Canadian Organization for Rare Disorders

Pre-Election Webinar Series: Can Canada Deliver the Best Healthcare for all Canadians?

June 26, 2019 | 12pm – 1pm

WEBINAR: OPPORTUNITIES AND PITFALLS IN BUILDING A NATIONAL DRUG LIST - LESSONS LEARNED

Today's speakers:

David Page
National Director of Health Policy, Canadian Hemophilia Society

Whitney Goulstone
Executive Director, Canadian Immunodeficiencies Patient Organization

Mina Mawani
President and CEO, Crohn's and Colitis Canada

Durhane Wong-Rieger
President & CEO, Canadian Organization for Rare Disorders (CORD)

CROHN'S AND COLITIS CANADA

ACHIEVING PATIENT STABILITY

crohnsandcolitis.ca

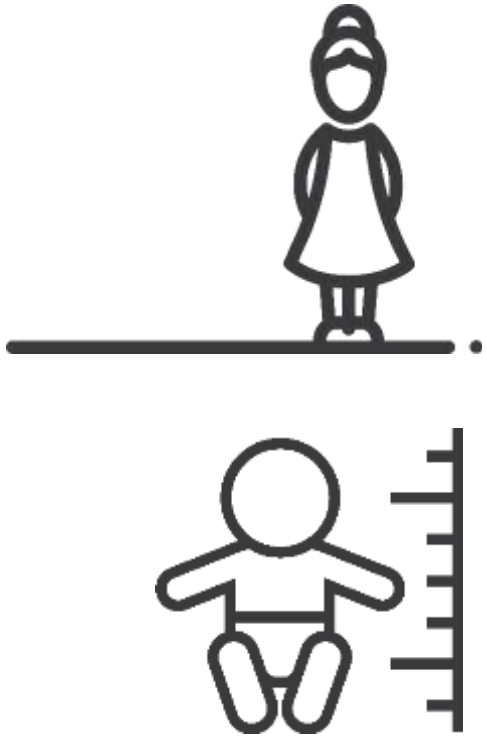
Crohn's and Colitis Canada
Crohn et Colite Canada

Canada continues to have among the highest prevalence of IBD in the world

Today, approximately **270,000** Canadians live with Crohn's or colitis – that's **1 in every 140** Canadians

By 2030 it is estimated that nearly 403,000 Canadians will have a diagnosis of IBD

IBD in Children



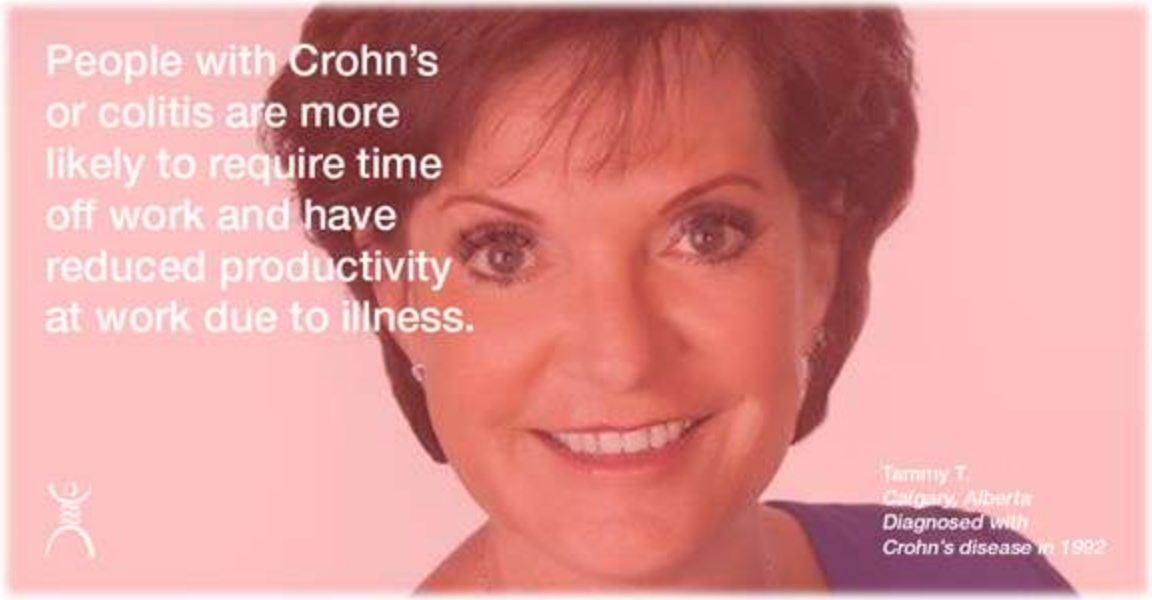
- Over 7,000 children and youth are living with IBD in Canada
- This represents a 53% increase in children with IBD over the last 10 years
- New diagnoses are rising most rapidly in children <5 years old
- In 2030, we project that almost 14,000 children and youth will be living with IBD living in Canada
  - almost double compared to 2018
  - almost triple compared to 2008

Seniors with IBD are the fastest growing group

- Approximately one out of every 160 individuals over the age of 65 in Canada is living with IBD
- The Canadian healthcare system must be prepared for a rising number of senior patients living with Crohn's or colitis
- Seniors are the fastest growing group of people living with Crohn's or colitis, which will present a challenge to patients, families, and care providers
- The rising rate in seniors is the result of new diagnoses made in this population as well as the advancing age of previously diagnosed patients who carry the disease with them for the rest of their lives

Quality of Life

- People living with IBD have significantly lower quality of life when compared to that of the general population
- IBD often affects individuals as they pursue employment, family planning, and personal milestones
- IBD affects the quality of life of those afflicted and their caregivers



Our position on biosimilars

Crohn's and Colitis Canada position statement:

Biosimilars or Subsequent Entry Biologics (SEBs)

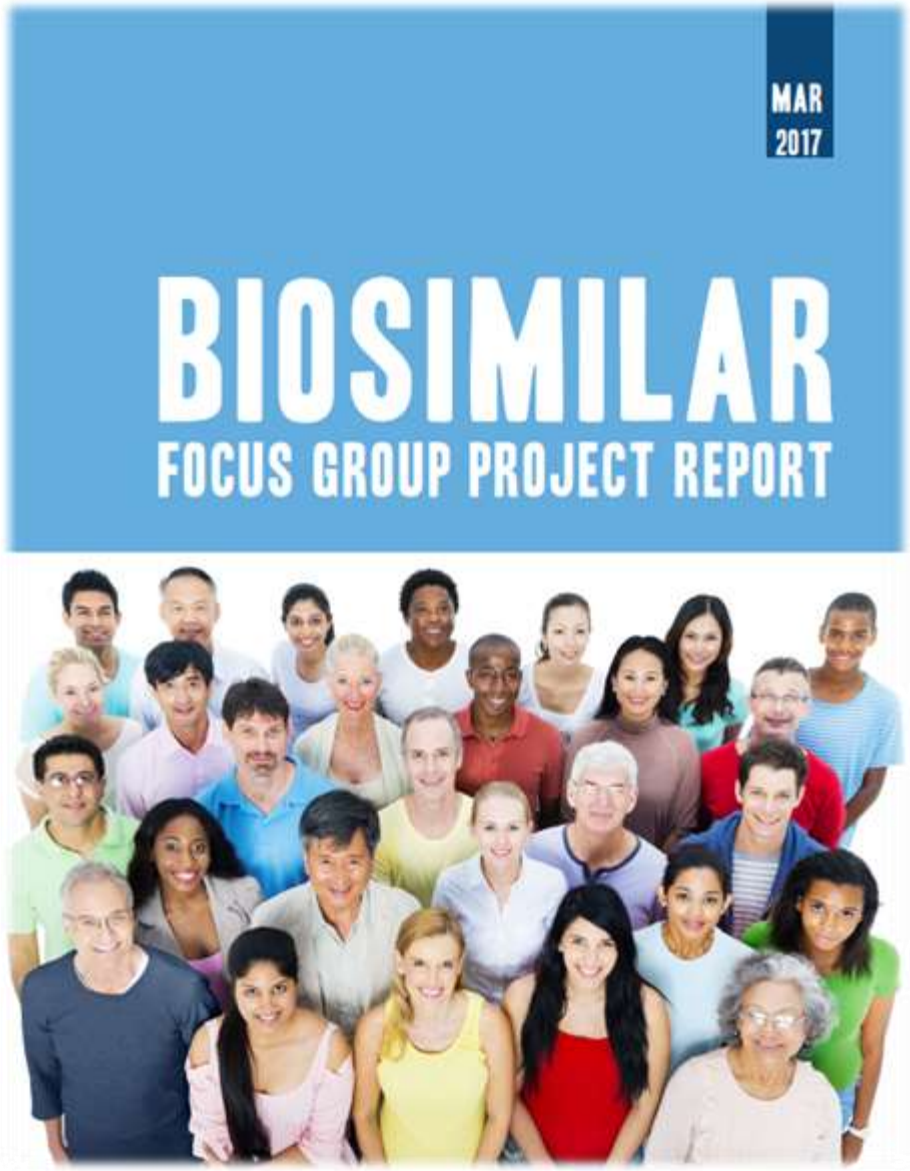
October 2016

Background

Biologics are drugs produced from living organisms. In the context of inflammatory bowel disease (IBD), biologics are drugs designed to target and block the cells responsible for inflammation. As patents expire on existing innovator biologics, drug manufacturers are developing new options based on existing biologics. These new drugs are called subsequent entry biologics (SEBs), though they are also commonly referred to as biosimilars. Unlike traditional generic drugs, biosimilars are not identical to their innovator biologic. This is due to complex manufacturing processes. Even the smallest variations in the manufacturing process between an innovator biologic and a biosimilar may have unforeseen and unanticipated impacts. Biosimilars represent a potentially effective and cost saving option for the management of IBD that may enhance access to biologic therapy.

Full statement: http://www.crohnsandcolitis.ca/Crohns_and_Colitis/documents/get-involved/advocacy/CCCBIOLOGICPOSSTATEMENT1016.PDF

Patient Biosimilar Focus Group: IBD patients reactions to biosimilars



Patient Concerns

Crohn’s and Colitis Canada’s January 2018 patient survey reveals gaps in patient education.

Clinician Concerns: The ‘Nocebo Effect’

Government Action on Biosimilars to Date

- Most public drug plans have preferential listings for biosimilars
  - (This includes provincial plans and federal plans (inmates, military personnel, and Indigenous Canadians)
  - Does not include Saskatchewan and Prince Edward Island

  - The Government of British Columbia announced on May 27 a forced switch policy

  - Crohn's and Colitis Canada is asking B.C. and all other governments to carefully consider several key factors in implementing a switch policy
    - Safety and efficacy, the accessibility of patient support programs, infrastructure and availability of infusion centres, and patient monitoring

Conclusion

- Patient choice is paramount: ‘no treatment is one size fits all’
  - Many other Canadian patient organizations agree on this principle

- Canadian IBD scientists and gastroenterologists are not in consensus regarding the safety and efficacy of a switch

Lessons From Canada's Blood System

IS A ONE SUPPLIER SYSTEM BETTER?

Overview

- Canada's need and use for plasma products
- Look at past 5 years – the state of affairs leading up to the last RFP for plasma products
- The most recent tender for plasma products
- The fallout
- Lessons learned?

Canadian Blood Services?

- Currently, the plasma protein products (PPP) budget is roughly %60 CBS entire operating budget
- PPPs are made from plasma
- PPP's make up a variety of treatment including:
  - Immune Globulin (Immunodeficiency, Gullain Barre, CIDP, ITP)
  - Albumin (burn victims and emergent patients)
  - C1 Esterase (Hereditary Angiodema)
  - Alpha 1 antitrypsin

2012-2017

- Large introduction of home use IG in Canada (Subcutaneous IG – SCIG)
- CBS RFP for IG from 2012-2017 has very few options. Contract 1 SCIG, and 2 IVIG (CSL Behring and Grifols)
- At the time, only one manufacturer of SCIG in Canada
- Development of provincial SCIG programs, with dedicated SCIG nurses (BC, AB, MB, ON)
- SCIG becomes method of treatment of choice: both of patients and physicians
- In 2017, new PPP RFP with many more players…

IG Transition

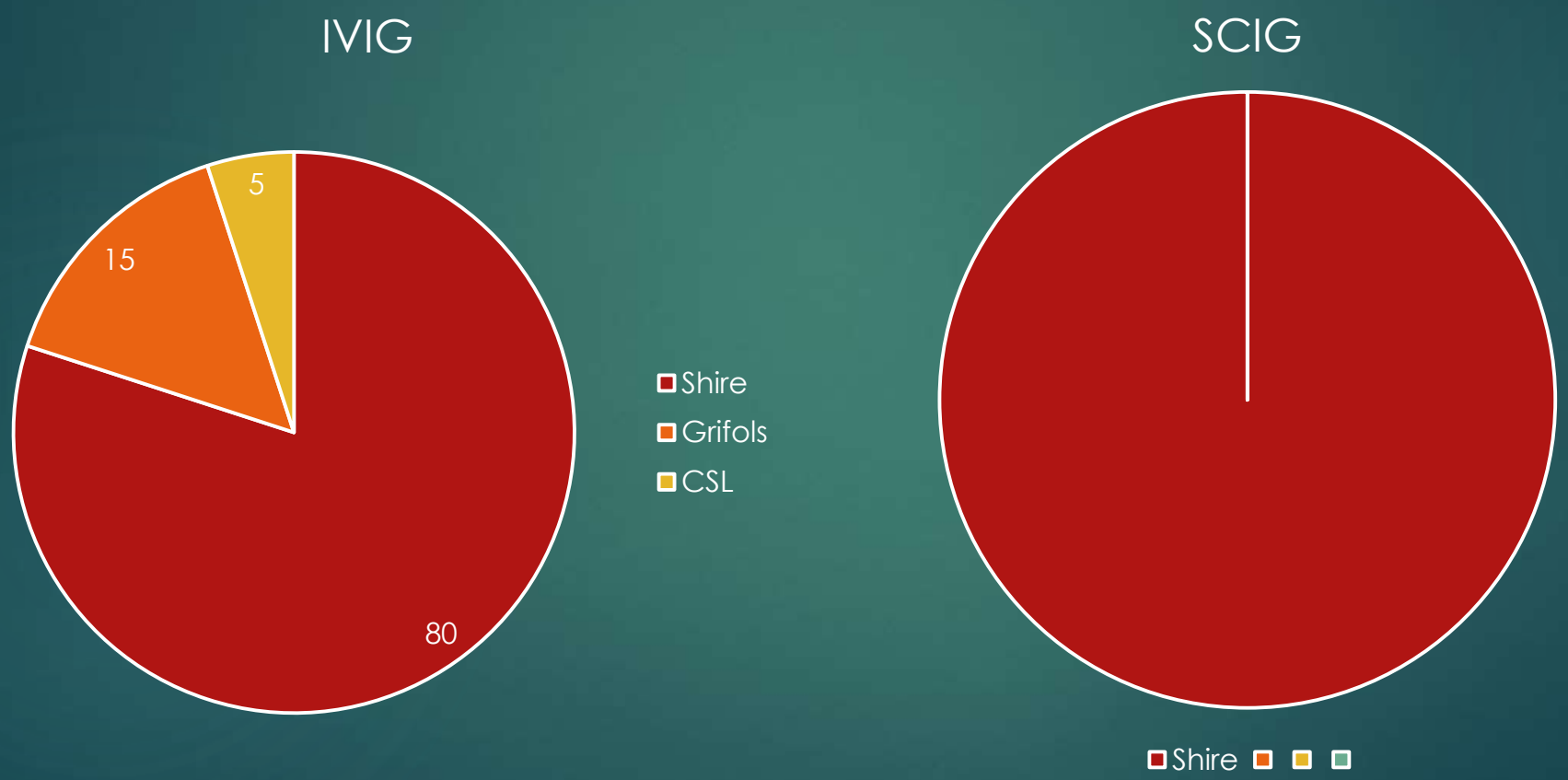
New IG Products

Product
Privigen
Gamunex
IGIVnex
Gammaguard Liquid
Panzyga
Hizentra

Old IG Products

Product
Privigen
Gamunex
IGIVnex
Gammaguard Liquid
Cuvitru

One Supplier Wins (really)



What Happened?

What Happened?

- Cost
- Shire bid aggressively in order to enter the Canadian market
- We knew CBS was running a low cost model – P/Ts wanted to save $$
- Contract saved $198 over 5 years (compared to the previous tender)
- CBS awarded them a 3 year contract with a 2 year option

Forced Switches

- CBS was warned of impending problems (administration constraints, patient upset, adverse reactions, etc.)
- Every patient in Canada (3500) on IVIG and SCIG was forced to switch product with very few exceptions
- CIPO organized a series of "transition events" across Canada, including webinars for patients

What Went Wrong

- Storage/temperature conflicts
- Expired product
- Introduction of the “named patient program”
- Clinic administration limitations
- The biggest fear with single manufacturer…

- Shortage

Shortage of Supply

- Recommendations made to stem use (no new starts!)
- Currently have 500 patients on hold
- It has cost provinces = no real savings
- Vial substitutions
- More switches! And this time it's temporary
- Will it happen again?

Lessons Learned

- Not a perfect process
- Single supplier can be dangerous
- Hidden costs
- Can be expensive (if emergency supply is needed)
- Need a review

Selecting, Procuring and Reimbursing Hemophilia Therapies: a Model for National Pharmacare?

CORD Webinar Series on National Pharmacare

June 26, 2019

David Page

National Director of Health Policy
Canadian Hemophilia Society

Therapies for hemophilia provided at no direct cost by CBS, Héma-Québec

Canadian Hemophilia Society
Help Stop the Bleeding
Société canadienne de l'hémophilie
Arrêtons l'hémorragie

Year	Therapy	Donated blood?
1950s & 1960s	Fresh frozen plasma	Yes
1960s & 1970s	Cryoprecipitate	Yes
1970s to now	Plasma-derived factor concentrates	Yes
1993 to now	Recombinant factor concentrates	No
2019	Monoclonal antibodies (e.g. emicizumab)	No
2021?	Gene therapy	No

CBS & Héma-Québec have formularies

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Fresh components

Red blood cells

Platelets

Fresh frozen plasma

Cryoprecipitate

Stable products

Plasma-derived factor concentrates

IV immunoglobulin

Sub-cu immunoglobilin

C1 esterase inhibitor

Albumin

30+ specialty products

Recombinant factor concentrates

Monoclonal antibodies*

* The first one, emicizumab to treat hemophilia A, was approved (with conditions) on May 30, 2019.

CBS & Héma-Québec have formularies

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- They supply coagulation products to Canadian hospitals for use by patients (in hemophilia, 90% via home treatment)
- Patients and hospitals are not charged
- Provinces pay manufacturers based on provincial consumption
- Private insurers are not involved*

* There is now a precedent for private insurance involvement with sub-cu immunoglobulin

How are products added to formulary?

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CBS		**Héma-Québec**
New "brand"	New "category"	Evaluation by l'INESSS Decision by Deputy Minister 4 to 12 months
Internal CBS evaluation for medical benefit & decision 2 to 4 months	Internal CBS evaluation for medical benefit Economic analysis by CADTH Decision by P/T Committee 1 to 2 years (or more)	

How are products procured?

***Orphan* drug**	**More than one *similar** drug in the market**
Negotiated agreement between manufacturer and CBS or Héma-Québec	"Request for proposal" or tender process

* Factor concentrates are not considered to be "biosimilars" or "follow-on biologics." They may be very "similar" in terms of pharmacokinetics (efficacy) and adverse effects (safety), and can be interchangeable. PK (pharmacokinetics), however, can vary from person to person.

Features of the tender process

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- Tenders are run by CBS and H-Q
- Typically 2- to 3-year contracts with possibility of 2 one-year extensions
- All suppliers are invited to bid
- Multiple suppliers are chosen (e.g. CBS currently distributes 5 factor VIII products and 3 factor IX products)
- Products can disappear after an RFP so patients can be forced to switch
- Licensed (but non-contractual) products are supplied if there is a demonstrated medical need

Features of the tender process

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- 2 patients and 2 physicians are full members of the Selection Advisory Committees
- The number and volume of products to be selected are determined in advance
- A scorecard on product quality is created before the RFP is sent out
- Products are evaluated (full consensus needed on each criterion) as per the scorecard (before price envelopes are opened)
- 70%: product quality and company reliability
  30%: price
- Final decision by CBS or H-Q senior management, endorsed by Boards (provinces have no say)

Advantages of the RFP process

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- Focus on product quality (safety, efficacy)
- Pre-defined criteria to determine quality
- Focus on reliability of suppliers
- Multiple suppliers and products where possible
- Patients/physicians maintain some product choice (not unlimited)
- Competitive process results in low prices (very close to lowest in world)
- Lower prices reduce temptation to constrain utilization (in hemophilia, more factor is better)
- Patient / physician involvement
- Ability to access licensed, non-contractual products if medical need
- Transparency

Disadvantages of the RFP process

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- Not all approved products are available by contract
- Patients can be forced to switch from a product they have used for years
- Patients may not accept the forced switch (their evaluation of product benefits may not be related to safety and efficacy)
- Patient evaluators must respect confidentiality
- Price can trump quality if quality differences are small and price differences are large
- Some manufacturers say that the “focus on price” will mean that they will not bid in future (we have not seen that yet)

Does this look like national pharmacare?

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Principle		Comments
Universal?	Yes	Quebec and RoC formularies (some rivalry is good)
Comprehensive?	Yes	Broad range of products but some limitations on choice following HTAs and RFPs
Accessible?	Yes	No cost to patients, excellent access via hospitals
Portable?	Yes	Differences in products between Quebec and RoC
Public	Yes & No	H-Q is a government body CBS is a private not-for-profit No involvement by private insurers

The devil is in the details

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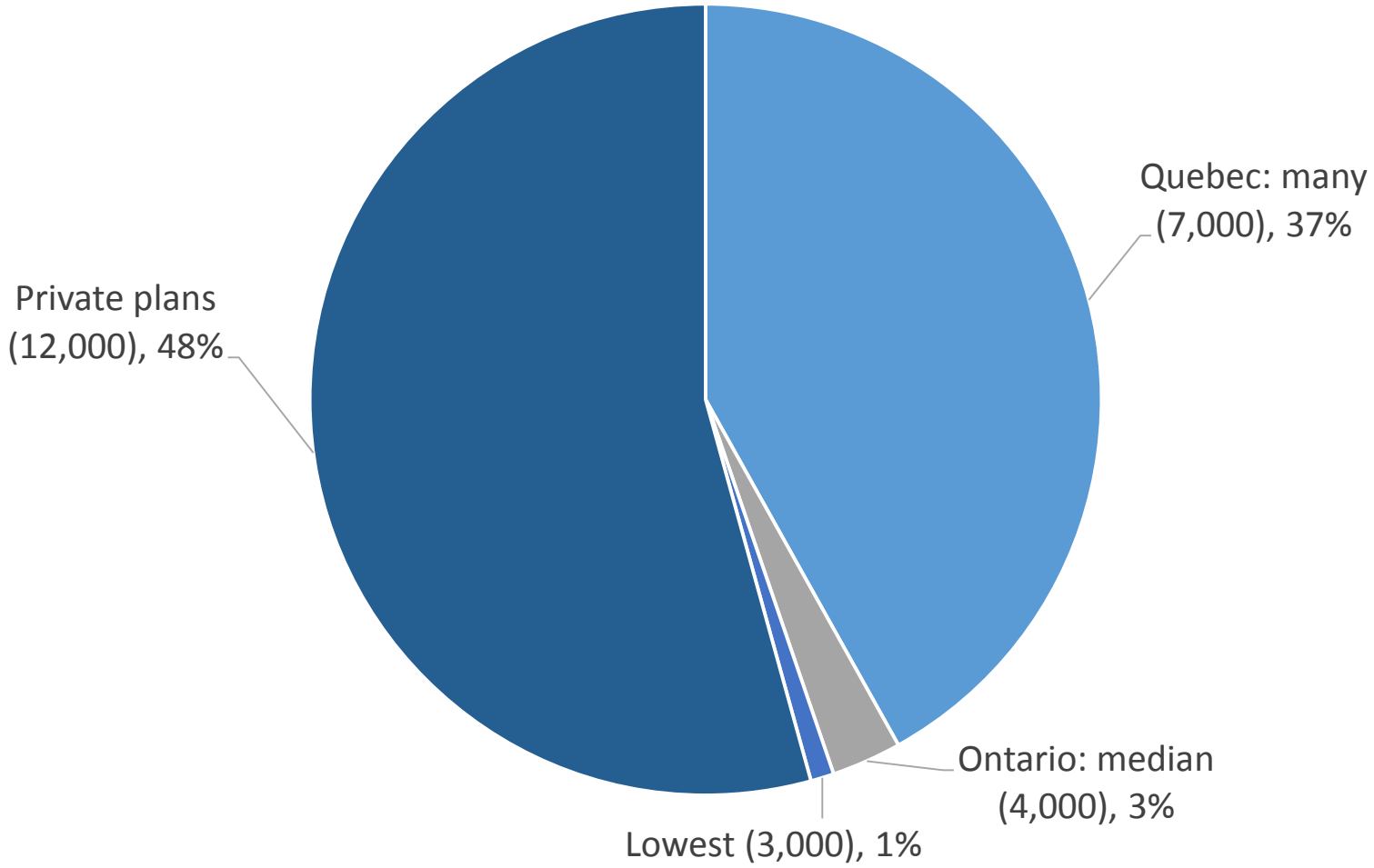
- The HTA process must be of high quality and timely
- The RFP/tender process must be rules-based and rigourous
- Product quality must be given more weight than price (value = benefits vs. cost)
- Expert patient and physician views must be heard and considered in both RFPs and HTAs
- A full range of products to meet patient needs should be procured
- Sole source suppliers should be avoided when possible
- Patients need to be informed and educated: switching is not always bad
- Reasons for product selection should be transparent (e.g. equivalent products saving $ tens of millions

Canadian Organization for Rare Disorders

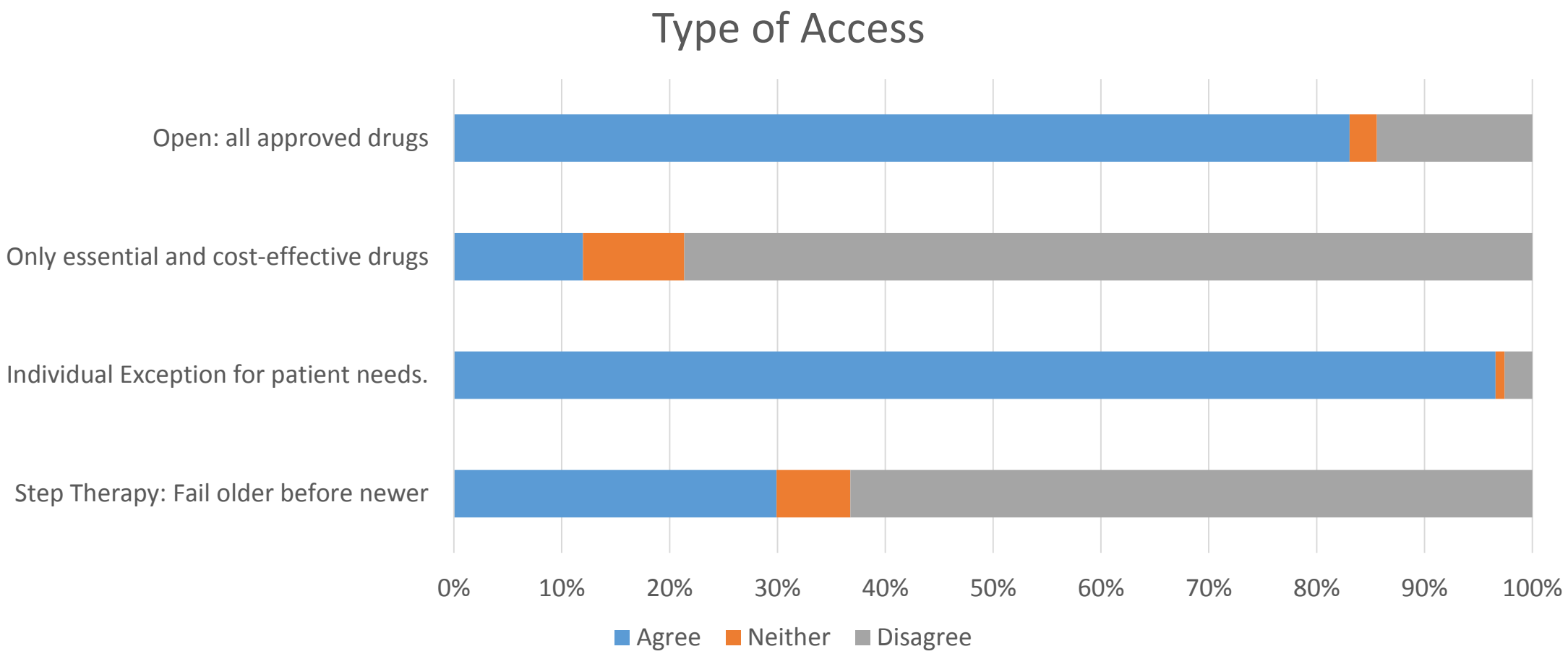
National Formulary Survey: Patient & Group Reponses

June 2019

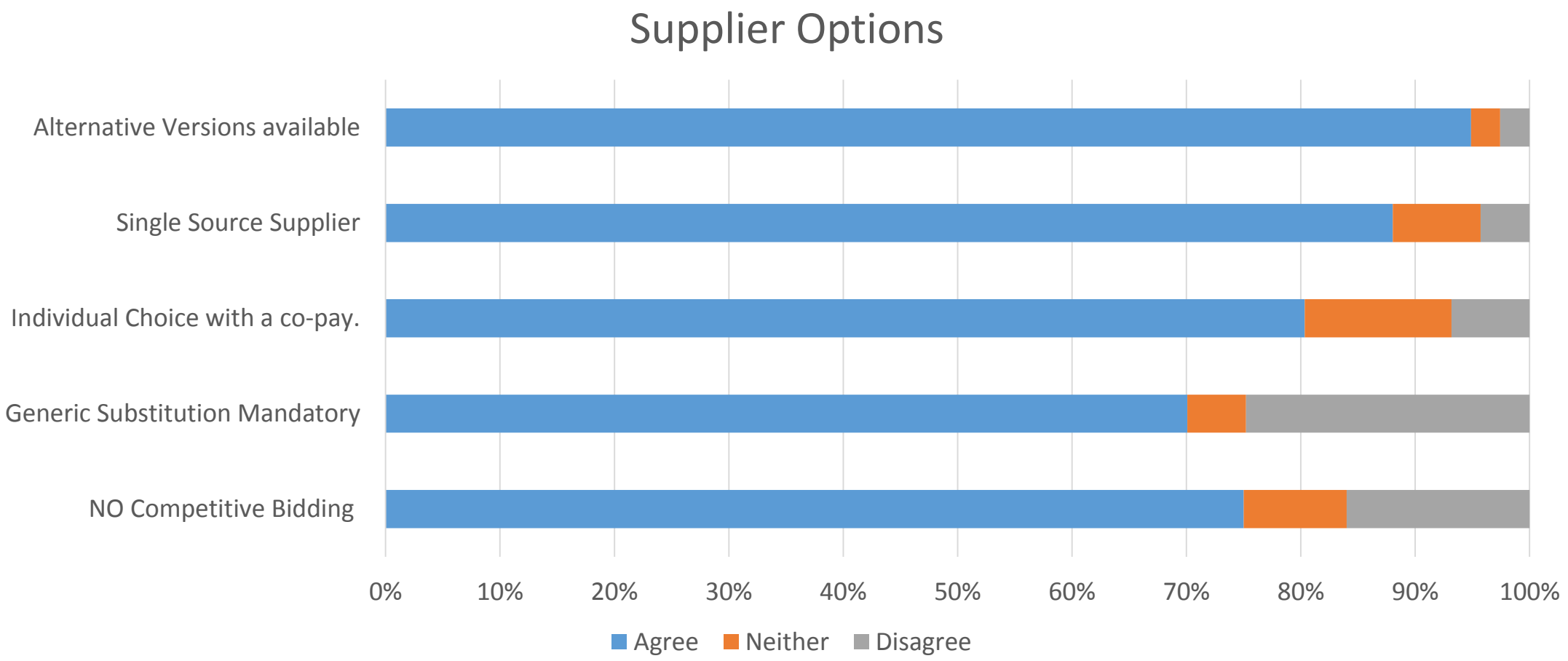
How Many Drugs in National Formulary



How to Build National Formulary



How to Build National Formulary



Current Drug Coverage

My family has …	Yes	No	Not Sure
Employer-provided drug plan	66%	33%	1%
Personally paid for private drug plan	32%	67%	1%
Public drug coverage	38%	59%	3%
Very high drug costs covered by public plan	45%	50%	4%
Been denied drug not on plan's list	55%	37%	8%
Experienced long delays and barriers to access needed drugs	57%	39%	4%
Been unable to access needed drugs due to cost or co-pay	41%	54%	5%

Question & Answer

Thank you!

For more information on CORD, please visit:

www.raredisorders.ca

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