Overcoming Biosimilar Barriers: Stakeholder Perspectives on Strategies to Overcome Challenges – A Cross-Sectional Study

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Background

- The market for biologic drugs in the US and its role in the country's health care system are increasing. In 2019, biologics were responsible for 43% of total medicine spending in the US.[i]
- The Biologics Price Competition and Innovation Act (BPCIA) of 2009 encourages the development of biological products that are highly similar to (i.e., biosimilar) or interchangeable with their reference biologics through an abbreviated regulatory pathway for FDA approval.
- The goal of BPCIA is to foster competition and lower medication costs, and thereby increase patient access to more affordable drugs.
- In 2018, AMCP (Academy of Managed Care Pharmacy) partnered with PRIME Education to assess managed care and specialty pharmacy professionals' views on the key barriers to and strategies for biosimilar adoption in the US.[ii]
- A follow-up survey of stakeholder groups was conducted in October 2020 to assess current perspectives on biosimilars, their barriers, and strategies to overcome them.

Objectives

1. To assess key stakeholder views on the barriers to biosimilar adoption in the US.
2. To assess key stakeholder views on the strategies to implement biosimilar adoption in the US.
3. To determine which stakeholder group is perceived to be the most influential in implementing biosimilar adoption.
4. To compare responses from the general respondents to responses from MDs and participants with oncology expertise.
5. To assess changes in perspectives on biosimilars since the 2018 survey.
6. To provide insights to guide discussion for the AMCP Partnership Forum, "Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions" in December 2020.

Methods

- A multiple choice, mixed qualitative-quantitative web-based survey, descriptive, (longitudinal) cross-sectional in design.
- The stakeholder groups assessed included health plans, pharmacy benefit managers, hospitals/clinics, specialty pharmacies, integrated delivery networks, pharmaceutical industry, and employer groups.
- The 2018 AMCP and Prime Education survey was used as a preliminary template.
- After modifying the original 28-item survey and including additional questions, the survey was circulated to 7 pilot respondents to assess content and face validity.
- To select the participants and identify the different stakeholder groups of interest, AMCP's internal CRM database was used, filtering using employer type, expertise, licensure, and job function designations:

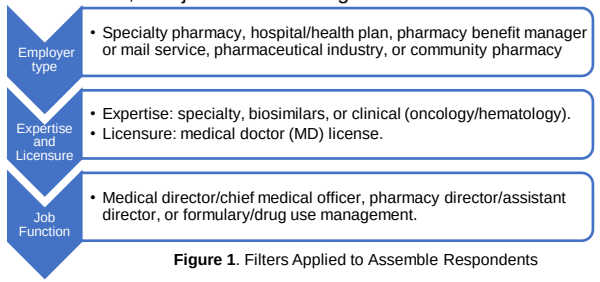


Figure 1. Filters Applied to Assemble Respondents

- A professional networking platform (social media) was used as well to gain additional participants.
- Participants completed a 26-item survey consisting of Likert scale, multiple choice and open-ended questions.
- The first 200 respondents who fully completed the survey are scheduled to receive a $10 Amazon e-gift card. The target for complete responses was 300.
- Survey was fielded from September 21-October 9, 2020.

Limitations

- Changes to several questions from the 2018 survey limited longitudinal analysis to 5 questions.
- Caution is advised when generalizing survey results. The respondents' level of expertise and awareness can neither be verified nor proven.
- Measures were taken to ensure an even distribution in the demographics. However, the results may be skewed towards the views of specific groups due to response rates.

Results

Table 1. Survey Respondent Characteristics

Characteristic	N (%)
Work organization	
Health plan	90 (32%)
Pharmacy benefit management (PBM)	56 (20%)
Pharmaceutical industry	36 (13%)
Hospital or clinic	33 (12%)
Integrated delivery network	27 (10%)
Specialty pharmacy	23 (8%)
Employer group	3 (1%)
Other	39 (14%)
Professional role	
Clinical pharmacist	101 (36%)
Pharmacy director	72 (26%)
Drug utilization/formulary management	54 (19%)
Administration, contracting, or operations	31 (11%)
P&T committee member	26 (9%)
Account manager	23 (8%)
Medical director	13 (5%)
Other	52 (19%)
Licensure	
PharmD	201 (72%)
MD	16 (6%)
Other	67 (24%)

Figure 2. Most Influential Stakeholder group on Biosimilar Adoption

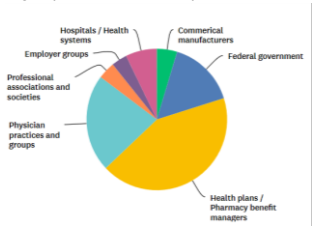


Figure 3. Barriers to Biosimilar Adoption

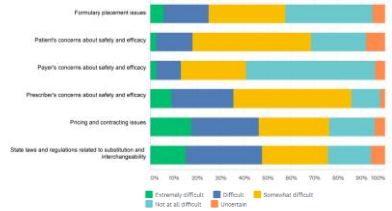


Figure 4. Investment in RWE on biosimilars in next 2-3 years

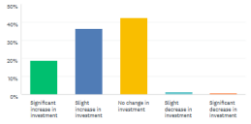
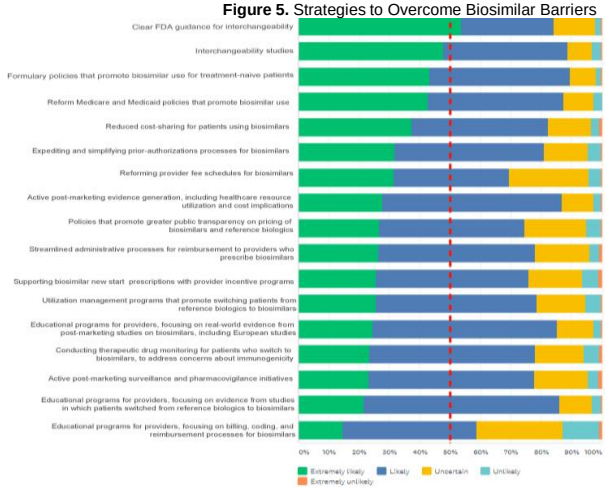


Figure 5. Strategies to Overcome Biosimilar Barriers



Additional results are pending for statistical analysis.

Conclusions

- Nearly all organizations were familiar with biosimilars. Most have policies or preferences on biologics and/or biosimilars. One-third (30%) have practices that have established biosimilar preferences in formulary tiering in their organizations.
- Pricing/contracting and state laws/regulations were the 2 barriers perceived to be the most difficult to overcome for biosimilar adoption.
- Health plans and PBMs are the stakeholder groups that are considered to be the most influential in implementing biosimilar adoption (43%). Employer groups, professional associations and commercial manufacturers appear to be least likely to be influential (<5% for each).
- The 17 different strategies to overcome biosimilar barriers were generally viewed to have positive impact (59-89% extremely likely and likely for each strategy). Only 2-13% of the responses were unlikely or extremely unlikely to overcome biosimilar barriers for each strategy.
- After stratifying respondents by oncology expertise, we saw that many of their views aligned with the general overall respondents' views. However, health systems were seen to be a more influential stakeholder group and utilization management a more powerful strategy.
- Real-world evidence is viewed to be very important in overcoming biosimilar adoption barriers. 55% of the respondents anticipate an increase in RWE investment in biosimilars over the next 2-3 years.

Acknowledgements

Special thank you to my preceptors for being the best and most supportive mentors:
Paula J Eichenbrenner, MBA, CAE, AMCP Foundation
Dr. John Spain, MA, PharmD, BCPS, Pfizer, Inc.
Dr. Annesha White, PharmD, MS, PhD, UNT
Dr. Kenneth Garcia, PharmD, Moda Health

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ii. L Green et al. *J Manag Care Spec Pharm*. 2019;25(8):904-912.

Poster presented at the Academy of Managed Care Pharmacy's Nexus Virtual, October 19 - October 23, 2020