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Dermatologists' Perspectives on Biosimilars

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ABSTRACT

Background: Biosimilars are biologic agents the Food and Drug Administration (FDA) has deemed to have no clinical difference from their reference biologics. In dermatology, biosimilars are approved for the treatment of psoriasis and hidradenitis suppurativa. Although dermatologists are high prescribers of biologics, they are more reluctant to prescribe biosimilars than other specialists. This survey-based study sought to characterize dermatologists' current perspectives on biosimilars.

Methods: A 27-question survey was distributed via email to dermatologists between September and October of 2022.

Results: Twenty percent of respondents would not prescribe a biosimilar for an FDA-approved indication. When asked about the greatest barriers to biosimilar adoption, 61% had concerns about biosimilar safety and efficacy, 24% reported uncertainty about state laws for interchangeability and substitutions, and 20% had concerns about biosimilar safety without concerns about efficacy. Thirty-five percent of respondents felt moderately or extremely knowledgeable about biosimilar interchangeability.

Conclusion: Biosimilars are safe and effective for treating approved dermatological conditions and may lower patient costs compared to their reference products. Patients are not always offered biosimilar therapy as an option, which may be due to unfamiliarity among dermatologists. This survey suggests a need for more research and educational initiatives, such as modules and workshops that focus on biosimilar safety, efficacy, and interchangeability guidelines.

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INTRODUCTION

Biologics are protein-based pharmaceuticals derived from living organisms that can treat autoimmune and inflammatory conditions.[1] Biosimilars are biologic agents the Food and Drug Administration (FDA) has deemed to have no clinical difference from their reference biologics.[2] Biosimilars are developed when the patent for the reference product expires.

The first biosimilar was approved by the FDA in 2015.[3] Currently, there are 39 biosimilars available, 11 of which are approved for psoriasis and hidradenitis suppurativa (HS), including biosimilars to adalimumab, etanercept, and infliximab.[4] Of these, only Cyltezo® (adalimumab-adbm) is considered interchangeable with its reference product, Humira® (adalimumab). Interchangeable biosimilars are FDA-approved to be substituted for their biologic at the pharmacy without input from the prescriber, although this is subject to state laws and regulations.[5] Although dermatologists are high prescribers of biologics, they are more reluctant to prescribe biosimilars than other specialists.[6,7] This survey-based study sought to characterize dermatologists' current perspectives on biosimilars.

MATERIALS AND METHODS

A 27-question survey was distributed via email to dermatologists who subscribe to the Dermatologist Magazine and those registered with IQVIA between September and October of 2022. Fifty-two dermatologists responded.

RESULTS

Survey Respondent Characteristics

Respondents' clinical practices focused on medical dermatology (71%), surgical dermatology (23%), pediatric dermatology (13%), cosmetic dermatology (13%), or a combination of all the above (27%). Most dermatologists worked in a single-specialty group practice with fewer than five offices (46%), followed by solo dermatology practice (31%) (Table 1). Sixty-four percent of practice revenue was derived from medical office visits and

TABLE 1.

Practice Setting (For this survey item, respondents were allowed to check all that apply)	
Answer Choices, % (n)	**Responses (n=52)***
Solo	31% (16)
Single-specialty group practice with fewer than 5 offices	46% (24)
Single-specialty group practice with more than 5 offices	8% (4)
Single-specialty group backed by private equity investment	2% (1)
Multispecialty group practice	8% (4)
Integrated health system	2% (1)
Hospital	4% (2)
Academic or research	4% (2)

*Respondents could select multiple practice settings, if applicable.

FIGURE 1. Patient characteristics who are most likely to be prescribed an interchangeable biosimilar.

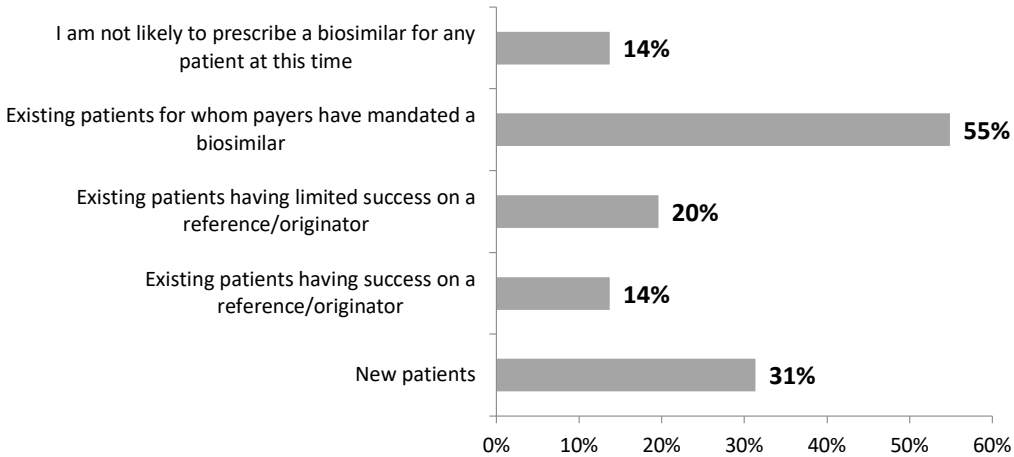

FIGURE 2. Understanding Biosimilar Interchangeability.

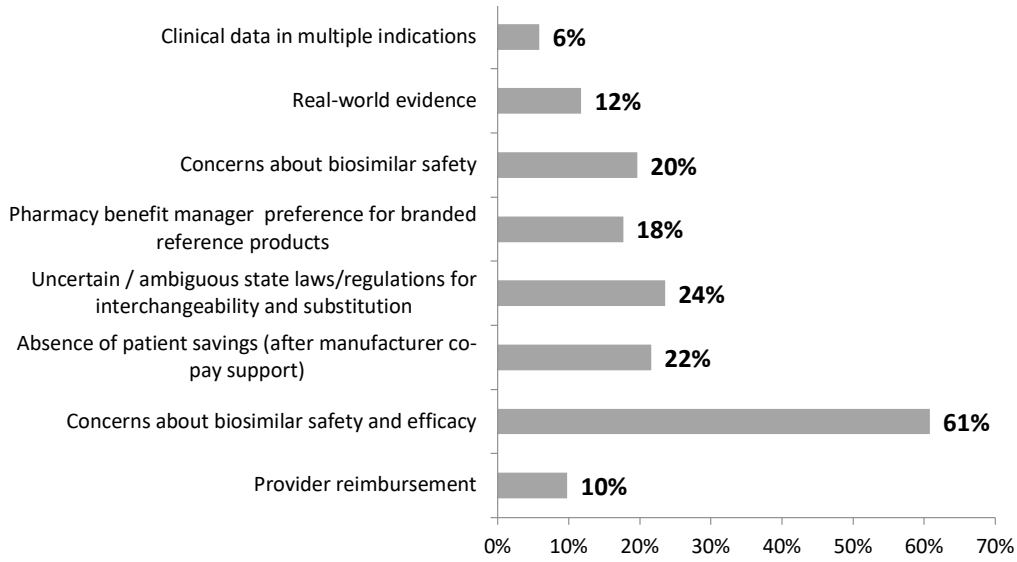

TABLE 2.

Understanding Biosimilar Interchangeability	
Answer Choices, % (n)	**Responses (n=51)**
Not at All Knowledgeable	10% (5)
Slightly Knowledgeable	20% (10)
Somewhat Knowledgeable	35% (18)
Moderately Knowledgeable	27% (14)
Extremely Knowledgeable	8% (4)

consults, followed by surgery (19%), non-surgical cosmetic procedures (8%), non-surgical medical procedures (7%), and office-dispensed dermatology product sales (2%).

Perspectives on Biosimilars

Twenty percent of respondents would not prescribe a biosimilar for an FDA-approved indication. Respondents were most likely to prescribe a biosimilar when it is mandated by payers (55%) and for new patients (31%). Fourteen percent of respondents were not likely to prescribe a biosimilar for any patient (Figure 1).

When asked about the greatest barriers to biosimilar adoption, 61% had concerns about biosimilar safety and efficacy, 24% reported uncertainty about state laws for interchangeability and substitutions, and 20% had concerns about biosimilar safety without concerns about efficacy (Figure 2). Thirty-five percent of respondents felt moderately or extremely knowledgeable about biosimilar interchangeability (Table 2).

Six percent of respondents were very unlikely to prescribe a biosimilar with an FDA interchangeability indication, while 16% were not likely, 22% were neutral, 47% were likely, and 10% were very likely. Eighteen percent of respondents were very unlikely to prescribe a non-interchangeable biosimilar, 38% were not likely, 30% were neutral, 12% were likely, and 2% were very likely.

DISCUSSION

Survey Respondent Characteristics

Most respondents' clinical practices focused on medical dermatology in a single-specialty group practice, where medical visits and consults comprised most of the revenue.

Factors That Discourage Biosimilar Adoption

There is hesitancy by dermatologists to prescribe biosimilars for indications that have been granted FDA approval, with a fifth of respondents stating they would not prescribe biosimilars. The average time to FDA approval for biologics is 12 years, and eight for biosimilars, and both share a similar approval process.[8] Dermatologists express a greater concern for the abbreviated FDA approval for biosimilars than other specialists, believing it impacts safety.[7] Concerns may also stem from the recent introduction of biosimilars for skin disorders.[3] Long-term safety and efficacy information for biosimilars is limited. Studies for psoriasis are limited to 52- and 55-week periods, while studies for HS are limited to international studies with small sample sizes.[9-13]

Knowledge of biosimilar interchangeability and the state laws that govern biosimilar substitution is also a barrier to biosimilar adoption. Only a third of respondents endorsed feeling moderately or extremely knowledgeable about biosimilar interchangeability. Although interchangeable biosimilars have comparable efficacy to their reference product and meet additional requirements for FDA approval compared to other biosimilars, only about half of respondents were likely or very likely to prescribe a biosimilar with an FDA interchangeability indication.[2] Uncertainty of state laws for interchangeability and substitution limit biosimilar adoption by placing the burden of understanding prescribing and substitution guidelines on the dermatologist and the pharmacist filling the prescription.[14]

Factors That Encourage Biosimilar Adoption

Our survey also identified organizational and patient factors that increased dermatologists' willingness to prescribe a biosimilar. Organizational factors include payor mandates. This may benefit patients as biosimilars cost up to 30% less than their reference biologic, which can exceed $10,000 for a single dose.[15] Respondents were also more willing to prescribe a biosimilar for new patients. Dermatologists may believe biosimilars are more effective in new patients who are treatment naïve. Alternatively, this may be evidence of dermatologists' hesitancy to switch established patients from a biologic to a biosimilar. However, nonmedical switches from a biologic to a biosimilar for psoriasis are supported by the biosimilar working group of the International Psoriasis Council.[16] In addition, nonmedical switches in psoriasis and HS do not impact clinical responses to therapy.[11,17]

CONCLUSION

Biosimilars are safe and effective for treating approved dermatological conditions and may lower patient costs compared to their reference products. Patients are not always offered biosimilar therapy as an option, which may be due to unfamiliarity among dermatologists. This survey suggests a need for more research and educational initiatives, such

as modules and workshops, that focus on biosimilar safety, efficacy, and interchangeability guidelines.

This survey was limited by a relatively small sample of respondents. Despite this, clear patterns emerged regarding provider factors limiting the adoption of biosimilars to treat dermatological conditions. Additionally, this survey explored a limited number of barriers and facilitators to the uptake of biosimilars by dermatologists.[18] Another potential limitation was the exclusion of dermatology residents and fellows, who may hold a different opinion of biosimilars than established, practicing dermatologists included in the survey.

Overall, the development of new biosimilars is ongoing due to market demand for cost-effective treatments. Although biosimilars in dermatology are currently limited to psoriasis and HS, the recent approval of biologics for other dermatologic conditions, such as pemphigus vulgaris and atopic dermatitis, foreshadows the development of biosimilars for these reference products. Biosimilars in dermatology are here to stay, with more in development, and there may be a need to educate dermatologists about their applications in clinical practice.

DISCLOSURES

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