AN ONLINE SURVEY AMONG US PATIENTS WITH IMMUNE-MEDIATED CONDITIONS: BELIEFS ABOUT BIOSIMILARS FROM PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background

- Biologic medicines, such as TNFα blockers, are widely used for a broad range of immune-mediated inflammatory conditions.
- The FDA defines a biosimilar as a biological product that is highly similar to and has no clinically meaningful differences in terms of safety, purity, and potency (safety and effectiveness) from the original FDA-approved reference product.[1]
- Biosimilar agents were introduced to improve access to lower cost treatment options.
- With more biosimilar drugs becoming available, it will be important for patients to be informed about biosimilars.

Objective

- This survey evaluated attitudes regarding biosimilars among US patients with rheumatoid arthritis (RA), psoriasis and/or psoriatic arthritis (PsO/PsA), inflammatory bowel disease (IBD), or multiple conditions.
- This analysis focuses on patients with IBD.

Methods

Patients

- Members of the Dynata® consumer panel were invited by WebMD, LLC via email to complete an online self-administered survey.
- Eligibility criteria:
  - US resident and aged ≥18 years (≥21 years in Alabama, Mississippi, Nebraska, and Puerto Rico).
  - Self-reported specialist diagnosis of RA, PsO/PsA, or IBD for ≥1 year.
  - Not currently receiving an infliximab biosimilar (Inflectra® [infliximab-dyyb], Renflexis® [infliximab-abda], or Avsola™ [infliximab-axxq]).
  - Provided informed consent via check box.
- Patients with multiple conditions answered questions about 1 condition only: those with RA+IBD reported about IBD, whereas those with PsO/PsA+IBD reported about PsO/PsA and those with RA+PsO/PsA reported about RA. Neither the RA nor PsO/PsA groups are included here.
- The target sample size (quota) was 500 patients, with quotas set based on US geographic region (25% each for Northeast, South, Midwest, and West) and medical condition (33% each for RA, PsO/PsA, and IBD).

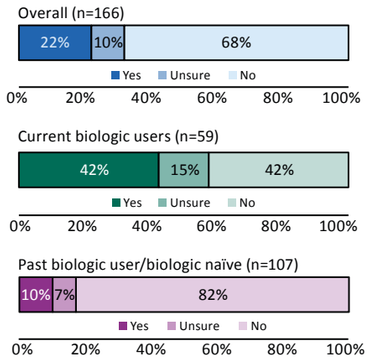
Survey

- The survey consisted of 16 items in a multiple-choice format; most used a 5-point Likert scale for responses.
  - Patients were asked about their use of biologics; they also were asked whether they had heard of biosimilars.
  - Patients were then shown the FDA definition of a biosimilar.[2]
  - Subsequent questions assessed attitudes in relation to initiating or switching to a biosimilar and interchangeability.
- The survey was conducted from December 2020 – January 2021.
- Responses to each survey item were analyzed descriptively.
- This survey received an exemption from Institutional Review Board oversight by Advarra (Columbia, MD).

KEY FINDINGS

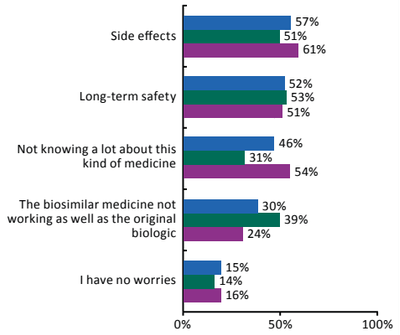
- The majority of patients who completed the survey had not heard of biosimilars.
- Most patients were receptive to biosimilar treatment, and considered cost as part of the decision-making process.
- Main biosimilar concerns among patients with IBD were side effects and long-term safety.
- Patients would benefit from educational programs to help them understand biosimilars and the treatment choices they provide.

Have you ever heard of biosimilars?

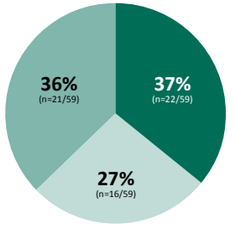


Numbers may not total 100% due to rounding.

Patients were shown the FDA definition of biosimiliars and then asked, thinking about taking biosimilars, do you worry about:

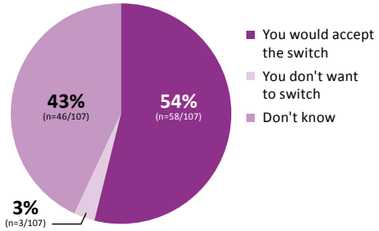


A switch from your current medicine to a biosimilar of the same medicine has been proposed to you. Do you think:



- Of those unwilling to accept a switch, 56% (n=9/16) about side effects, 50% (n=8/16) were concerned about financial support, and 50% (n=8/16) about the biosimilar not treating their condition as well.
- Of note, 56% (n=33/59) of current users said they received co-pay assistance.

You are not currently taking a biologic. If your doctor prescribed an original anti-TNFα medicine, but your insurance company requires the prescription to be switched to its biosimilar:



- When non-users were asked their preference if their doctor prescribed a biologic, 10% (n=11/107) would prefer the original, 11% (n=12/107) would take the biosimilar if it was available, 26% (n=28/107) had no preference, and 52% (n=56/107) responded that it depended on cost.

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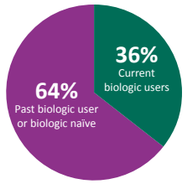
RESULTS

Sample Disposition

Total Responses	2013
Screening terminates	226
Said "no" to Survey consent	38
Selected all three conditions	8
Selected "None" to conditions	49
Not diagnosed by specialist doctor	54
Diagnosed <1 year prior	46
Not in US State or territory	2
<18 years of age*	2
Currently receiving Inflectra® (infliximab-dyyb), Renflexis® (infliximab-abda), or Avsola™ (infliximab-axxq)	22
Failed ReCaptcha	5
Over quota	1287
Total Completes	**500**

*<21 years of age in Alabama, Mississippi, Nebraska, and Puerto Rico

- A total of 500 patients completed the survey, one third of whom (n=166) had IBD as per quota (72% ulcerative colitis only, 12% Crohn's disease only, 4% ulcerative colitis + Crohn's disease, 11% any IBD+RA, 1% IBD+PsO+RA).
- Mean age of the IBD cohort was 50.1 (SD 15.0) years; 67% (n=112) were female, 32% (n=53) male.



- **64% (107/166)** were **currently not using a biologic** (19% [31/166] past users and 46% [76/166] biologic naïve).
- **36% (59/166)** of IBD patients were **currently receiving a biologic.**
  - Among current biologic users, 61% (36/59) were on a TNFα blocker.
    - Most of these patients were currently receiving adalimumab: 50% (n=18/36) adalimumab, 19% (n=7/36) infliximab, 17% (n=6/36)etanercept, and 6% (n=2/36) golimumab.

Declaration of conflicting interests

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AG is a consultant/advisor for AbbVie, Lilly, Horizon Pharma plc, Novartis Pharmaceuticals, Pfizer, and Samumed; speakers' bureau for AbbVie, Amgen, Lilly, and Pfizer; stock ownership in AbbVie, Amgen, Bristol-Myers Squibb, Horizon Pharma, and Pfizer. **LPB** reports personal consulting fees from Merck Sharp & Dohme, AbbVie, Janssen, Takeda, Celltrion, Pfizer, Bristol-Myers Squibb, Pharmacosmos, Shire, Genentech, Mitsubishi, Ferring, Norgine, Tillots, Vifor, UCB-Pharma, Hospira, Boehringer Ingelheim Pharmaceuticals, and Lilly. **DM** is an employee of Boehringer Ingelheim Pharmaceuticals, Inc. **MM** was an employee of Boehringer Ingelheim Pharmaceuticals, Inc at the time the survey was conducted. **SO, AF,** and **GJ** report no disclosures.

Abbreviations

FDA, US Food and Drug Administration; IBD, inflammatory bowel disease; PsO/PsA, psoriasis or psoriatic arthritis; RA, rheumatoid arthritis; TNFα, tumor necrosis factor α.

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References

1. US Food and Drug Administration. Biosimilars and interchangeable products. https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (Accessed August 10, 2021).
2. US Food and Drug Administration. Biosimliar basics for patients. https://www.fda.gov/drugs/biosimilars/patient-materials (Accessed December 17, 2019).

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