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Patients' Knowledge and Beliefs about Biosimilars

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Patient Survey on Biosimilars

- WHAT is current status of biosimilars?
  - Increasing number of biosimilars approved and available for use
  - Increasing evidence about safety, effectiveness, and quality
  - Uncertainty about long-term outcomes and interchangeability
- WHY were patients surveyed about biosimilars?
  - Learn patient knowledge, beliefs, and opinions about biosimilars
  - Identify sources of patient and public information
  - Engage patients to contribute to evolving understanding of biosimilars
- HOW will learning from survey be used to engage patients?
  - Develop up-to-date information accessible by patients and public
  - Assure balanced approach to promote informed decision making

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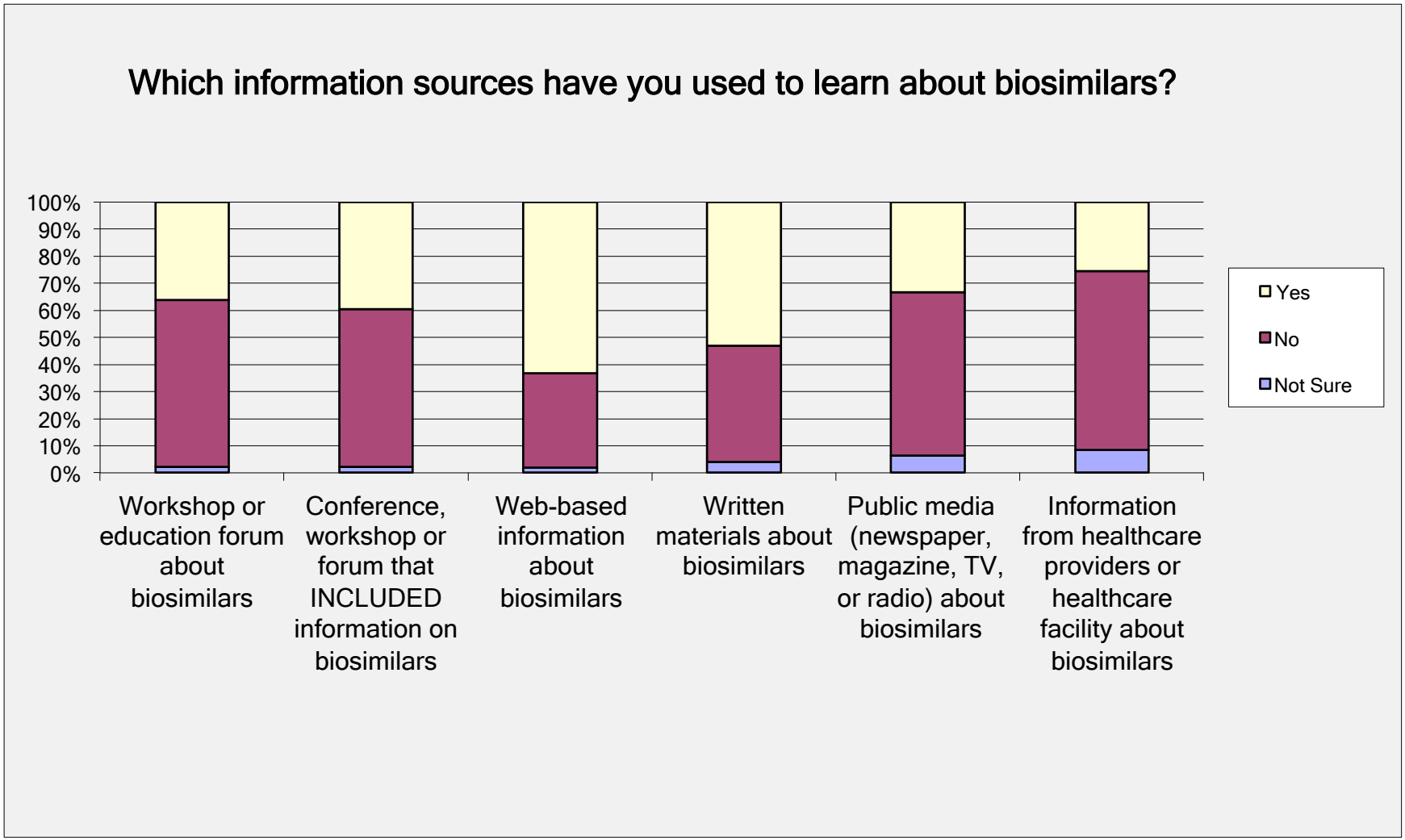
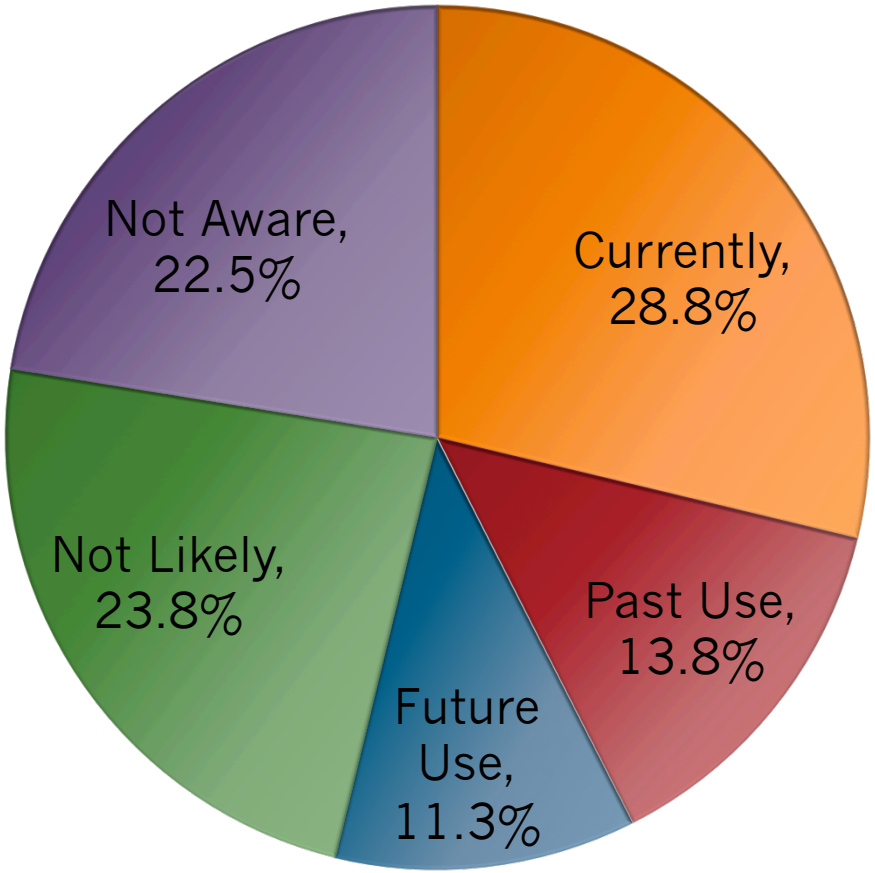
How was Survey Implemented

- Canada-wide Web-based survey
  - Directed to existing patient cohort of 2,000+
  - Secondary distribution to patient organizations and umbrella associations
  - Promoted through Facebook and Twitter
- Preliminary Findings (May-June 2016)
  - Respondents = 320; Complete survey = 200
  - Conditions = inflammatory, blood disorders, immune-related, diabetes, cancers, multi-systemic, lysosomal storage, cardiovascular

Biosimilar Information Sources



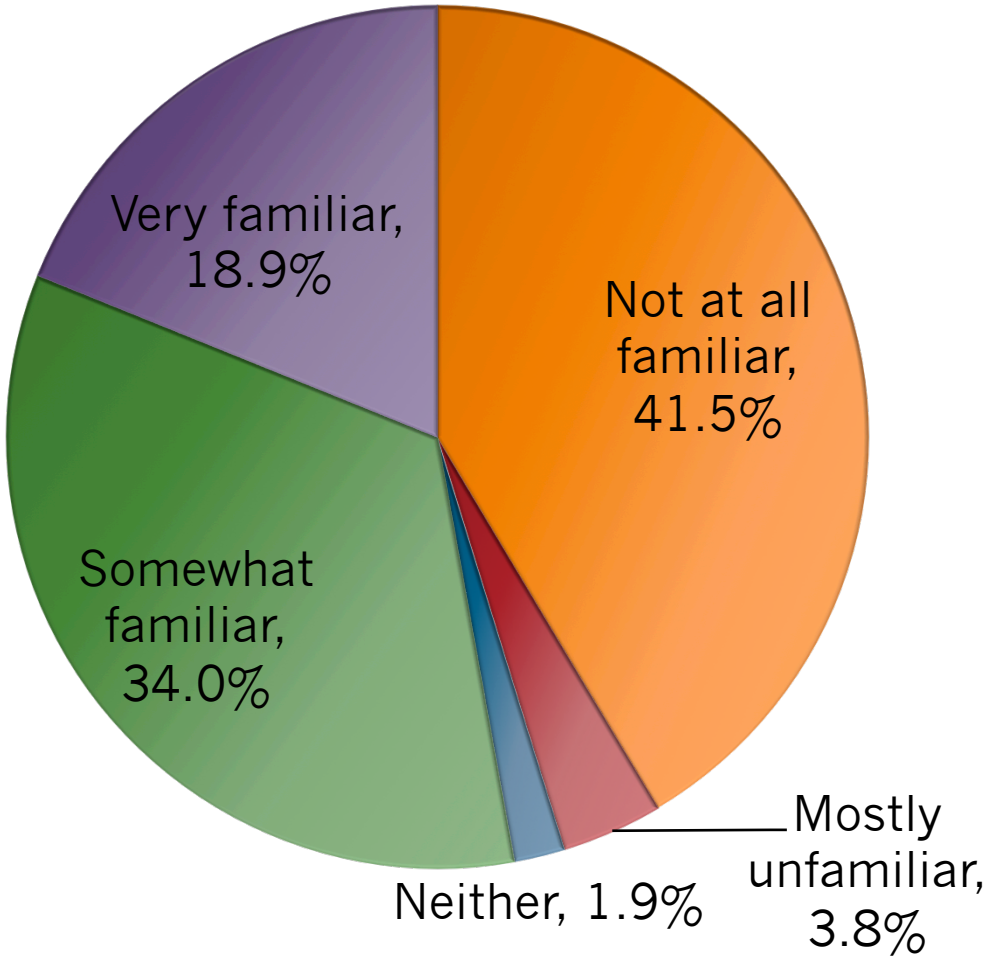
Respondents' Use of Biologics



Preliminary results Web-based survey (May - June 2016) n = 320

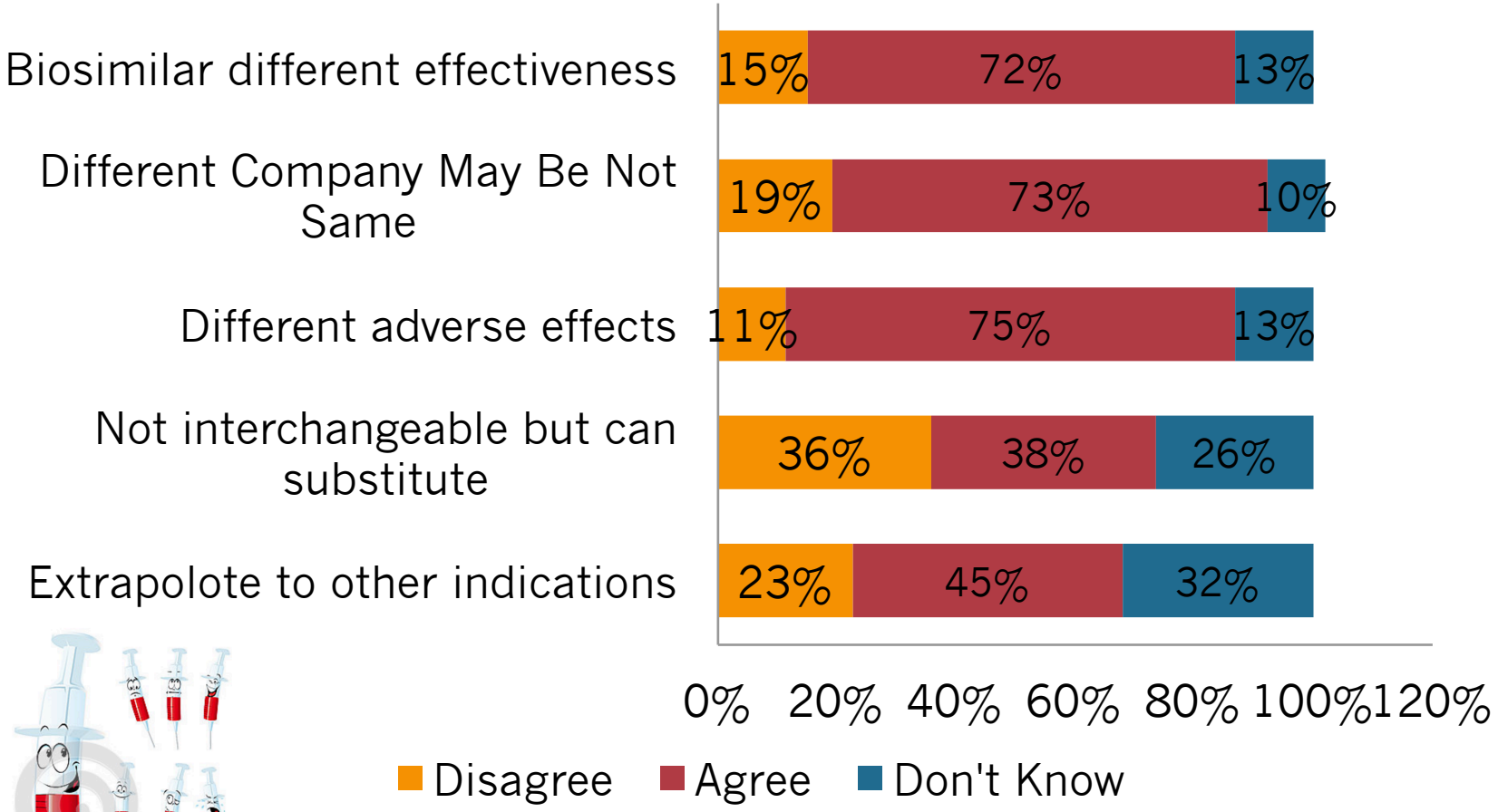
Familiar with Definition of Biosimilars

Prior to survey, were you familiar with the definition of biosimilars? n=200



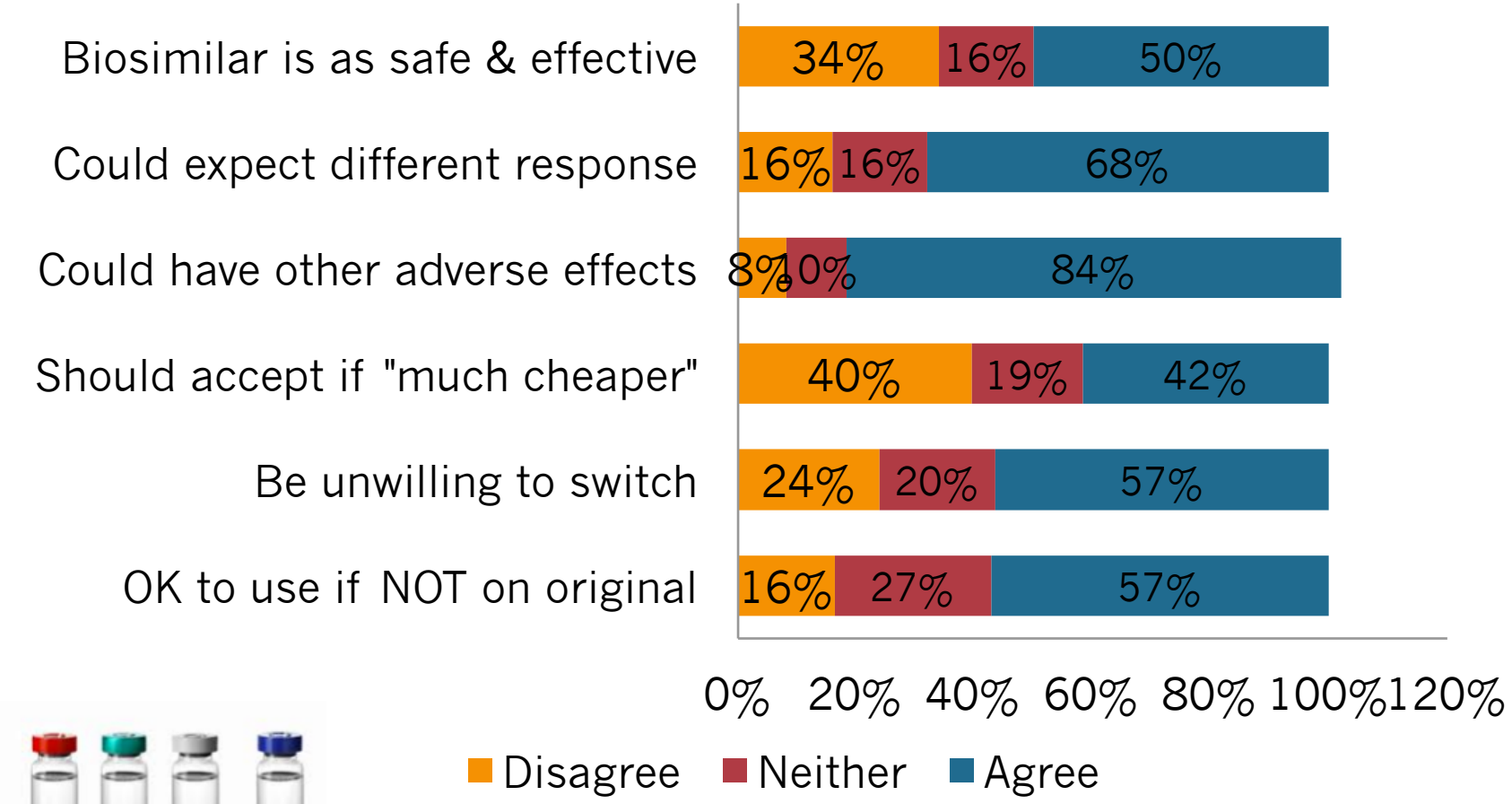
Patient Perceptions of Biosimilars

To what degree do you agree that biosimilars compared to original …?



Patient Perceptions of Biosimilars

To what degree do you agree a biosimilar as compared to the original …?



Patient Perceptions of Biosimilars

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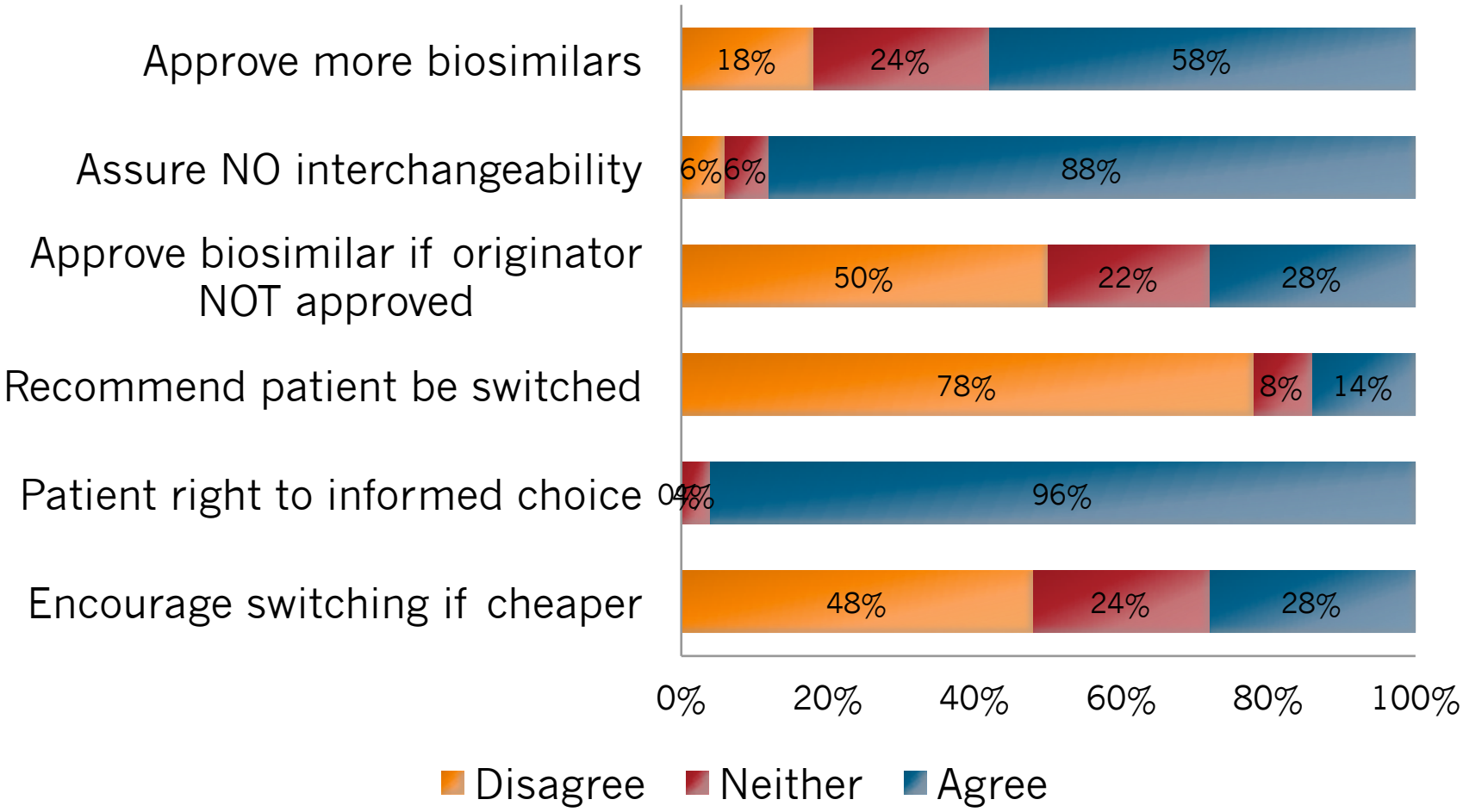
Should government regulator, drug plan, HTA, or payer do following?



Attitudes About Use of Biosimilar

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1 = disagree completely; 3 = neither agree nor disagree; 5 = agree completely

Do you agree with statement regarding switching …	Avg (1-5)
Same scientific name (INN) implies identical drug	3.3
All biologics should have unique INN or suffix	2.7
Patient should receive exact biologic prescribed	3.1
Patient MAY be switched to biosimilar with consent	3.2
Patient SHOULD be switched if biosimilar lower price	2.1
Patient NOT on original MAY be given biosimilar	3.1
Patient NOT on original SHOULD be given biosimilar	2.7
OK to use biologic for indicators other than approved	2.7
Need monitoring plan to track adverse events	3.5
OK to promote preferential use of biosimilars	1.8
Collect real-world data to update usage guidelines	3.7
Biosimilars save money to allocate to other needs	2.9

Summary Patient Attitudes re: Biosimilars - 1

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- Web is most frequent source of information about biosimilars (65%); healthcare provider least frequent (25%)
- More than half now, in past or in future use biologic medicines; one-fourth will not
- 2/5 respondents were unfamiliar with biosimilars; 1/5 very familiar
- About 3/4 to 4/5 believe biosimilars are different and will have different adverse effects than originator
- About 2/5 believe may substitute biosimilar for originator; about 2/5 believe may NOT substitute
- About ¼ say okay to extrapolate biosimilar use to other indications of originator even without clinical trials; about ¼ say not okay to extrapolate

Summary Patient Attitudes re: Biosimilars - 2

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- About ½ agree biosimilar as safe and effective as originator; about 1/3 disagree
- About 2/3 agree biosimilar could have a different effect than originator
- More than 4/5 agree could have different adverse effects than originator
- About 2/5 believe patients should accept a biosimilar if it is much cheaper than originator; 2/5 believe patients should not accept on basis of price
- About 3/5 would be UNWILLING to switch from originator to biosimilar
- About 3/5 say it is OKAY to prescribe biosimilar if patient has no experience with originator

Summary Patient Attitudes re: Biosimilars - 3

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- About 3/5 agree government should approve more biosimilars
- One-half say should NOT approve biosimilar if originator not approved for use in country
- Almost 9/10 say government (drug plans) should assure NO interchangeability
- Almost 8/10 say government (HTA) should NOT recommend switching from originator to biosimilar
- Almost 100% say patients have right to informed consent
- Almost one-half say governments should NOT encourage switching on basis of "cheaper" cost; about ¼ agree should encourage switching based on cost

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Recommendations

- Develop and make available to all patients accurate, balanced and evidence-based information about biosimilars.
- Establish means to address patients' concerns in open and honest ways.
- Provide tools to monitor patient use of biologics that can track outcomes to specific biologic.
- Develop and implement platforms to collect and analyze real-world evidence to support and update appropriate use guidelines.
- Engage patients as partners in every step of the process

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Resources

- **Market Access and Uptake of Biosimilars (Steering Group of the Process for Corporate Responsibility in the field of Pharmaceutical)**
  http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform_access/index_en.htm

- **European Medicines Agency**
  Biosimilars
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000318.jsp&mid=WC0b01ac0580281bf0

- *Medicines Safety Monitoring*
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000456.jsp&mid=WC0b01ac05801ae8fb

- *Guidance document for patient organisations on EU pharmacovigilance legislation:*
  http://www.eu-patient.eu/Initatives-Policy/Policy/Pharmaceutical-Package/Pharmacovigiliance/

- **Patient Organisations' Resources**
  The International Alliance of Patients' Organisations Biosimilars Toolkit
  https://www.iapo.org.uk/biosimilars-toolkit

- National Rheumatoid Arthritis Society (UK) Position Paper on Biosimilars
  http://www.nras.org.uk/data/files/About%20RA/How%20is%20RA%20managed/NRAS%20Biosimilars%20Position%20Paper%20Final.pdf

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