Oncologists' Perspectives on Biologic Substitution

Michael Reilly, Esq,[1] and Andrew Spiegel, Esq[2]

[1]Alliance for Safe Biologic Medicines, Arlington, VA, USA; [2]Global Colon Cancer Association, Bala Cynwyd, PA, USA

Introduction

- Biosimilars are similar but not identical to originator biologics
- In an increasingly resource-constrained environment, pharmacy or hospital-level substitution of biologics with biosimilars is becoming a commonly adopted approach to realize cost savings
- As a result, physicians may be excluded from decisions regarding the treatment of their patients
- The Alliance for Safe Biologic Medicines (ASBM) conducted 15-minute web-based surveys among biologics prescribers, including oncologists, around the world to determine their opinions on biologic substitution

Methods

Eligibility Criteria

- ✓ Must have been in practice for at least one year
- ✓ Must prescribe biologic medicines in their practice
- ✓ Specialize in one of seven therapeutic area: oncology, dermatology, endocrinology, neurology, gastroenterology, nephrology, or rheumatology

Online Surveys

- Surveys were administered in June 2016 by Industry Standard Research, LLC.
- Prescribers were asked to rate the:
  1. importance of authority to decide the most suitable biologic for their patients
  2. importance of designating a biologic as "dispense as written" (DAW, or equivalent)
  3. acceptability of biologic substitution
  4. importance of notification of biologic substitution

Regional Differences in Survey Questions

- Australia survey did not have a DAW question
- US survey did not have a "sole authority" question or an "acceptability of pharmacist substitution" question and had a different response scale for the "DAW" question and the "importance of notification" question
- Some questions were worded slightly differently from country to country because of regional variations in clinical practice

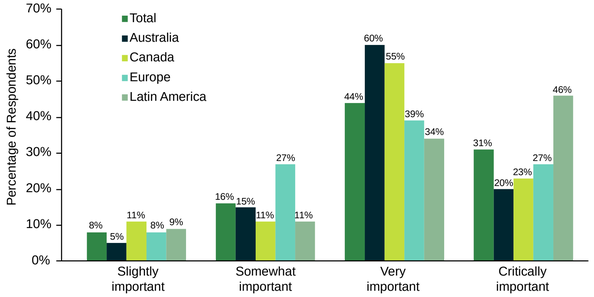
Results

- A total of 1,856 responses were received:
  - Europe: 470 (25%)
  - Canada: 427 (23%)
  - USA: 400 (22%)
  - Latin America: 399 (21%)
  - Australia:160 (8.6%)
- Across regions, most prescribers were from the hospital setting, and most had ≥ 11 years in practice
- Between 10% and 25% of prescribers were oncologists:
  - Europe: 16%
  - Canada: 10%
  - USA: 16%
  - Latin America:18%
  - Australia: 25%

Survey Responses From Oncologists

How important is it for you, as the prescribing physician, to have the sole authority to decide, together with your patient, the most suitable biologic medicine for your patient?

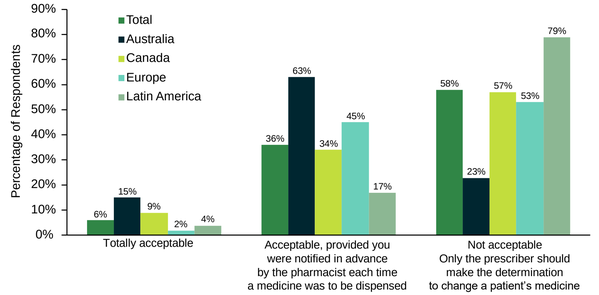
Most respondents feel that it is either "Very Important" or "Critically Important" for them to decide which biologic medicine is dispensed to their patients.



None of the respondents felt that this issue was "Not Important".
The US survey did not have a "sole authority" question.

How acceptable would it be for you if the pharmacist made the determination which biologic (innovator or biosimilar) to dispense to your patient on initiation of treatment?

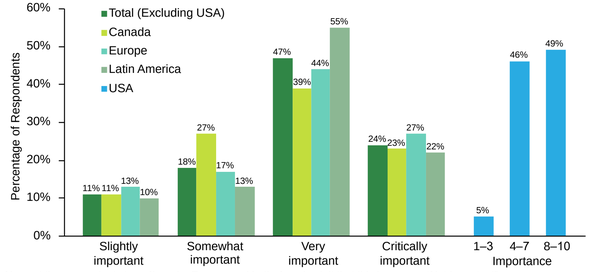
Approximately two-thirds of respondents (63%) believe that pharmacy-level substitution is acceptable, provided that they are notified in advance.



The US survey did not have an "acceptability of pharmacist substitution" question.

In a situation where substitution by a pharmacist was an option in your country or province, how important would it be to you to have the authority to prevent pharmacist substitution/designate a biologic medicine as 'dispense as written' or 'do not substitute'?

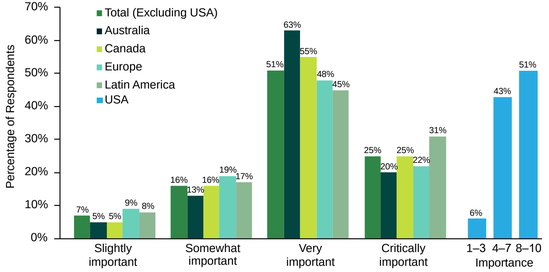
Most respondents feel that it is important for them to have the authority to prevent pharmacist substitution.



None of the respondents from Canada, Europe, and Latin America felt that this issue was "Not Important".
The US survey had a different response scale for this question: 1 = Not Important at All; 10 = Very Important.
The Australia survey did not have a "DAW" question.

How important would it be for you to be notified by the pharmacist that your patient has received a biologic medicine other than the one you prescribed (eg, if a reference biologic medicine was substituted for its biosimilar)?

Most (83%) respondents feel that it is important that they be notified if the prescribed biologic medicine has been substituted.



2% of oncologists in Europe felt that this issue was "Not Important".
The US survey had a different response scale for this question: 1 = Not Important at All; 10 = Very Important.

Conclusions

- Our survey indicates that most oncologists believe it is important for them to be able to control which biologic—original product versus biosimilar—they prescribe for their patients.
- This is likely to become increasingly important with the availability of biosimilars used for curative intent.
- When a biologic substitution occurs, it is important to accurately trace which biologic medicine a patient receives. This can be achieved through the use of distinguishable non-proprietary names as well as notification and documentation of any substitutions that occur after a medicine has been prescribed.
- While controlling costs associated with an episode of cancer care is a priority, it is important to keep clinical decisions in the hands of clinicians and their patients.

Disclosure

- The ASBM is a group of physicians, pharmacists, patients, researchers, manufacturers, and others working together to promote the safe introduction and use of biosimilars. This survey was funded by ASBM, Amgen Inc., and AbbVie Inc.

For questions about this study, please contact Michael Reilly: Michael@safebiologics.org.

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