or conditions (Takahashi et al., 2014). Recently, interchangeable biosimilars (Adé et al., 2017) have been approved as alternatives for biological reference products offered to increase patient access (O'Callaghan et al., 2019) and cost-saving biological alternatives (Hara et al., 2019). However, despite their potential benefits, many physicians were hesitant (Gibofsky et al., 2019) to prescribe or switch to biosimilars (Kurki et al., 2021) due to clinical concerns (Azevedo et al., 2019) about the efficacy or immunogenicity effect (Beck et al., 2016). Immunogenicity, indicating a substance's capacity to stimulate an immune reaction, remains a prominent issue in clinical practice (Cohen et al., 2018). Biosimilars offer a promising solution for healthcare systems to decrease treatment expenses (Aladul et al., 2018) and broaden the availability of biological medicines (Herndon et al., 2021), particularly for patients' accessibility (Chong et al., 2022).

Nevertheless, understanding the interchangeability process (Chen et al., 2019) could improve the adoption of biosimilars (Mohd Sani et al., 2022). Previous studies on health professionals' beliefs have examined their attitudes toward improving vaccination coverage (Herzog et al., 2013), among other topics. However, no prior study has utilized the theory of planned behavior (TPB) to comprehensively investigate healthcare beliefs and attitudes. Therefore, we chose the theory of planned behavior in our study to understand the beliefs of healthcare providers, including pharmacists and physicians, and to survey their attitudes across various domains toward biosimilars. The aim is to assess the effectiveness of the Theory of Planned Behavior (TPB) in predicting healthcare provider perceptions of biosimilar use.

### Methods

This study utilized a correlational survey design to examine the predictors of intentions toward biosimilars using a logistic regression model. Using convenience sampling, data were collected from licensed physicians and pharmacists in South Florida from December 16, 2022, to February 20, 2023.

### Hypotheses

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

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3. There is no significant difference in healthcare professionals' control beliefs toward biosimilars.

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

#### Aims

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

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

#### Research Questions

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

#### Instrument

Healthcare providers (physicians or pharmacists) participated in surveys conducted via the REDCap platform. Two instrument surveys were used to measure the pharmacists' and physicians' perceptions in South Florida. The analysis focused on predicting intentions toward biosimilars, using constructs from the Theory of Planned Behavior (TPB) and sociodemographic variables. Essential variables included behavioral beliefs (Bb), normative beliefs (NB), control beliefs (CB), and behavioral intention (BI), as shown in **Figure 1**. The survey scales were based on validated methodologies from prior studies (Lee et al., 2018).

#### Theory of Planned Behavior (TPB) Questionnaire

The TPB constructs comprised four domains: three as independent variables (Behavioral beliefs, Normative beliefs, and Control beliefs) and one as the dependent variable, representing the research outcome (intention). The scale consisted of four items rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicated a more positive perception (high attitude) toward biosimilars. Two surveys were employed to measure physicians' and pharmacists' perceptions (refer to **Table 1** and **Table 2**).

#### Data Collection Procedures

We conducted cross-sectional online surveys using REDCap electronic data capture tools hosted at Nova Southeastern University (NSU). Approval to conduct research on human subjects was granted by the Institutional Review Board (IRB)

Protocol Number 2022-404 at NSU. Study data were collected and managed using REDCap electronic data capture tools hosted at Nova Southeastern University (PA Harris, 2019 May 9). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. Participants received a follow-up email after two weeks, and \$20 Amazon gift cards were provided as incentives for participation.

#### Data Analyses

The data were analyzed using the Statistical Package for Social Sciences (SPSS) Statistics version 27. Descriptive statistics were used to categorize demographics into eight categories. A logistic regression model was employed, with behavioral intentions as the dependent variable and three independent variables (behavioral belief, normative belief, and control belief). The Pearson correlation coefficient and Cronbach's alpha coefficient ( $\alpha$ ) were calculated, with alpha values less than 0.05 considered statistically significant.

#### Results

A convenience sampling approach was used to gather beliefs from healthcare professionals. After excluding incomplete responses, data from 510 participants (231 pharmacists and 279 physicians) were suitable for analysis.

#### Physicians: Descriptive Statistics

The results reveal demographic distributions among physicians. Of the 279 respondents, 71.0% were male, with the majority aged 61 or older. Internal Medicine had the highest frequency (17.9%), followed by Family Medicine (7.2%). Most participants worked in the private sector (76.3%) and were White Caucasian (46.2%). The significant level (Under the alpha (less than 0.05) was considered statistically significant. A cross-tabulation analysis revealed a significant association only between years of practice and physicians' intention to prescribe biosimilars. The associations between gender differences and intention ( $p = 0.488$ ), age and intention ( $p = 0.176$ ), as well as professional specialization and intention ( $p = 0.162$ ), were not statistically significant.

#### Physicians: Research Question (RQ) 1

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

The awareness of biosimilars approved, safety, and effectiveness knowledge of biosimilars ( $r = 0.471$ ,  $p < 0.001$ ;  $r = 0.511$ ,  $p < 0.001$ ) were most highly correlated with *intentions*. The lowest-ranking behavioral beliefs were the awareness of immunogenicity and the authority to use biosimilars ( $r = 0.161$ ,

$p < 0.001$ ;  $r = 0.342$ ,  $p < 0.001$ ). Cost-saving advantages of understanding biosimilars ( $r = 0.464$ ,  $p < 0.001$ ;  $r = 0.453$ ,  $p < 0.001$ ;  $r = 0.446$ ,  $p < 0.001$ ).

Physicians: Research Question (RQ) 2

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

The internal project team control, including the Pharmacy and Therapeutics (P&T) Committee and the professional association impacts ( $r = 0.398$ ,  $p < 0.001$ ;  $r = 0.317$ ,  $p < 0.001$ ), were the most highly correlated with intentions. The lowest-ranking normative beliefs were the beliefs about the perception of the communicating impact of the P&T Committee with professional associations ( $r = 0.178$ ,  $p < 0.001$ ;  $r = 0.134$ ,  $p = 0.025$ ). The most important influences of normative beliefs in the group of physicians appeared to be “internal project team control” and “the professional association impacts.”

Physicians: Research Question (RQ) 3

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

Awareness of biosimilar designations as interchangeable was correlated most highly ( $r = 0.494$ ,  $p < 0.001$ ), followed by the extrapolation indication ( $r = 0.444$ ,  $p < 0.001$ ). The lowest correlations were found in the items 'I am aware the FDA has regulatory guidelines regarding the use or prescribing of biosimilars' ( $r = 0.335$ ,  $p < 0.001$ ) and 'I have a basic understanding of biosimilars but would like to know more about their efficacy and safety' ( $r = 0.230$ ,  $p < 0.001$ ). Beliefs about both interchangeability and extrapolation indication are essential to control beliefs.

Physicians: Research Question (RQ) 4

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

The significance value of the Chi-Square Test is  $< 0.001$ , which is less than 0.05. Therefore, at the 0.05 level of significance, the null hypothesis can be rejected, concluding that the fitted logistic regression model is a significantly good fit ( $\chi^2(3) = 115.061$ ,  $p < 0.001$ ). **Table 3** shows that behavioral beliefs (Bb\_total) and control beliefs (Cb\_total) are significant predictors of physicians' intention toward biosimilars. However, Normative beliefs (Nb\_total) do not show a significant impact based on the p-value.

Pharmacists: Descriptive Statistics

The demographic profile of 231 pharmacists highlights a mostly female population, with the majority falling within the 31-41 age range. Community pharmacists represent the highest professional specialization group, followed by clinical and hospital pharmacists. Most pharmacists have the rank of

RPh/Pharm-D, with a minority in residency or fellowship positions. The private sector employs most participants, with a significant percentage working in the government/federal sector. White Caucasian Anglo-Americans and Hispanic Latinos include the largest ethnic groups. Regarding experience, a majority have 11 or more years of practice. Florida-Broward and Florida-Miami-Dade are the most common locations. Crosstab analysis demonstrated no significant gender or age differences in intention, but professional specialization was significantly associated with intention, with a higher proportion of community pharmacists showing stronger intentions.

Pharmacists: Research Question (RQ)1

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

The item 'I am aware that biosimilars are safe and effective as the reference product' and 'I am aware there is no clinically meaningful difference between biosimilars and reference products' ( $r = 0.591$ ,  $p < 0.001$ ;  $r = 0.559$ ,  $p < 0.001$ ) 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,' and 'I am aware that biosimilars are less expensive than the reference product in the market' ( $r = 0.360$ ,  $p < 0.001$ ;  $r = 0.459$ ,  $p < 0.001$ ).

Pharmacists: Research Question (RQ) 2

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

The highest ranking was given to the items: 'The Pharmacy and Therapeutics (P&T) Committee has promoted biosimilars,' and 'Biosimilars were introduced and discussed in health professional associations, including the American Pharmacists Association (APhA)' ( $r = 0.547$ ,  $p < 0.001$ ;  $r = 0.507$ ,  $p < 0.001$ ). The lowest-ranking normative beliefs were related to 'My institution has a Pharmacy and Therapeutics (P&T) Committee that does not recommend adding biosimilars to the formulary' and 'My institution has a Pharmacy and Therapeutics (P&T) Committee that continuously communicates with professional associations' ( $r = 0.179$ ,  $p = 0.006$ ;  $r = 0.251$ ,  $p < 0.001$ ). The most influential factors of normative beliefs among pharmacists appeared to be the 'Pharmacy and Therapeutics (P&T) Committee' and 'health professional associations'.

Pharmacists: Research Question (RQ) 3

*Are pharmacists' control beliefs (Cb) positively associated with the intention to substitute or switch biosimilars?*

'I am aware that the FDA has approved biosimilars as interchangeable' was highly correlated ( $r = 0.525$ ,  $p < 0.001$ ), followed by 'I am satisfied with the extrapolation indication of biosimilars' ( $r = 0.493$ ,  $p < 0.001$ ). The lowest correlations were observed for the items: 'I am familiar with payer policies

regarding biosimilars, e.g., insurance companies' ( $r = 0.353$ ,  $p < 0.001$ ), and 'I have a basic understanding of biosimilars but would like to know more about their efficacy and safety' ( $r = 0.330$ ,  $p < 0.001$ ). Beliefs regarding the interchangeability and extrapolation indications of biosimilars in the US market appear to be influential control beliefs.

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?*

The significance value of the Chi-Square Test was  $< 0.001$ , indicating statistical significance at the 0.05 level. These results suggest that approximately 44.2% to 60.8% of the variation in intention toward behavior can be explained by behavioral beliefs (Bb), normative beliefs (Nb), and control beliefs (Cb). Regression model outputs are presented in **Table 4**. These results provide valuable insights into the factors influencing pharmacists' inclination toward adopting biosimilars, particularly concerning their behavioral and normative attitudes.

## Discussion

The discussion section interprets important findings on healthcare providers' attitudes toward biosimilars. Also, it discusses how demographic characteristics and beliefs impact their willingness to use biosimilars:

### Physicians

#### *Association of Sociodemographics and Psycho-Social Behavioral Attributes*

The study demonstrated a connection between sociodemographic characteristics and psycho-social behavior toward biosimilars. Attending internal and family medicine physicians showed a stronger inclination toward biosimilar prescriptions.

#### *Knowledge and Experience*

The study highlighted that intention levels correlated directly with the level of experience or expertise, specifically among oncology physicians (Fahmi et al., 2022).

#### *Factors Influencing Intentions*

Key determinants of strong intentions to prescribe biosimilars were physicians' confidence in the efficacy of biosimilars (Gerdes et al., 2018) for chronic illnesses and their satisfaction in prescribing them.

#### *Gender and Age Associations*

The analysis determined higher intentions among male physicians than female physicians. Physicians over 60 showed high intentions toward biosimilar prescriptions.

#### *Specialties Impacting Intention Levels*

Attending physicians in internal medicine and family medicine indicated notably high intentions to prescribe biosimilars compared to other professional specialties.

### Pharmacists

#### *Specialties and Intention*

There were disparities in intentions towards biosimilars observed among pharmacists' specialties, notably with community pharmacists showing a higher intention than others.

#### *Behavioral Beliefs*

Containing perceptions about biosimilars' safety, efficacy, and relative advantages significantly influenced pharmacists' attitudes.

#### *Normative Beliefs*

These beliefs were highly correlated with biosimilar acceptance by the Pharmacy and Therapeutics (P&T) Committee and professional associations like the American Pharmacists Association (APhA). Approvals from these entities exerted normative influence.

#### *Control Beliefs*

Pharmacists' perceptions of control over their treatment decisions are mainly correlated to their knowledge of biosimilars, including factors like interchangeability and familiarity with biosimilar methods. Furthermore, the binary logistic regression model validated the value of three predictors for pharmacists' intentions toward biosimilars. The behavioral beliefs factors helped to shape pharmacists' attitudes and beliefs about the safety and efficacy of biosimilars, which influenced their willingness to dispense or substitute biosimilars (Stevenson et al., 2022).

### Limitations

The study's limitations include a small sample size of physicians and limited generalizability due to the focus on four counties in South Florida, USA. Additionally, more consideration for past behavior needs to be given to impact the applicability of findings to other states or countries.

## Conclusion

Significant associations were found for behavioral, normative, and control beliefs with intentions among physicians and pharmacists, highlighting the need for international harmonization (Niazi et al., 2023) in biosimilar guidelines. Educating healthcare professionals (Coe et al., 2012), especially across different specialties, is needed to understand the regulatory situation for biosimilars, which is essential for advocating policies that ensure efficient biosimilar approval and appropriate utilization. Furthermore, future research should explore attitudes among nurses, physician's assistants, physicians, pharmacists from other countries or US states, and

patients for comprehensive insights. Additionally, there were significant disparities in allocating pharmacists' intentions regarding biosimilars across different professional specializations. Investigation endeavors may be warranted to examine the underlying factors contributing to these variances and their consequences for pharmacy practice.

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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*

Sociodemographic Variables	Items
Gender	Male, Female
Age	25-30, 31-35, 36-41, 42-50, 51-60, 61 or above
Professional Specialty	Rheumatologist, Gastroenterologist, Oncologist, Dermatologist, General Physician, Family Medicine, Medical Genetics, Internal Medicine, Neurologist, Other
Professional Rank	Pharmacist (RPh / Pharm-D), Residency, Fellowship, Specialist, Attending
Employment Sector	Government/ Federal sector, Private sector, Other
Ethnicity	American Indian- Native American, Asian, Asian American- Pacific Islander, Black, African American, Hispanic, Latino, White, Caucasian, Anglo American, I choose to not provide this information, Other
Years of Practice	Less than five years, 5–10 years, 11 years or above
State and County	Florida-Broward, Florida-Miami-Dade, Florida-Lee, Florida-Collier, Other

**Table 3.** *Binary Logistic Regression of Physicians Intention Toward Biosimilars*

Independent variable	OR	*p-value	95% CI
<b>Bb_total</b>	1.129	< 0.001	[1.064 - 1.199]
<b>Nb_total</b>	1.042	0.551	[0.911 - 1.191]
<b>Cb_total</b>	1.170	< 0.001	[1.077 - 1.271]

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

**Table 4.** *Binary Logistic Regression of Pharmacist's Intention Toward Biosimilars*

Independent variable	OR	p-value	95% CI
<b>Bb_total</b>	1.202	< 0.001	[1.106- 1.307]
<b>Nb_total</b>	1.233	0.018	[1.036- 1.467]
<b>Cb_total</b>	1.072	0.213	[0.961- 1.196]

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

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

