

eAppendix: Provider and Patient Knowledge Gaps on Biosimilars: Insights From Surveys

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eAppendix Table 1. Summary of Key Information From Biosimilar Surveys of US Healthcare Providers.

Reference	Study description	Objective	Main findings
Cohen 2017 ¹	<ul style="list-style-type: none"> No. of participants: 1201 Methods: online survey Sample: speciality physicians who already prescribe biologics Date: November 2015-January 2016 	To assess current levels of awareness, knowledge, and perceptions of biosimilars	<ul style="list-style-type: none"> 5 major knowledge gaps were identified: <ul style="list-style-type: none"> defining biologics, biosimilars, and biosimilarity; understanding the approval process and the use of “totality of evidence;” understanding that the safety and immunogenicity of a biosimilar are comparable to those of the reference product; understanding the rationale for extrapolation of indications; and defining interchangeability and the related rules regarding pharmacy-level substitution.
Teeples 2019 ²	<ul style="list-style-type: none"> No. of participants: 297 Methods: online survey Sample: rheumatologists, gastroenterologists, and dermatologists Date: December 2016-January 2017 	To obtain perspectives on switching biologic treatments for nonclinical reasons in stable patients with certain autoimmune conditions	<ul style="list-style-type: none"> 84% did not want stable patients undergoing a nonmedical switch to a biosimilar. 60% believed nonmedical switching to biosimilars may have a <i>positive</i> impact on healthcare system costs. 59% anticipated a <i>negative</i> impact on patient mental health; negative impacts on treatment efficacy (57%), patient safety (53%), and physician office management (60%) also anticipated.

Greene 2019 ³	<ul style="list-style-type: none"> No. of participants: 300 Methods: online survey Sample: managed care and speciality pharmacy professionals Date: October 2018 	To assess perceptions regarding strategies for overcoming barriers to biosimilar adoption	<ul style="list-style-type: none"> 84% agreed or strongly agreed that FDA-approved biosimilars are safe and effective for patients who switch from a reference biologic. 91% indicated that prescriber education about evidence from switching studies was extremely likely/likely to overcome barriers to biosimilar adoption (highest rated strategy). 39% indicated that therapeutic drug monitoring for patients who switch to biosimilars was extremely likely/likely to overcome barriers to biosimilar adoption (lowest rated strategy). Respondents identified 6 stakeholder groups that have a primary role for strategy implementation, including: biosimilar manufacturers (40%), the federal government (26%), and managed care organizations (15%).
Kolbe 2021 ⁴	<ul style="list-style-type: none"> No. of participants: 507 Methods: online survey Sample: dermatologists, gastroenterologists, hematologists, oncologists, nephrologists, and rheumatologists Date: December 2019-January 2020 	To understand the factors that affect biosimilar uptake	<ul style="list-style-type: none"> < 50% had a baseline understanding of key elements of biosimilarity, even among those who had previously prescribed a biosimilar; knowledge improved after respondents received additional information about biosimilarity. Formulary status was the primary factor in prescriber choice of the reference product or biosimilar. Factors that influenced willingness to prescribe a biosimilar included financial savings to the patient, pharmacovigilance,

			<p>patient experience, and education on the FDA approval process.</p> <ul style="list-style-type: none"> • 37% indicated a preference for reference products vs biosimilar. • 48.5% indicated a hesitancy to try biosimilars until they have been on the market longer.
Gibofsky 2021 ⁵	<ul style="list-style-type: none"> • No. of participants: 320 • Methods: online survey • Sample: rheumatologists who prescribe TNF-α inhibitors • Date: May 2019-June 2019 	To evaluate perceptions of biosimilars among rheumatologists who prescribe TNF- α inhibitors	<ul style="list-style-type: none"> • 83% of respondents were familiar with the FDA definition of a biosimilar. • 96% were aware that an infliximab biosimilar was FDA approved; fewer realized that biosimilars for adalimumab (56%), etanercept (62%), and rituximab (39%) were FDA approved. • 84% were aware that an approved biosimilar was not automatically deemed interchangeable by the FDA. • Respondents were more likely to initiate biosimilar treatment for a biologic treatment-naive patient with an RA (73%) than they were to switch to the biosimilar for a patient with an RA doing well on the reference product (35%).
Wilde 2021 ⁶	<ul style="list-style-type: none"> • No. of participants: 602 • Methods: online survey • Sample: hematologists/oncologists, rheumatologists, 	To understand stakeholder perceptions of biosimilars	<ul style="list-style-type: none"> • 78% believed biosimilars are equally safe and effective as the brand biologics. • 94% were very or somewhat comfortable prescribing FDA-approved biosimilars.

	<p>gastroenterologists, dermatologists, and ophthalmologists who prescribe biologics</p> <ul style="list-style-type: none"> • Date: NR 		<ul style="list-style-type: none"> • Physicians were more likely to prescribe a biosimilar to patients who were newly starting therapy than to patients who were already successfully established on a branded biologic treatment. • Physicians were largely opposed to automatic substitution by pharmacists. • Physicians believed that out-of-pocket costs for biosimilar were lower than those for branded biologics, but that drug discount programs may mitigate differences in patient costs. • Physicians sought additional transparency about prices for brand biologics and biosimilars, which could encourage greater prescribing.
<p>Stevenson 2021⁷</p>	<ul style="list-style-type: none"> • No. of participants: 507 • Methods: online survey • Sample: pharmacists • Date: March 2021 	<p>To assess pharmacists’ understanding of biosimilars, including interchangeability</p>	<ul style="list-style-type: none"> • 87% and 91% knew that the biosimilar had equivalent efficacy and safety, respectively, to its reference product. • 81% knew that if a biosimilar is approved for all the same indications as its reference product, it cannot be automatically assumed to be interchangeable with the reference product. • 53% understood that a pharmacist can dispense an interchangeable biosimilar for its reference product without prescriber authorization if consistent with state law. • 20% knew that “FDA approval as interchangeable” meant that the biosimilar could be substituted without contacting the prescriber.

			<ul style="list-style-type: none">• 11% knew that none of the existing biosimilars have been designated as interchangeable.
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NR, not reported; RA, rheumatoid arthritis; TNF, tumor necrosis factor.

^a52 physicians, 16 pharmacists, and 9 advanced practice providers

eAppendix Table 2. Summary of Key Information From Biosimilar Surveys of Patients

Reference	Study description	Objective	Main findings
Teeples 2019 ⁸	No. of participants: 1696 Methods: online survey Sample: patients with autoimmune disease currently receiving a biologic Date: December 2016-January 2017	To evaluate patient attitudes regarding nonmedical switching to biosimilars	<ul style="list-style-type: none"> • 85% were concerned that biosimilars would not treat their disease as well. • 85% did not want to switch to a biosimilar if their current biologic was helping their disease, with 83% concerned that switching may cause more adverse effects. • 20% had previously received an insurance notification about a potential nonmedical switch to another biologic (that was not a biosimilar), with 79% of these patients taking at least 1 action to avoid the switch. • Among the 44% of 150 patients who did switch, 67% did so to avoid paying a higher cost. • 56% went without therapy for administrative reasons during the period of transition from the old biologic to the other treatment.
Wilde 2021 ⁶	No. of participants: 618 Methods: online survey Sample: patients prescribed a biologic in the previous 12 months Date: NR	To understand stakeholder perceptions of biosimilars	<ul style="list-style-type: none"> • 99% of patients trusted their doctors’ treatment recommendations somewhat (17%) or a great deal (82%). • 71% indicated that they would be fully confident and accept the biosimilar if their physician prescribed it. • 77% and 79% believed that biosimilars were equal or better in terms of efficacy and safety, respectively, as the brand biologics.

			<ul style="list-style-type: none"> • 42% of patients indicated that pharmacists should be able to automatically substitute a biosimilar, but focus group participants voiced concerns. • Patients believed that biosimilar out-of-pocket costs were lower than those of branded biologics.
Gibofsky 2021 ⁹	<p>No. of participants: 167 Methods: online survey Sample: self-reported specialist diagnosis of RA (including juvenile RA) of ≥ 1 year Date: NR</p>	To assess beliefs about biosimilars	<ul style="list-style-type: none"> • 36% of current biologic users had heard of a biosimilar vs 16% of biologic nonusers. • Adverse effects and long-term safety were the main concerns identified. • 44% of current biologic users indicated that they would accept a switch to a biosimilar; 25% would not switch, and 31% were unsure. • 43% of biologic nonusers indicated that they would accept the switch if their doctor prescribed an original anti-TNF-α but the insurance company required a biosimilar; 12% would not switch, and 45% were unsure. • 41% of biologic nonusers expressed no preference if their doctor prescribed a biologic, 37% responded that it depended on cost, 13% responded that would take the biosimilar if available, and 8% preferred the original treatment. • 71% responded that they need general information to help them learn more about biosimilars.

NR, not reported; RA, rheumatoid arthritis; TNF, tumor necrosis factor.

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