Canadian Patient And Caregiver Perspectives On Subsequent Entry Biologics For Inflammatory Bowel Disease

Gail Attara[1], Robert Bailey[2], Brian Bressler[3], John Marshall[4], Remo Panaccione[5], Guy Aumais[6]

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Gastrointestinal Society
Canadian Society of Intestinal Research

Background

Biologic medications have revolutionized the treatment of inflammatory bowel disease (IBD). Subsequent Entry Biologics (SEBs) are not identical in structure, therapeutic equivalence, or approved indications, but are biosimilar to an original biologic medication. Given the recent presence of SEBs in Canada, there might be implications for IBD patients and/or caregivers.

Aims

To understand the perspectives of IBD patients and caregivers regarding SEBs and how Canadian drug programs will manage these products.

Methods

During early 2015, the Gastrointestinal Society hosted a survey on its two websites: www.badgut.org and www.mauxdeventre.org. The physicians included in this project shared the links with their patients. To qualify, survey participants confirmed they either had IBD or were a caregiver of a person with IBD. Questions included demographic information, disease characteristics, as well as their understanding and opinions regarding SEBs, including the possibility of switching from an innovator biologic to a biosimilar.

Conclusions

IBD patients who responded to our survey were quite familiar with SEBs, although they expressed high concerns around safety, efficacy, and regulatory process. The patient choice directive is very strong and shows the need for open dialogue among patients, physicians, manufacturers, and regulatory bodies for the safe introduction of SEBs into the marketplace.

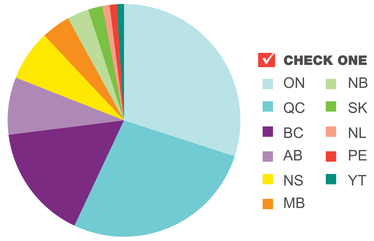
1. Gastrointestinal Society, Vancouver, BC
2.University of Alberta, Edmonton, AB
3.University of British Columbia, Vancouver, BC
4.McMaster University, Hamilton ON
5.University of Calgary, Calgary, AB
6.Université de Montréal, Montréal, QC

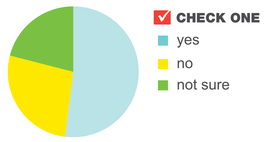
Results

423 respondents: 317 English, 106 French. 68% had Crohn's disease, 30% ulcerative colitis, 2% indeterminate IBD. 77% had at least a basic understanding of biologics and were currently prescribed an originator biologic (Remicade®, Humira®, or Simponi®). 76% had heard about SEBs. Majority of patients selected cost then manufacturing process, as the top ways SEBs might differ from originator biologics. 52% believed that having the same international non-proprietary name (INN) implied that patients could safely switch between the products during a course of treatment and expect the same effectiveness and safety, even though Health Canada states they are not interchangeable. 95% of those surveyed said that it is important their physician, together with them, have sole authority to decide the most suitable biologic medication to treat their disease. The most important considerations in choosing SEB treatment for patients were safety, efficacy, and that both the originator and biosimilar have identical review and approval processes. 96% of respondents were concerned about limited medication choice during induction and/or maintenance therapy.

DEMOGRAPHICS

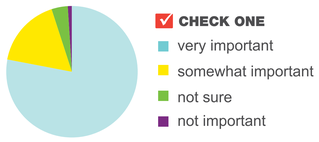
- respondents were from all ten provinces and Yukon, with close proportional representation to the corresponding populations
- the majority (66%) were female
- 91% were between 18-59 years of age, less than 1% were caregivers of children with IBD (n=5), and the remainder were older than 59
- 68% had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





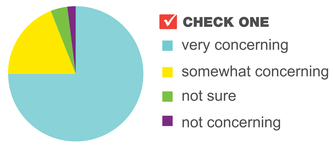
ALL medications have a brand name and an international non-proprietary (scientific) name (INN). For example, Aspirin® is the brand name and acetylsalicylic acid is the INN. If two medicines have the same INN, does this suggest to you, or imply that a patient could safely switch between the products during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

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



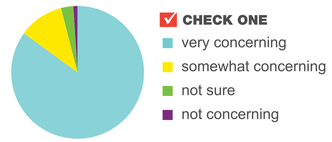
HOW important is it to you for your physician to have the sole authority to decide, together with you, the most suitable biologic medicine to use to treat your disease?

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



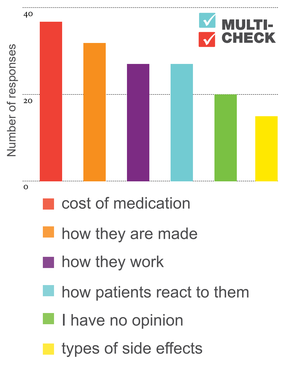
HOW concerning would it be for you if the pharmacist or government/ private insurance plan made the determination which biologic (innovator or biosimilar) to **dispense to you on initiation of treatment**?

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

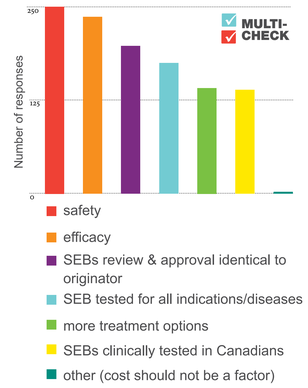


HOW concerning would it be for you if the pharmacist or government/ private insurance plan made the determination which biologic (innovator or biosimilar) to **dispense to you during your treatment, including maintenance therapy** (switch medicines without telling you)?

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



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



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

The **Gastrointestinal Society**, a Canadian registered charity patient group, represents gastrointestinal and liver patients on a variety of health care fronts, including access to medications.

For access to all this study's results contact:

Gail Attara, President & CEO
Gastrointestinal Society
gail@badgut.org | www.badgut.org

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