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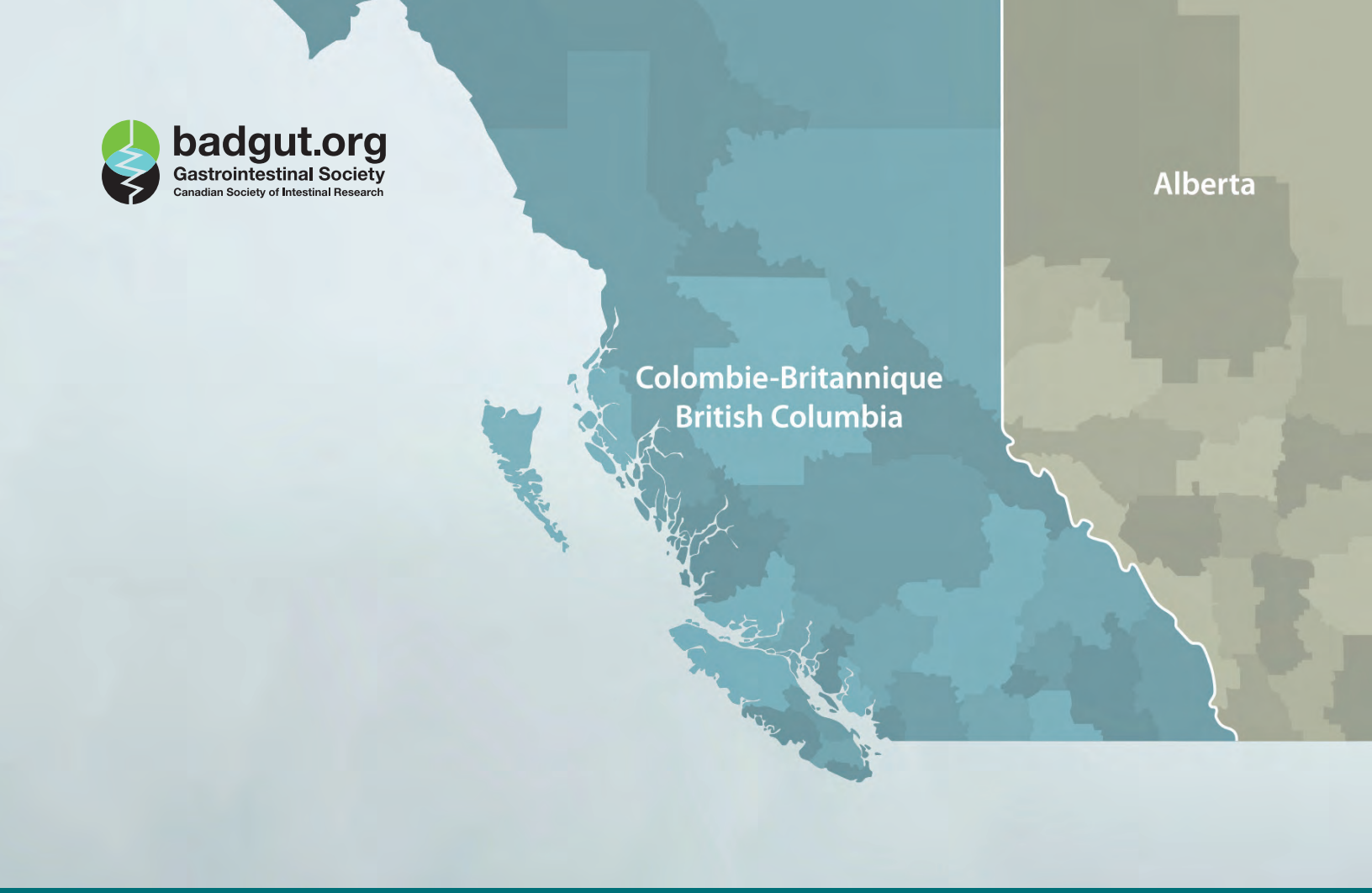
Gastrointestinal Society
Canadian Society of Intestinal Research



Biosimilars in Alberta and BC

SURVEY RESULTS

December 2021 // **Gastrointestinal Society**

Background

Four provinces across Canada have implemented non-medical switching (NMS) policies for biologic medications. In these jurisdictions, to maintain public coverage, individuals must switch from their originator biologic to a corresponding biosimilar. In May 2019, the government of British Columbia (BC) launched their NMS policy and Alberta followed shortly after in December 2019.[1] New Brunswick announced their policy in April 2021 and Quebec in July 2021. Other provinces may soon follow.

Biologics are very specific and highly effective medicines made in living cells. Biosimilars are highly similar to an already approved originator biologic but, unlike a generic drug, are not identical. To view current policies in Canada and to learn more about biologics and biosimilars, visit www.badgut.org/biosimilars.

Methods

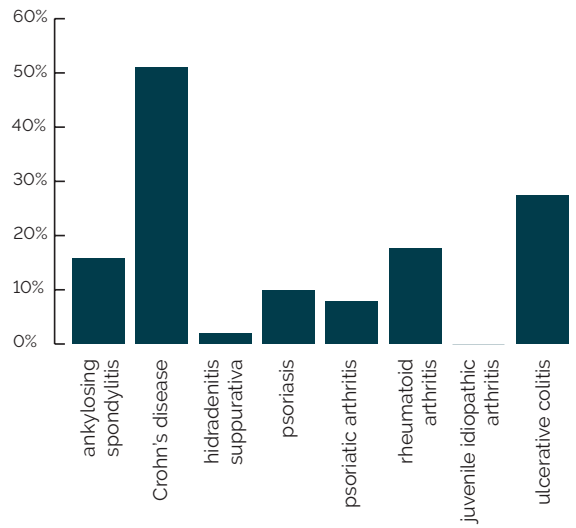
We hosted a survey on our website and shared it across our social media platforms from August 31, 2021 to October 11, 2021. We are grateful to the other patient groups that also shared the survey link. Our intent was to focus on the opinions and outlook of individuals in BC and Alberta affected by NMS policies. Qualifying respondents had to live in these provinces, had to have been on an originator biologic and then switched to a biosimilar due to the NMS policy, and had to have a diagnosis of one of the following conditions: ankylosing spondylitis, Crohn's disease, hidradenitis suppurativa, psoriasis, psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, and/or ulcerative colitis.

Specifically, they must have switched from the **originator** to one of the following biosimilar medications: **Humira**® (adalimumab) to Abrilada®, Amgevita®, Hadlima®, Hulio®, Hyrimoz® or Idacio®; **Enbrel**® (etanercept) to Brenzys® or Erelzi®; or **Remicade**® (infliximab) to Avsola®, Inflectra®, Renflexis®, or Omvyence™. We did not include New Brunswick and Quebec as they only recently announced their NMS policies.

Demographics

We received 51 qualified responses, 63% from BC and 37% from Alberta. Most had a diagnosis of inflammatory bowel disease, with 51% of them living with Crohn's disease and 27% with ulcerative colitis. A further 16% were living with ankylosing spondylitis, 10% psoriasis, 8% psoriatic arthritis, and 18% rheumatoid arthritis. Only one respondent indicated hidradenitis suppurativa. Some individuals had comorbidities among these conditions. Respondents' ages varied, with 27% 55-64 years old, 24% 45-54, and 22% 35-44. The remaining participants were 18-34 years old (12%) and 65-84 years old (16%). Respondents were mostly female, at 69%, and 23% were male, while 8% preferred to not disclose their sex.

With which of these diseases have you been diagnosed?



Biologics

A majority (84%) of survey participants were on an originator biologic for two years or more. This includes 43% who were on a biologic for two to five years and 21% for more than 10 years. 14% were on the originator biologic for less than one year before they switched to a biosimilar.

Switching Experience

When NMS policies were introduced in their province, 57% of respondents switched to an infliximab biosimilar, 31% switched to an adalimumab biosimilar, and 12% switched to an etanercept biosimilar, with 75% of all respondents continuing to take the first biosimilar they were switched to.

However, 25% are no longer taking that medication. Interestingly, physicians switched 10% of respondents from the biosimilar to an originator biologic that is different from the one they were taking before the NMS policy, 8% are no longer taking any biologic medication at all, while 4% switched to another biosimilar, and 4% switched back to the originator biologic they were taking before switching. Some individuals shared why they discontinued using the biosimilar they first switched to, most of whom experienced side effects or found the medication to be ineffective, with one individual stopping after having a surgery that adequately controlled their symptoms.

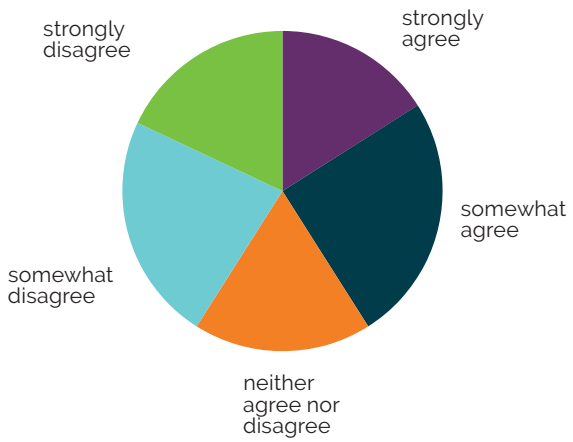
Switching Process

Respondents had very different experiences and reactions to the process of NMS. When asked to what extent they agree that the process for switching to a biosimilar was clear and simple, 41% of respondents agree, 18% neither agree nor disagree, and 41% disagree. Experiences also varied among individuals with the same diagnosis. Those who agree included 63% of all respondents who indicated a diagnosis of ankylosing spondylitis, 43% with ulcerative colitis, 40% with psoriasis, 38% with Crohn's disease, 33% with rheumatoid arthritis, and 25% with psoriatic arthritis. Those who disagree included 50% of all respondents with a diagnosis of Crohn's disease, 44% with rheumatoid arthritis, 40% with psoriasis, 36% with ulcerative colitis, 36% with ankylosing spondylitis, and 25% with psoriatic arthritis.

Biosimilars Experience

Similarly, 55% do not feel confident about the continued management of their condition with the biosimilar and 39% do feel confident. While 45% indicated they do not believe that the biosimilar they are currently taking provides similar benefits to the originator biologic, 31% believe that the benefits are similar. Respondents listed different effectiveness, adverse reactions, increased symptoms, and the quality of the patient support program as some of the reasons why they do not believe the biosimilar provides comparable benefits to the originator biologic.

The process to switch to a biosimilar was clear and simple.



When comparing biosimilars experiences by disease, survey participants also had mixed answers, as 50% of all those with ankylosing spondylitis agree that the biosimilar provides similar benefits while 25% disagree, 27% with Crohn's disease agree and 46% disagree, 33% with rheumatoid arthritis agree and 55% disagree, 25% with psoriatic arthritis agree and 25% disagree, 21% with ulcerative colitis agree and 64% disagree, and 20% with psoriasis agree and 40% disagree. Quite a few respondents (24%) were unsure.

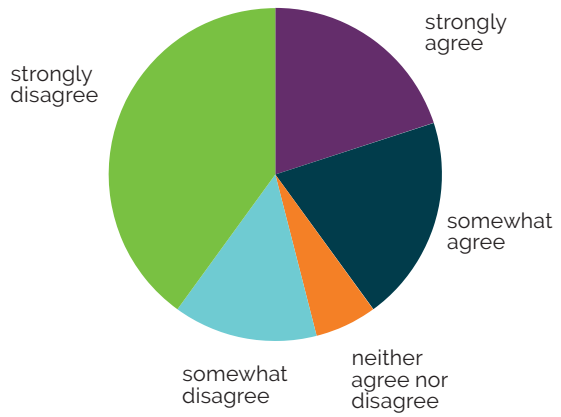
These divisions among survey participants also emerged when 80% responded to an open-ended question about their overall experience with the biosimilar. Some said it was "positive," "so far, so good," and "same as original." One mentioned that they prefer the biosimilar to the originator biologic and another said that the "first injection didn't sting like the originator biologic, which was a nice change."

However, another person said that "the biosimilar

injection hurts more than the biologic." Several respondents had difficulties with the biosimilar, which included adverse reactions to the drug itself and barriers to support services, including patient support programs (PSPs) and pharmacy supply. Side effects ranged from moderate to severe, and included diarrhea, headache, nausea, fatigue, and respiratory issues, as well as skin and pouch infections. Several were in remission with the originator biologic but are now experiencing flares since the beginning of biosimilar treatment. It is important to note that flares are a natural occurrence in the disease journey, so it is impossible to tell whether a flare might have occurred while on the originator biologic. A few switched to another biologic medication and others stopped taking biologics completely.

Several respondents indicated that they recently started their biosimilar treatment and could not provide any comment on their overall experience, which might explain why a few respondents were neutral and/or unsure about NMS. This may also be due to the recent addition of the originator biologic for adalimumab (Humira®) in NMS policies.[1] We expect more biosimilars to come to Canada and for governments to add these medications to their policies, leading to more individuals who will need to switch. This could also mean that those who switched to a different originator biologic might need to change their medications again. A few respondents in our survey already had shuffled through originator biologics and biosimilars, as none had worked as effectively as the originator biologic they were taking before NMS. We still do not fully understand the impact that multiple switches have on a person's quality of life and wellbeing.

I feel confident about the continued management of my condition with the biosimilar treatment.



Loss of Treatment Control

Most participants wished to simply have a choice in their treatment. One person said, "I feel I was not allowed a choice over my own health and forced into being taken off a drug that gave me quality of living." Even if individuals had private coverage and wanted to stay on the originator biologic, most private insurers aligned their policies with the public policies,[2] leaving few options.

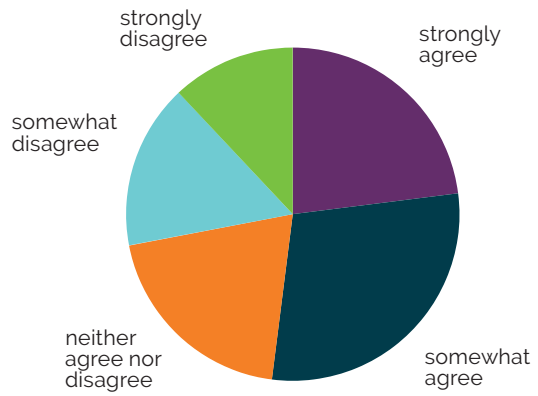
Information and Support

Survey participants learned about the government's biosimilar policy changes from several sources. Close to 75% cited a healthcare professional, including 49% from physicians and 16% from pharmacists. 29% received a letter in the mail, followed by 20% who learned about it from the government, and 16% from the news. Other sources of information were private insurance (8%), social media (6%), and patient groups (4%).

One concern that we had when the NMS plans were announced was that the provincial governments did not give patients enough time to switch. However, due to the COVID-19 pandemic, the Alberta government postponed their deadline for switching and 53% agree that they had sufficient time after notification of the policy to make the necessary arrangements for switching to a biosimilar, 20% neither agree nor disagree, and 27% disagree.

Most respondents had extra communications with their healthcare team to facilitate the switch, including telephone calls (57%), in-person appointments (31%), virtual appointments (20%), and email communications (20%). Only 12% of respondents said they did not have any extra communication. Of those who did, 69% estimated that this took less than one to two hours. Close to 10%

I had sufficient time after notification of the policy change to make the necessary arrangements to switch to the biosimilar.



said it was more than two hours due to difficulties with scheduling appointments, requiring additional testing, and challenges with coordinating the biosimilar product in a different healthcare setting (e.g., from infusion clinic to in-hospital care).

In an open-ended question on support, information, or education that respondents would have liked to receive, a few individuals said they needed more regular check-ins from the PSP after the switch. They felt that there was inadequate coordination of care as "it was like playing broken telephone." Several phases of these biosimilar policies occurred during COVID-19, which may have had an impact on the delivery of care and availability of services and medications. Since then, PSPs adopted measures to improve the timeliness, accessibility, and coordination of care.

Conclusion

Our survey is a small snapshot of individuals' experiences with NMS, which continue to show that a 'one-size fits all' policy approach to increasing biosimilar uptake might not have been well-thought out. It echoes earlier findings in our Biosimilars Survey Report 2020.[3] We have been cautioning decision-makers on the unintended consequences of NMS. Yet, alternative policies without NMS exist, and these can increase biosimilar uptake and achieve significant budget savings while still ensuring continuity of care and access to medications for people living with chronic diseases. Fortunately, other provinces are paying attention to the experiences within BC and Alberta, and they hope to avoid the negative issues.

Note: We have rounded percentages to the nearest whole number.

1. Provincial and Territorial Biologics Policies. Gastrointestinal Society. Available at: https://badgut.org/information-centre/a-z-digestive-topics/provincial-biologics-policies/. Accessed 2021-10-11.
2. Pharmacy Consulting Team. Drug Plans Decoded: Biosimilars Part 2. TELUS Health. 2021. Available at http://ow.ly/tGSW50GknVu. Accessed 2021-10-01.
3. Gastrointestinal Society. Forced to Switch: Canadian Biosimilar Experience Survey Report. 2020. Available at: https://badgut.org/biosimilars-survey-report-2020/. Accessed 2021-10-11.

Please Note

The Gastrointestinal Society does not intend that this report replace the knowledge or diagnosis of your physician or healthcare team, and we recommend seeking advice from a medical professional whenever a health problem arises.

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