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Biosimilars: What pharmacists should know and a survey

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Abstract

Biosimilars are biologic products that are highly similar to existing reference biologics and provide cost-effective treatment alternatives. As more biologic patents expire, biosimilars are becoming increasingly important in healthcare, requiring healthcare professionals to have a solid understanding of their development, regulatory pathways, and clinical implications. Despite their potential benefits, biosimilars face barriers such as limited awareness, concerns about safety and efficacy, and complex regulatory processes. This study aimed to evaluate the effectiveness of an educational program designed to address these challenges and enhance healthcare professionals' knowledge and confidence in biosimilar use.

Methods: The Howard University College of Pharmacy, in collaboration with the FDA, Academy of Managed Care Pharmacy (AMCP), and Biologics & Biosimilars Collective Intelligence Consortium (BBCIC), conducted a symposium on biosimilars. The program, funded by an unrestricted educational grant from Pfizer, included two primary sessions featuring expert presentations and workshops. Feedback was collected from 114 participants using post-program surveys to assess learning outcomes, program relevance, and its impact on practice. Participants included pharmacists (44.74%), students (44.74%), and other healthcare professionals (10.52%) from various states, with a strong representation from Maryland and Washington, D.C.

Results: The program received highly positive feedback, with 86.96% rating the applicability of the program to their practice as "Excellent" and 13.04% as "Good." In terms of knowledge enhancement, 89.13% rated the program as "Excellent," and 10.87% as "Good." Overall, 84.78% rated the program as "Excellent" and 13.04% as "Good," with only 2.17% being "Neutral." No participants rated the program negatively. The program was effective in meeting specific educational objectives, with 89-93% of respondents marking "Strongly Agree" for understanding key biosimilar concepts, such as recognizing their role in practice and understanding development pathways. The objective on using biosimilars in practice received slightly lower ratings, with 73.91% "Strongly Agree" and 19.57% "Agree."

Conclusion: The study demonstrates the effectiveness of structured educational programs in enhancing healthcare professionals' understanding and confidence in the use of biosimilars. The overwhelmingly positive reception underscores the need for continued education, particularly as more biosimilars enter the market. Future programs should focus on addressing remaining barriers, such as provider hesitancy and practical implementation strategies, to ensure that healthcare professionals are well-prepared to integrate biosimilars into clinical practice. This will ultimately contribute to better patient outcomes, increased adoption of cost-effective therapies, and a more sustainable healthcare system

Keywords: Biosimilars; Pharmacists; Survey; Education; Continuing Education; Students

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1 Introduction

Biosimilars are biologic medical products that are highly similar to an already approved reference product, often called the "originator" or "innovator" biologic. As more biologic patents expire, biosimilars are becoming increasingly prevalent in healthcare, providing cost-effective alternatives to expensive biologics. Given the complexities involved in their production, regulation, and clinical use, pharmacists need to understand the key aspects of biosimilars, including their development, approval processes, safety, and the potential impact on healthcare (U.S. Food and Drug Administration, 2020).

1.1 History of Biosimilars

The development of biosimilars began as a response to the high costs associated with biologic medications and the growing demand for affordable alternatives. The first biosimilar was approved in Europe in 2006, which marked the beginning of a new era in the pharmaceutical industry. The European Medicines Agency (EMA) led the way in establishing regulatory pathways for biosimilars, setting a precedent for other regions to follow. In the United States, the Biologics Price Competition and Innovation Act (BPCIA) was passed in 2009 as part of the Affordable Care Act, creating a legal pathway for the approval of biosimilars (Mulcahy et al., 2017).

The first biosimilar approved by the U.S. Food and Drug Administration (FDA) was Zarxio® (filgrastim-sndz) in 2015, which was based on the reference biologic Neupogen®. This approval marked a significant milestone, as it paved the way for future biosimilars in various therapeutic areas. Since then, the number of FDA-approved biosimilars has grown rapidly, covering oncology, autoimmune diseases, and diabetes management (Blackstone & Joseph, 2013).

1.2 Challenges of Developing Biosimilars

Developing biosimilars is a complex and resource-intensive process. Unlike small-molecule generics, which are chemically synthesized and relatively straightforward to replicate, biologics are large, complex proteins produced using living cells. This complexity leads to several challenges:

- **Manufacturing Complexity**: The production of biosimilars involves recombinant DNA technology, cell culture, and sophisticated purification processes. Minor changes in production conditions can significantly affect the product's structure, function, and immunogenicity (Sharma & Jacob, 2020).
- **Analytical Characterization**: Thorough analytical characterization is required to demonstrate that the biosimilar is "highly similar" to the reference product. This includes evaluations of primary and secondary structures, post-translational modifications, and functional activity (U.S. Food and Drug Administration, 2020).
- **Clinical Testing Requirements**: While biosimilars must demonstrate similarity to the reference product, they also need to undergo clinical testing to confirm safety and efficacy in one or more of the reference product's indications. This often includes immunogenicity studies, which are not required for small-molecule generics (Blackstone & Joseph, 2013).
- **Regulatory Hurdles**: Different regions have varying regulatory requirements for biosimilar approval, adding complexity to global development strategies. For example, the FDA and EMA have different guidelines for establishing interchangeability, which impacts the ability of biosimilars to be substituted for their reference biologic without prescriber intervention (Mulcahy et al., 2017).

1.3 Approved Biosimilar Drugs and Their Categories

Biosimilars are classified into different categories based on the therapeutic area and the reference biologic they are designed to replicate. Below are some notable biosimilar drugs categorized by their indication:

1.3.1 Oncology Biosimilars

Oncology biosimilars provide alternative options to expensive cancer biologics, thereby enhancing patient access to treatment.

- **Zarxio® (filgrastim-sndz)**: Approved as a biosimilar to **Neupogen®** for the treatment of neutropenia in cancer patients receiving chemotherapy.
- **Mvasi® (bevacizumab-awwb)**: A biosimilar of **Avastin®**, used in the treatment of colorectal cancer, non-small cell lung cancer, and other types of cancer.
- **Kanjinti® (trastuzumab-anns)**: A biosimilar to **Herceptin®**, indicated for HER2-positive breast cancer and metastatic gastric cancer.

1.3.2 Rheumatology and Autoimmune Biosimilars

- Biosimilars for rheumatologic and autoimmune diseases target key pathways involved in inflammation and immune regulation.
- **Inflectra® (infliximab-dyyb)**: A biosimilar to **Remicade®**, used in the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, and psoriasis.
- **Amjevita® (adalimumab-atto)**: A biosimilar of **Humira®**, used in multiple inflammatory conditions, including rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.
- **Erelzi® (etanercept-szzs)**: Approved as a biosimilar to **Enbrel®**, indicated for rheumatoid arthritis, plaque psoriasis, and ankylosing spondylitis.

1.3.3 Diabetes Biosimilars

Insulin biosimilars are a significant category in diabetes management, providing more affordable options to patients.

- **Basaglar® (insulin glargine)**: A biosimilar to **Lantus®**, used for the management of both type 1 and type 2 diabetes.
- **Semglee® (insulin glargine-yfgn)**: A newer biosimilar also approved for glycemic control in diabetes patients (Sharma & Jacob, 2020).

1.4 FDA Regulations and Approval Process

The U.S. FDA oversees the approval of biosimilars under the BPCIA, which created an abbreviated pathway known as the 351(k) pathway. This allows manufacturers to seek FDA approval by demonstrating that their biosimilar product is "highly similar" to the reference biologic with no significant clinical differences (U.S. Food and Drug Administration, 2020).

The FDA's approval process for biosimilars involves multiple phases, including:

- **Analytical Studies**: To demonstrate that the biosimilar is highly similar to the reference product in terms of structure and function.
- **Animal Studies**: To assess toxicity and pharmacokinetics.
- **Clinical Trials**: To evaluate safety, immunogenicity, and efficacy in one or more of the reference product's approved indications (Mulcahy et al., 2017).

1.5 Future Prospects for Biosimilars

The future of biosimilars is promising, with a growing number of biologics losing patent protection in the coming years, creating opportunities for biosimilar development. The global biosimilars market is expected to expand rapidly, driven by increasing demand for cost-effective biologic therapies (Sharma & Jacob, 2020). Advances in biotechnology and manufacturing processes are expected to improve the quality and reduce production costs, making biosimilars more accessible to a broader patient population (Blackstone & Joseph, 2013).

The primary objectives of the symposium were to educate healthcare professionals about the science and regulatory framework surrounding biosimilars, discuss the clinical use of biosimilars including safety and efficacy considerations, provide updates on the current pipeline and the impact of biosimilars on healthcare costs and patient access, and evaluate their understanding by assessing their knowledge level to determine whether the information gained will influence their clinical practice and impact their application of biosimilars at their respective practice sites.

2 Methods

The Howard University College of Pharmacy, in collaboration with the Food and Drug Administration (FDA), Academy of Managed Care Pharmacy (AMCP) and the Biologics & Biosimilars Collective Intelligence Consortium (BBCIC), organized a symposium to educate healthcare professionals about biosimilars. This educational program, funded by unrestricted medical education grant from Pfizer, included multiple sessions and workshops focusing on the development, regulation, and clinical implementation of biosimilars.

The symposium consisted of two primary sessions: a morning grand round and an afternoon regulatory science seminar. Each session featured expert presentations from professionals in academia, regulatory bodies, and healthcare

institutions. Participants included pharmacists, researchers, and other healthcare professionals. Feedback was collected through surveys at the end of each session to evaluate participant satisfaction and learning outcomes.

3 Results

The program was held on April 5, 2023. A total of 200 participants registered for the program. However, only 114 of them completed the post program evaluation and received their certification as shown in Table 1. The table categorizes the participants into three main groups: pharmacists, students, and pharmacy technicians. Pharmacists are the majority made up 44.74% of the total participants, which included general pharmacists, health-system/hospital pharmacists, and community/retail pharmacists. Similarly, students represented 44.74% of the attendees, totaling 51 participants, with student pharmacists forming the majority. Pharmacy technicians, on the other hand, accounted for only 1.75% of the participants. The remaining 8.77% of the participants, were classified as "Others," which included various roles not specified within the main categories.

Table 1 Attendees Profession Breakdown (N=112)

PROFESSION	**(N)**	**(%)**
Pharmacist (Total)	**51**	**44.74**
Pharmacist	35	30.70
Health-System/Hospital Pharmacist	10	8.77
Community/Retail Pharmacist	6	5.26
Students (Total)	**51**	**44.74**
Student Pharmacist	39	34.21
All other Student	12	10.53
Pharmacy Technicians (Total)	**2**	**1.75**
Health-System/Hospital Pharmacy Technician	2	1.75
Others	**10**	**8.77**
Others (Physicians, Nurse Practitioners, Nurses, Social Workers)	3	2.63
Others (Not Specified)	7	6.14

As shown in Table 2 the states represented in the participant group were diverse, with the majority coming from Maryland (43.21%) and Washington, D.C. (37.04%). Virginia was the next highest with 8.64% of the participants. Other states, including Washington, New Jersey, North Carolina, New York, Georgia, Florida, and Texas, were represented in smaller numbers, each making up 2.47% or 1.23% of the total participants. This distribution highlights a strong presence from the mid-Atlantic region, particularly Maryland and Washington, D.C., with fewer attendees from other states.

Table 2 Attendees States Represented

STATE	**# PEOPLE**	**% OF WHOLE**
Maryland	35	43.21
District of Columbia	30	37.04
Virgina	7	8.64
Other States	9	2.47

Overall, as shown in Table 3, participants rated the program highly, with most objectives receiving strong positive feedback. For the objectives focused on recognizing the role of biosimilars, key concepts of biologic product development, and identifying available biosimilars, 89-93% of respondents marked "Strongly Agree." Similarly, 86-87% "Strongly Agreed" that the program met objectives related to explaining barriers to adoption, FDA's approach to

biosimilar development, and available resources for healthcare providers. The use of biosimilars in practice had a slightly lower rating, with 74% "Strongly Agree" and 20% "Agree." Across all objectives, there were no responses indicating disagreement, showing the program's overall effectiveness and relevance to the participants.

Table 3 Summary of Participants' Responses on Meeting Program Objectives and Their Impact (N=46)

Objective	**5 (Strongly Agree)**	**4 (Agree)**	**3 (Neutral)**	**2 (Disagree)**	**1 (Strongly Disagree)**
Recognize the role of biosimilars in practice and their impact on access to treatment, cost of care, and patient outcomes.	43 (93.48%)	3 (6.52%)	0 (0%)	0 (0%)	0 (0%)
Identify currently available biosimilars and those expected to be approved in the next year and their impact on pharmacy practice.	41 (89.13%)	4 (8.70%)	1 (2.17%)	0 (0%)	0 (0%)
Explain the barriers to adoption and strategies to overcome these barriers.	40 (86.96%)	4 (8.70%)	2 (4.35%)	0 (0%)	0 (0%)
Describe the resources available for healthcare providers to learn more about biosimilar and interchangeable products.	39 (84.78%)	5 (10.87%)	2 (4.35%)	0 (0%)	0 (0%)
Describe and explain the key concepts of biologic products development.	43 (93.48%)	3 (6.52%)	0 (0%)	0 (0%)	0 (0%)
Describe and explain FDA's approach to the development of biosimilars.	40 (86.96%)	6 (13.04%)	0 (0%)	0 (0%)	0 (0%)
Explain the use of biosimilar and interchangeable products in practice.	34 (73.91%)	9 (19.57%)	3 (6.52%)	0 (0%)	0 (0%)
Describe and explain the resources available for healthcare providers to learn more about biosimilar and interchangeable products through the enhanced Purple Book and other FDA educational resources.	39 (84.78%)	5 (10.87%)	2 (4.35%)	0 (0%)	0 (0%)

As shown in Table 4, the program was highly rated by participants across all categories. For "Applicability and Usefulness," 87% rated it as "Excellent" and 13% as "Good." Similarly, 89% of participants found that the program increased their knowledge/understanding, with 11% rating it as "Good." The overall evaluation of the program was also positive, with 85% marking it as "Excellent," 13% as "Good," and only 2% as "Neutral." No respondents rated the program as "Poor" or "Very Poor" in any category, indicating a strong endorsement of the program's content and delivery

Table 4 Summary of Program Evaluations (N=46)

Category	**Excellent (5)**	**Good (4)**	**Neutral (3)**	**All Others (2 or 1)**
Applicability and Usefulness of the Program to Practice	40 (86.96%)	6 (13.04%)	0 (0%)	0 (0%)
Program Increased My Knowledge/Understanding	41 (89.13%)	5 (10.87%)	0 (0%)	0 (0%)
Overall Evaluation of the Program	39 (84.78%)	6 (13.04%)	1 (2.17%)	0 (0%)

4 Discussion

The goal of this study was to evaluate the effectiveness of an educational program aimed at enhancing healthcare professionals' knowledge and confidence in using biosimilars. As biosimilars become increasingly prominent in clinical practice, there is a critical need to ensure that healthcare providers are equipped to understand their role in treatment, navigate the regulatory landscape, and incorporate these products effectively into patient care. The program addressed these needs by delivering comprehensive content on regulatory frameworks, clinical applications, and strategies for overcoming common challenges associated with biosimilar adoption.

Biosimilars, which are highly similar to their reference biologics, have the potential to increase access to advanced therapies and reduce treatment costs, making them highly significant in improving public health. However, the widespread adoption of biosimilars has faced barriers, such as limited provider awareness, concerns about safety and efficacy, complex regulatory processes, and hesitancy stemming from a lack of clinical experience. Educational programs targeting these areas are vital to achieving the cost savings and enhanced therapeutic outcomes that biosimilars can offer.

The findings from this study show that the program was highly successful in meeting its objectives, as evidenced by the overwhelmingly positive feedback from participants. Nearly 90% rated the program as "Excellent" in terms of enhancing their knowledge and understanding, indicating the effectiveness of structured educational interventions in closing knowledge gaps in this field. Additionally, the high ratings for applicability, with over 85% of respondents finding the content relevant to their practice, suggest that the program provided valuable, actionable insights that participants could immediately implement in their clinical settings. Such positive feedback underscores the importance of designing educational initiatives that not only deliver foundational knowledge but also address practical challenges faced by healthcare professionals in real-world scenarios.

The positive reception of this program highlights the need for ongoing education on biosimilars, especially as more products enter the market and their role in therapy continues to expand. Programs like this are crucial for demystifying complex concepts, clarifying the safety and efficacy of biosimilars, and equipping healthcare providers with the confidence to recommend and integrate these therapies into patient care. The absence of any negative ratings further suggests that the program's content and delivery were well-suited to the audience. Elements such as interactive discussions, detailed resources, and real-world examples were particularly effective in engaging participants, and these strategies should be incorporated into future educational efforts to maintain high levels of satisfaction and applicability.

Ultimately, this study supports the continued prioritization of educational programs that address emerging topics like biosimilars. Such programs play a key role in ensuring that healthcare professionals remain up-to-date and well-prepared to navigate new treatment options, ultimately leading to better patient care, more informed clinical decisions, and increased adoption of cost-effective therapies. As the use of biosimilars grows, providing evidence-based, practical guidance through structured education will be essential in fostering greater confidence and competence among healthcare providers.

5 Conclusion

The Howard University Biosimilars Symposium successfully achieved its objectives by providing a comprehensive overview of biosimilar science, regulation, and clinical application. The high level of engagement and positive feedback from participants indicate that there is a strong demand for continued education on biosimilars. Future programs should continue to focus on emerging trends in biosimilar development, practical case studies, and strategies to incorporate biosimilars into routine clinical practice.

By staying informed and engaged in the evolving biosimilar landscape, pharmacists can play a pivotal role in ensuring the safe and effective use of these therapies, ultimately contributing to improved patient outcomes and healthcare sustainability.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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