

BIOLOGICS AND BIOSIMILARS

ATTITUDES AND EXPERIENCES

Patients Rising University conducted a survey to better understand patient experiences and attitudes regarding biologics and biosimilars. We wanted to know just how aware patients are about these treatments, what makes them different in the patient perspective and what their general attitudes are on related issues.

Building and Sharing the Survey

We built a survey tool using Google Forms. We drafted some questions then gathered feedback from patient support organizations (PSOs) that represent patient communities that use biologics and biosimilars as treatment options. We applied ideas and feedback provided by the PSOs who then helped disseminate the survey to their audiences. We also shared the survey with biologics/biosimilar industry contacts to present to clinical populations. Finally, we presented the survey as an open opportunity (no compensation) to our social media audience.

Cohort and Demographics

Following a prescribed 14-day period (in August 2020) in which the survey would remain open for response, we gathered a total of 127 responses, all of whom completed the survey in full.

Respondents were receiving treatment for diverse chronic conditions that included allergic asthma, anemia, ankylosing spondylitis, chronic migraine, colon cancer, Crohn's disease, diabetes, Ehler's Danlos Syndrome, familial hypercholesterolemia, fibromyalgia, Graves' disease, Hashimoto's thyroiditis, hidradenitis suppurativa, hypoparathyroidism, infertility, lymphocytic colitis, multiple sclerosis, osteoporosis, positional orthostatic tachycardia syndrome, primary sclerosing cholangitis, psoriasis, psoriatic arthritis, rheumatoid arthritis, Sjorgen's syndrome, systemic lupus, ulcerative colitis, and uveitis.



Patients Rising University is the education and empowerment arm of Patients Rising. Our goal is to give patients and caregivers the information they need (never to be confused with medical advice, ever) to have greater success in their pursuit of good healthcare. We believe that can be achieved by increasing knowledge and improving communication between patients, providers, insurers, legislators—anyone playing a role in healthcare. We don't claim to be experts on the topics we write about, which is why we gather the best quality information from resources that are. You're welcome to visit the [Patients Rising University](#) to explore the content that is posted there.

Experience with Biologics/Biosimilars

A majority of the cohort that was surveyed included patients who were either taking a biologic currently (79%) or had taken one in the past (8%) = (total 87%). Few persons (5%) were currently on biosimilars though none had past experiences with them. Therefore, most respondents (92%) had experience with biologics or biosimilars currently or previously and so may have had basic knowledge of them.

Meanwhile, a small fraction of respondents:

- had never been prescribed a biologic or a biosimilar (0.39%)
- were unfamiliar with whether the treatment they were receiving was a biologic or a biosimilar drug (0.31%). This could either mean that the respondents
 - did not know if they were on a regular, small molecule drug or a biologic, or
 - whether the drug was a biologic or a biosimilar

Insurance status

A majority of survey participants had employer-sponsored insurance (68.3%) or were enrolled in a marketplace plan (17.5%). A small number were enrolled in Medicare or Medicare Advantage (11.9%) or Medicaid (9.5%). There was one participant enrolled in a Medigap plan and one was on a VA plan. Five persons (0.39%) reported having no insurance coverage.

Knowledge and Attitudes

We tested some baseline True/False assertions to **assess fundamental knowledge of biologics**:

Assertions	Correct response	% of correct answers
Biologic drugs are sourced from living organisms	True	88.2%
Biologic drugs tend to be relatively expensive	True	97.6
Biologic drugs are considered controlled substances	False	69.3
Biosimilars are exact copies of biologics	False	85.0
Unlike biologics, biosimilars are available over-the-counter	False	91.3

A majority (88.2%) of our survey respondents were aware that biologic drugs are developed in living organisms and that they are expensive (97.6%). A surprisingly high number (85%) of respondents were aware that biosimilars are not exact copies of biologics, and over 90% knew that biosimilars, just like biologics, need a prescription. However, 30% of respondents thought that biologics are controlled substances.

We also tested other assertions with the intention of **better understanding attitudes**:

Assertions	Agree	Disagree	No opinion
Biologics have more dangerous side effects than other kinds of drugs	51.9%	30.8%	17.3%
Biosimilars should not be automatically interchangeable with the biologic they are similar to	59.1	5.5	35.4
A doctor should be able to write a prescription for whatever drug or treatment they feel will best help their patient, without interference	92.1	2.3	5.5
Biologics should cost more because it takes so long to study and develop them	18.9	66.9	14.2
If the FDA approves a biologic, I will trust its safety and effectiveness	60.6	24.4	15.0
If the FDA approves a biosimilar, I will trust its safety and effectiveness as much as I would trust a biologic	47.3	26.7	26.0
The cheaper a drug is, the less faith I have that it will work as planned	6.3	82.7	11.0

Substitution/Interchangeability

When asked about automatic substitution with a biosimilar, nearly 60% of respondents said they do not want an automatic substitution of the reference biologic with a biosimilar. A little over 35% did not have an opinion about substitution, which could mean that they may not have enough knowledge about substitution/interchangeability to form an opinion. Nearly 70% trust their doctor to make a decision for them and are of the opinion that prescribing a medicine should be at their physician's discretion alone.

Cost and safety

Over 65% of those surveyed do not agree that the time and cost invested in developing biologic drug products justifies their cost. More than 80% do not correlate high drug price with its efficacy. Taking these responses into consideration, in addition to showing that their drug is bioequivalent, biosimilar manufacturers could curtail drug price and make them less expensive than the reference biologic.

While 60% of survey participants had faith in the safety and effectiveness of an FDA-approved product, less than 50% said they had faith in the safety and efficacy of an FDA-approved biosimilar. This indicates that there remains skepticism about biosimilars as a class.

Biologic/Biosimilar Experiences

We then wished to make distinctions among those who had experience on a biologic or biosimilar.

The majority of respondents had some experience on biologics. We learned that 87.4% of respondents were either on, or had been on, a biologic. We also learned that only 5.5% were either on, or had been on, a biosimilar (of a total 92.9%, N = 118). The rest had either been on neither (3.9%) or did not know if their drug was a biologic or biosimilar (3.1%). It is unclear if those who did not know, were unsure about whether their drug was a biologic versus a biosimilar or non-biologic versus a biologic, so they are not counted among those who are considered positive users.

Of respondents that indicated they did not take a biologic/biosimilar (N=10), they reported that their choice was based on concerns about:

- cost (1 of 10)
- side effects (6 of 10)
- interaction with other drugs/treatments (3 of 10)

Positive or Negative Experience

115 respondents reported on their experience with a biologic/biosimilar drug. A significant number of respondents (67.1%) cited a positive experience with their biologic treatment while (18%) cited a poor experience.

Since 86% of our respondents answered yes to taking a biologic, but over 83% selected N/A for experience on biosimilars, that means these 83% may have never taken a biosimilar.

However, of the 15.8% of respondents who used a biosimilar (N=20):

- 9 of 19 reported a neutral experience
- 8 of 19 reported a poor or very poor experience
- 3 of 19 reported a positive or very positive experience

Paying for the Drug

We asked participants how their biologic drug was paid for. 113 participants (those who are, or were, on either a biologic or biosimilar, or were not sure if their drug was one or the other) responded to this question, and one reported user did not respond.

Was/Is your biologic drug paid for:	N=113	
Completely (or almost completely) by my insurance	60/113	53.0%
Only partially by my insurance	32/113	28.3
By a patient assistance program, drug coupon, or similar	19/113	16.8
Completely (or almost completely) out of pocket	2/113	1.7

A majority of patients (81.3%) had their biologic drug covered by their insurance to some degree; the majority of those had complete or almost complete coverage. A smaller number (16.8%) utilized a patient assistance program or drug coupon (or similar) to cover the cost of the drug to some extent. Of the 113 respondents, 2 reported having to pay out of pocket for the biologic despite those individuals reportedly having “employer sponsored” health insurance.

Conclusions

The knowledge of and trust towards biologics in this cohort seems to be greater than the knowledge of and trust towards biosimilars. This suggests that there needs to be more educational opportunities about biosimilars. Even though relatively small percentages incorrectly identified biosimilars as “exact copies of biologics” (15% incorrect) or that they are “available over the counter” (8.7% incorrect) it points to a knowledge gap. This may be reinforced by the lower rate of trust in an FDA approved biosimilar (47.3% felt trust) compared to an FDA approved biologic (60.6% felt trust).

Additionally, patients might benefit from better understanding of the existence of patient assistance programs (PAPs). For instance, of the 28.3% of respondents whose biologic was only partially covered by their insurance, and certainly for the 2 individuals who reportedly paid out of pocket, if they were aware of PAPs they might have saved a considerable amount of money. The existence of PAPs can also address the common public concern about drug costs.

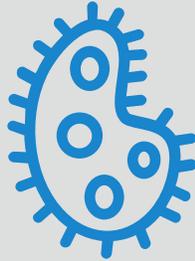
BIOLOGICS

Attitudes around cost, safety and efficacy

A survey of 127 patients

88.2%

knew that biologic drugs are sourced from living organisms



Compared to the traditional chemically-synthesized drugs with which most of us are familiar, **biologics** are larger, more complex molecules that require some component from a living organism in order to be made.



85%

believed that biosimilars are exact copies of the biologic they reference

A **biosimilar** is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that's already approved by the FDA (known as the **originator biologic** or **reference product**).

When we asked people if they would trust the safety and effectiveness of products approved by the FDA,

60.6%

said they agreed that they would trust a **biologic** approved by the FDA



47.3%

said they agreed that they would trust a **biosimilar** approved by the FDA

82.7%

said they would not have less faith in a drug working as expected only because it was **cheaper**



The FDA standards ensure that variations between biosimilars and their reference product remain within limits, ensuring **clinical efficacy**.

Biosimilar manufacturers ensure their product is as clinically effective as the originator biologic.

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