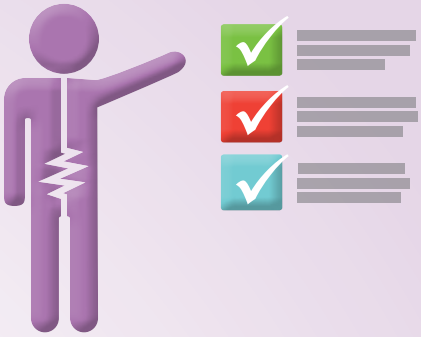
Survey Results



SUBSEQUENT ENTRY BIOLOGICS

Gastrointestinal Society

badgut.org
Gastrointestinal Society
Canadian Society of Intestinal Research

2015

The GASTROINTESTINAL SOCIETY represents inflammatory bowel disease (IBD) patients on a variety of health care fronts, including access to medications. During the first part of 2015, we hosted a survey on our English (www.badgut.org) & French (www.mauxdeventre.org) websites to help understand IBD patients' opinions and outlooks regarding subsequent entry biologics (SEBs). To qualify, survey participants had to confirm that they were either a person with IBD or a caregiver of a person with IBD. We had 423 respondents, 317 in English; 106 in French, but not everyone answered each question, as they were not mandatory.

BACKGROUND

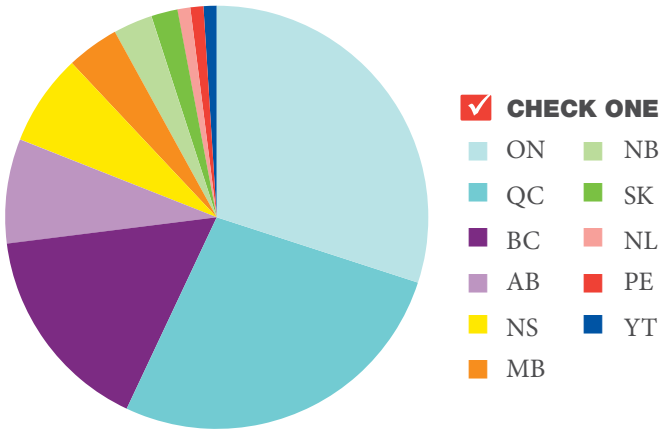
Biologics are medicines made from living cell systems, and are intended to act in certain ways in the body to correct malfunctions that might lead to disease. They can also block disease in its early stages from progressing.

Unlike most generic drugs, biosimilars/SEBs are not identical to the original biologic medicine on which they are based; they have slightly different structures, are not therapeutically equivalent, and might not be approved or tested for all the disease areas (indications) for which the reference product was approved, e.g., Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis.

Health Canada (the government agency responsible for drug safety) might not require a biosimilar to be tested for safety and effectiveness through clinical trials in a specific disease area before approving it for use in that disease area. (The regulations are in flux.) This is in contrast to the approval process for the original biologic, which required extensive studies in all of the disease areas for which Health Canada has approved it. The biosimilar agent has to demonstrate structural and quality aspects for Health Canada to denote it as similar to the original biologic and, therefore, relies on the original medicine's clinical experience, not the biosimilar's own data.

DEMOGRAPHICS

- respondents were from all ten provinces and Yukon, with close proportional representation to the corresponding populations
- the majority (66%) were female
- 91% were between 18-59 years of age, less than 1% were caregivers of children with IBD (n=5), and the remainder were older than 59
- 68% had Crohn's disease, 30% had ulcerative colitis, and 2% had indeterminate IBD

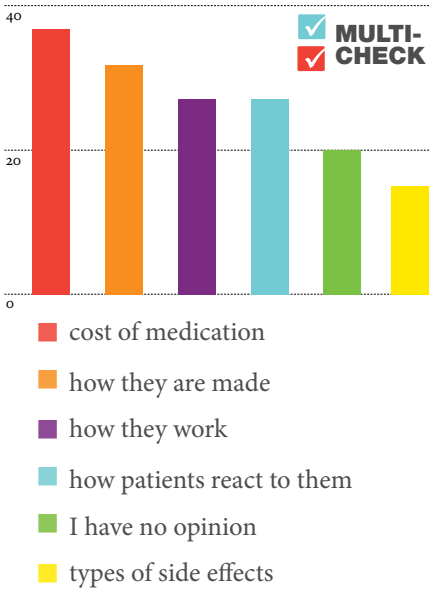


UNDERSTANDING BIOLOGIC MEDICATIONS

- 77% had at least a basic understanding of biologic medications and were currently taking an originator biologic (Remicade®, Humira®, or Simponi®)
- 76% of respondents had heard about SEBs, mostly from a physician or nurse
- 23% had heard about SEBs from the GI Society/seminar

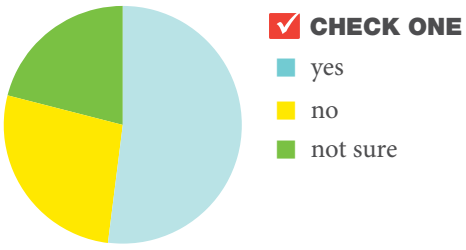
SUBSEQUENT ENTRY BIOLOGICS

HOW do you think subsequent entry biologics are different from originator biologics?



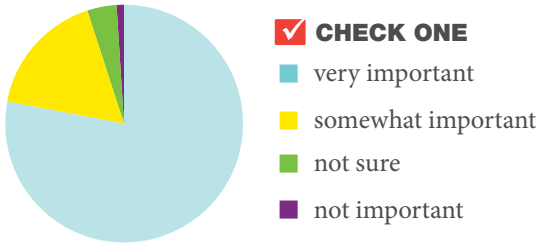
ALL medications have a brand name and an international non-proprietary (scientific) name (INN). For example, *Aspirin*® is the brand name and *acetylsalicylic acid* is the INN. If two medicines have the same INN, does this suggest to you, or imply that a patient could safely switch between the products during a course of treatment and expect the same effectiveness and safety?

» 52% said yes, 27% said no, and 21% were not sure

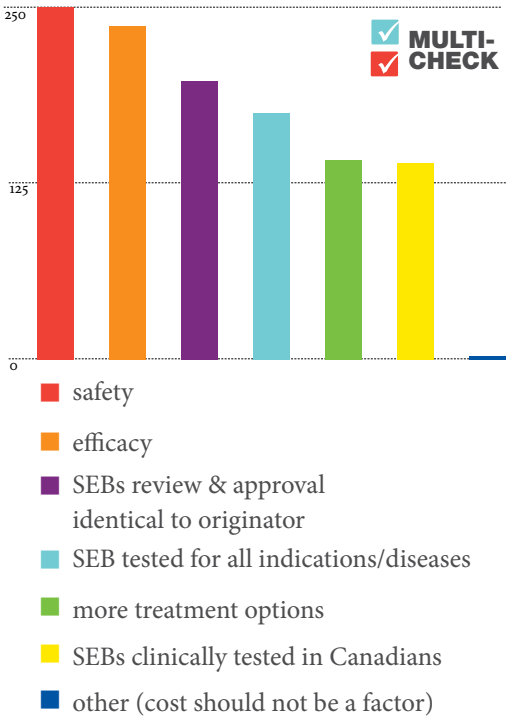


HOW important is it to you for your physician to have the sole authority to decide, together with you, the most suitable biologic medicine to use to treat your disease?

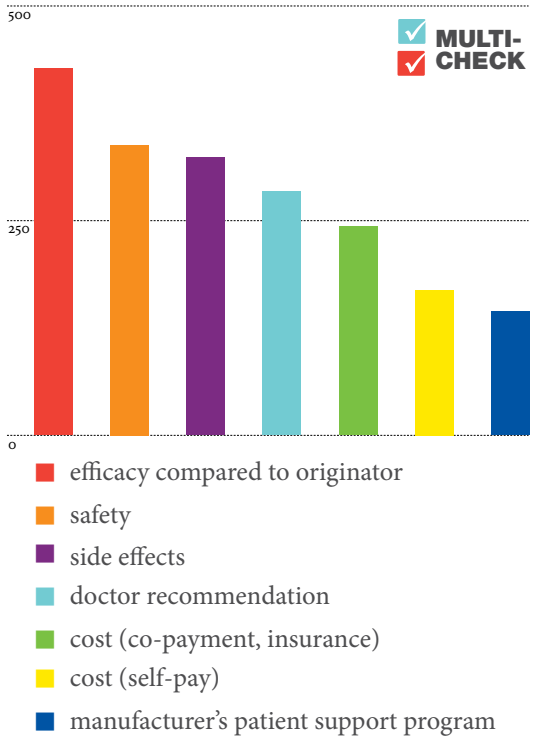
» 78% said very important, 17% said somewhat important, 4% were not sure, and 1% said it was not important



WHAT factors are important to you for biosimilar/subsequent entry biologics regulation in Canada?

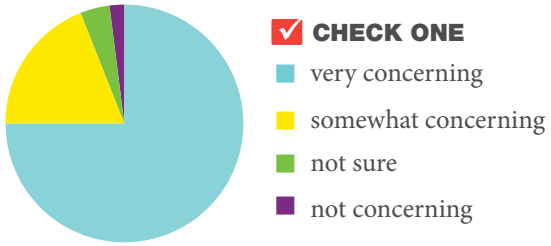


WHAT would be the most important consideration in choosing subsequent entry biologic treatment?



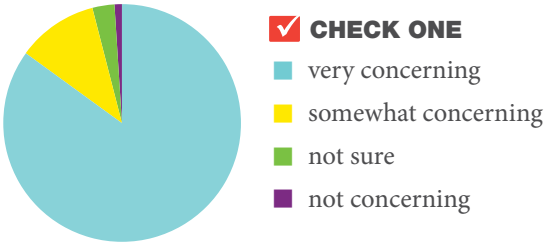
HOW concerning would it be for you if the pharmacist or government/private insurance plan made the determination which biologic (innovator or biosimilar) to dispense to you on **initiation of treatment**?

» 75% said very concerning, 19% said somewhat concerning, 4% were not sure, and 2% said it was not concerning



HOW concerning would it be for you if the pharmacist or government/private insurance plan made the determination which biologic (innovator or biosimilar) to dispense to you **during your treatment**, including maintenance therapy (switch medicines without telling you)?

» 85% said very concerning, 11% said somewhat concerning, 3% were not sure, and 1% said it was not concerning



CONCLUSION

Canadians with inflammatory bowel disease who responded to our survey were quite familiar with biologics, in fact, 77% are currently taking these medications. However, while many had heard about SEBs, they expressed confusion and concern around the use of subsequent entry biologics. In particular, they were concerned about the safety and efficacy of these products for treatment of inflammatory bowel disease, and how Health Canada will regulate them. They do not want these medications for the wrong reasons, that is, simply because they might be less expensive than the originator medications. These individuals are concerned about the possible switching of drugs between the originators and biosimilars, particularly if the government or private insurance plans switch patients to these drugs without their knowledge or consent.

Not surprisingly, 95% said that it was important for their physician to have the sole authority to decide, together with them, the most suitable biologic medicine to use to treat the disease. This patient directive is very strong.

Acknowledgements

We thank these gastroenterologists, who helped us recruit patients for this survey: Dr. Guy Aumais, Dr. Robert Bailey, Dr. Brian Bressler, Dr. John Marshall, and Dr. Remo Panaccione.

Gastrointestinal Society
GAIL ATTARA, Chief Executive Officer
gail@badgut.org |1-866-600-4875
www.badgut.org

We received funding from Janssen Inc. to conduct this independent survey.