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BIOSIMILAR

FOCUS GROUP PROJECT REPORT



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EXECUTIVE SUMMARY AND KEY MESSAGES

This unique partnership of five patient organizations demonstrated the benefits of collaboration across disease groups with clinical and therapeutic commonalities. Five patient organizations came together to make this project possible:

- Canadian Arthritis Patient Alliance,
- Canadian Psoriasis Network,
- Crohn's and Colitis Canada,
- Gastrointestinal Society and
- The Arthritis Society (project lead).

Scientists from the Krembil Research Institute provided advice and analytic support to the project.

Funding for the project was provided by AbbVie and Janssen.

Six autoimmune diseases accompanied by inflammation: ankylosing spondylitis; Crohn's disease; psoriasis; psoriatic arthritis; rheumatoid arthritis and ulcerative colitis affect 2.25 million Canadians. Six hundred and fifty seven individuals completed an online recruitment survey over a two week period in August. Forty-six individuals were chosen to participate in one of five focus groups based on pre-established inclusion/exclusion criteria. Three in-person focus groups were held in Vancouver, Toronto, and Montreal (French) and two online groups were held in the Atlantic and Prairie regions. A standardized moderator guide was used for the focus groups. All participants were asked to complete a brief survey immediately before the focus group to establish a baseline of knowledge about biosimilars.

The project captured the perspectives of people who live with at least one of six immune-mediated inflammatory diseases for which biologics are a treatment and who had experienced at least one change in their biologic. The original goal of having a significant proportion of participants with experience taking the biosimilar/subsequent entry biologic approved for use was not possible as too few Canadians had been prescribed the biosimilar at the time of the project.

The project was designed to allow a broad range of perspectives and themes to be raised. The project did not allow for exploration of the differences across the diseases, age cohorts, sex, etc., however, the focus groups identified a significant degree of commonality in themes identified.

The purpose of the project did not include recommendation of follow up actions. Rather the findings will be used by the project partners to inform planning for communications, education and awareness programs and will help to empower patients with inflammatory diseases to take a more active role in their own treatment. As well, the results of the project will be collectively and individually disseminated by the project partners, enabling the findings to be used across Canada.

The project participants reported:

- A high degree of emotional impact from the disease itself, and the treatment decision process and delays;
- The desire to be more empowered - more involved in treatment decisions and better connected to sources of support;
- Having a poor understanding of biosimilars, coupled with poor understanding of the health care and prescription drug funding systems in general;
- Being opposed to a forced switch of their biologic for non-medical reasons;
- Recognizing a role for biosimilars for new patients (those not taking the 'originator' biologic);
- Wanting more clinical studies on the impact of biosimilars and of switching to them; and
- Any switch in medications prompts anxiety-provoking questions about access, coverage and adjustment period.

The findings illustrated that these chronic diseases take a significant emotional toll. Participants reported that they were looking to achieve 'new normal' and that anxiety resulted from:

- The 'trial-and-error' approach to treatments;
- Cost/availability of coverage for their biologics; and
- The complexity of experiences related to the treatment selection processes.

The participants expressed a desire to be empowered to actively engage in decision-making. Physicians, particularly specialists, are seen as trusted advisors, but the participants identified that they often felt a lack of control over treatment decisions. Additional support beyond physicians was felt to be necessary. Many reported valuing the support programs (programs offered by the pharmaceutical company). However, they expressed concern that a switch in their biologic would affect access to these programs. As well, better direction to other sources of support is needed.

PROJECT DESCRIPTION

Mandate / Goals

The purpose of the project was to obtain in depth information that would promote a better understanding of the perspectives and needs of Canadians who take biologic medication for the management of Ankylosing Spondylitis, Crohn's Disease, Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis.

This included collection of information on:

- The implications and issues relating to a switch to a different biologic therapy, including a biosimilar/subsequent entry biologic; and
- Knowledge and resources individuals need to feel empowered to take a more active and informed role in decisions about their treatment, including changes to their biologic medication.

The findings of the project will be made available to each partner organization and used to inform communications and mission delivery.

Project Partners

Five patient organizations came together to make this project possible:

- Canadian Arthritis Patient Alliance,
- Canadian Psoriasis Network,
- Crohn's and Colitis Canada,
- Gastrointestinal Society and
- The Arthritis Society (project lead).

Information on the project partners can be found in Appendix 1.

The work of the project was made possible through educational grants from AbbVie and Janssen.

Scientists from the Krembil Research Institute provided advice and analytic support to the project.

“I enjoyed the focus group but was surprised at how different the coverage for biologics is across Canada and the level of knowledge the participants had about biologics and biosimilars.”

Corrie, living in the Prairies

LIVING WITH ONE OF THE SIX INFLAMMATORY DISEASES

The project was designed to capture the perspectives of people who live with one or more of six immune-mediated inflammatory diseases for which biologics are a recommended treatment. As a result of the overlap in the impacts of the diseases, the project included individuals living with each of these diseases to better understand perspectives related to treatment, changes in treatment and supports. However, the project did not allow for exploration of the differences across the diseases, age cohorts, gender, etc.

Ankylosing spondylitis, Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis and ulcerative colitis are all autoimmune diseases accompanied by inflammation. Information on each of these diseases can be found in Appendix 2. These diseases may result from, or be triggered by, a malfunctioning of the normal immune response. For each of these diseases the cause is unknown, there is no cure and no known way to prevent it. Effective treatments now exist for these diseases, but response to these treatments often varies by individual. While these conditions can manifest in quite different ways they share a number of similarities. Some people live with more than one of these diseases.

These diseases have similar impact on people's lives, including unpredictable episodic flare ups. Even with the best treatment, there is no cure for these diseases and their control can be uncertain, with episodic flare ups that can result in discomfort or be debilitating. Flares can last for days or weeks and each person can experience a flare differently. Moreover, a medication can work well for years and reduce symptoms, but sometimes it needs to be changed. This can be because a person has to stop the medication for a health reason and it does not work after it is restarted, or because, for no apparent reason, a medication stops working for an individual. These uncertainties result in anxiety and stress for many of the individuals who live with these conditions, often leading to depression.

These medications have offered patients significantly improved quality of life however, people living with these conditions often report that they now have to accept a 'new normal'; even with effective treatment the disease is not 'cured' and life will never be the same as it was before. Research suggests that acceptance of this 'new normal' may be more difficult for those affected by the diseases at an earlier stage in life. People may experience grief for the life they perceive that they have lost and this can sometimes lead to depression. The treatments themselves can result in challenges and limitations, for example some medications are contraindicated in pregnancy forcing a person to weigh continued management of the disease with desire for parenthood. In many cases the disease is 'invisible', with few or no overt signs, leading to others not appreciating the impact and constraints resulting from the disease, including the variability of symptoms.

Treatment for these diseases often is lifelong use of medications that can be very costly. In Canada the system of funding for pharmaceuticals is complex and the



funding options for treatment often change depending on a person's life circumstance and sometimes when a medication is changed.

Each province and territory offers coverage for prescription medications. Who qualifies for coverage, what drugs are covered and how much is paid varies. Most governments offer coverage for seniors and those on social support. Each plan has an application and re-application process that may vary by the medication.

Many workplaces provide health and drug coverage for employees. Smaller workplaces are less likely to offer coverage or might impose limitations on coverage. The coverage is normally provided through a contract with an insurance company that is periodically renegotiated. In larger workplaces, there may be a variety of plans available to different categories of employees. What drugs are covered and how much of the cost is paid is unique to each plan. This results in a variety of out-of-pocket payments each employee is expected to contribute (co-payments, annual fees, deductibles, annual payment caps, etc.). Some adult children may be covered under their parent's plan up to a defined age. The number of workplace plans that extend coverage beyond retirement is shrinking.

Private insurance may be purchased by individuals directly from insurance companies, or through associations such as Canadian Automobile Association (CAA), CARP, etc. As for workplace insurance plans, the coverage under each plan and the purchase cost varies. Pre-existing conditions may not be covered under these plans, or coverage may come with a high cost and/or limitations or caps on what is covered.

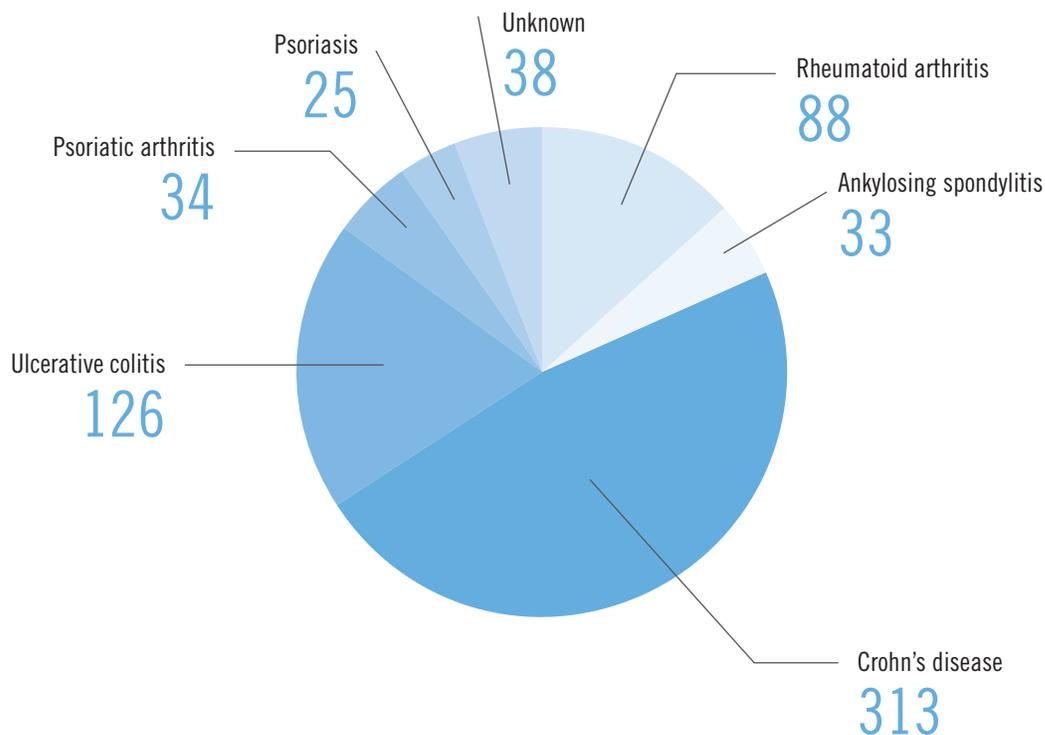
Compassionate and co-payment coverage may be provided by the pharmaceutical company where an individual has been prescribed an expensive medication, like a biologic, but is unable to cover the cost. The conditions and duration of this coverage vary.

METHODOLOGY

Recruitment

The five partner organizations were the primary source for recruitment of study participants. In August 2016 the partners sent out communications by email and through social media encouraging people living with ankylosing spondylitis, Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis and/or ulcerative colitis to complete an online pre-selection survey (Appendix 3, template communication). The recruitment communication targeted people living with at least one of the specified diseases and who had taken at least two different biologics for that disease. The survey was open for just over two weeks (Appendix 4, online pre-selection survey).

In total 657 replies were received. Of these 242 (36.8%) completed the majority of the survey, but did not provide contact information and so were not able to be considered for participation in the focus groups.



398 respondents reported being on their first biologic, 148 on a second biologic and 91 reported having taken more than two different biologics. Twenty individuals reported not knowing or did not provide information on the number of biologics they had taken. Ten individuals reported having taken or currently were taking the only biosimilar that, at that time, was approved for use to treat their disease in Canada.

Inclusion/exclusion criteria were established prior to the survey closing and were used to select respondents to be considered for participation in the focus groups (Appendix 5). The criteria were developed with input from the project partners and the researchers supporting the project.

In addition, issues of feasibility, particularly geographic proximity to the in-person focus group locations and reported availability were considered when developing a list of possible participants. This list was provided to the market survey firm selected to provide logistical support and conduct the focus groups.

Focus Group Structure

Five focus groups were held:

- Three in-person in Vancouver, Toronto, and Montreal (French); and
- Two online - Atlantic and Prairies.

The market survey firm selected to support the project contacted the candidates on the list provided and extended invitations to individuals meeting the inclusion criteria. Where there were insufficient qualified candidates available for a focus group, the market survey firm applied the inclusion/exclusion criteria to its internal database to identify the required number of participants. In total, eight focus group participants were chosen from the market survey firm's database; two for Toronto, three for Vancouver, one for the Prairies, and two for Atlantic.

The same moderator was used for all but the French language focus group (Montreal).

A total of 46 people participated in the focus groups:

- ten in Toronto,
- ten in Montreal,
- ten in Vancouver,
- eight for the online Atlantic group, and
- eight for the online Prairies group.

Pre-Survey

Each participant was asked to complete a short pre-survey immediately before the focus group (Appendix 6). The survey collected sample information and some baseline information on knowledge and perception of biosimilars.

Input to the development of the pre-survey was provided by the project partners, the academic researchers and the market survey firm, with final decisions being made by project partners.

Focus Group Moderator Guide

A moderator guide was developed for use at all focus groups (Appendix 7). Themes used to create the guide were developed with input from the project partners. The final questions and prompts for the guide were developed with input from the academic researchers and the market survey firm. There was concern that not all participants might be aware of biosimilars. Therefore, to help provide some context for this aspect of the focus group discussion, an existing video on biosimilars was selected. It was shown during the focus groups to ensure participants were familiar with basic information about these medications before entering into the discussion on biosimilars. The video was selected based on length, availability in English and French, understandability of message and objectivity. The video selected for use was <http://www.arthritispatient.ca/projects/biosimilars>. Although the video focused on inflammatory arthritis, participants were told by the moderator that the general information about biosimilars applied to other inflammatory diseases.

The moderator guide was intended to optimize the consistency and comparability of the focus group discussions. However, there were some differences in questions asked, especially related to support. This resulted in unique themes being raised in some focus groups.



Reporting and Analyses

Descriptive analyses (e.g., means, percentages) were conducted on the pre-survey information to describe the sample.

The market survey firm provided detailed notes from each focus group for analysis. The notes did not differentiate speakers or link comments to a particular disease. Verbatim transcripts were not available. Thus the analysis was not able to assess whether themes differed across disease groups, age, and stage of disease or other potentially relevant factors. At the same time, similar themes arose across many of the groups, suggesting that many issues were relevant across a wide range of participants.

FINDINGS*

Achieving Stability

Stability was reported to mean different things to different people. Generally, it did not mean the absence of variability. Many participants noted that they had good and bad days, despite feeling that their disease was relatively stable. Of interest was that stability was often equated with remission in the disease or an ability to engage in important life roles and activities – the freedom to do what the individual wanted. Moreover, when participants reported that they were stable, it did not mean they were feeling good or were satisfied with their health. For some participants it related to whether they were able to accept their current symptoms and limitations.

About half of the focus group participants reported that they were not in remission or had only achieved remission for a short period of time. The process of achieving a diagnosis and/or a working treatment was reported to be lengthy.

Medication was seen as only part of the process related to achieving stability. A number of participants credited surgery with making the largest difference in their health.

“It has been a challenge to get where I am now, it’s not perfect but switching drugs for any reason but a medical one is scary to me. I had to stop taking my biologic for surgery, when I restarted I had a severe allergic reaction and couldn’t take it any longer.”

Gail, living in Toronto

*The views and opinions expressed in this document are those of the focus group participants and do not necessarily reflect the positions of patient group partners.

Pre-survey results

Duration living with disease

- 7% – less than 12 months
- 9% – 1-3 years.
- 29% – 3-8 years
- 49% – more than 8 years

Living with what disease (some reported living with more than one)

- 18% – Rheumatoid arthritis
- 11% – Ankylosing spondylitis
- 16% – Psoriatic arthritis
- 11% – Psoriasis
- 16% – Ulcerative colitis
- 47% – Crohn’s disease

Focus group participants told us:

I just want to be normal and live a normal life.

In 16 years I’ve never managed to get in remission.

Every day can be different. Everyone living with chronic pain has to have a level of acceptance and learning to live with it.

Compared to the bad days, life’s good right now. It’s manageable.

Focus group participants told us:

I'm no longer young and invincible. It's a shock.

I feel like I have no choice but to put up and shut up.

Fear. The first [biologic] worked at first, so will this one? A lot of anxiety and what-ifs going through my mind.

Focus group participants told us:

I had to lobby hard.

Didn't have too much trouble, but you have to fail every other cheaper drug, and then you have to fight for coverage.

When a drug doesn't work, you're like, "Okay, let's try something new", but it took 10 months for them to change the medication.

The side effects of my disease seemed less problematic than those from the biologic.

Compared to the bad days, life's good right now. It's manageable.

Psychological Perceptions

Some participants reported that their health difficulties created problems for them in establishing an identity. Some individuals felt that they were 'sick people' rather than 'normal' and disliked that the sick identity was how others perceived them. Variability or limited success with biologics meant that some participants had re-prioritized the meaning of health. They believed that their current health difficulties may be 'as good as it gets', and that you need to learn to put up with the disease and its treatment. A number of participants reported that they didn't feel like they had any control – over the progression of their disease, over treatment decisions, or other aspects of their care.

Some participants reported being in denial early in their disease and resisted taking medications. A lot of ongoing stress, fear and anxiety was reported related to:

- the potential that their current biologic will fail and other options might not be available;
- side effects – how much can I / must I tolerate, especially where options for treatment are limited; and
- uncertainty when starting a new treatment – the long periods waiting to see if a drug will work, long periods of trial and error with any dosage changes, and uncertainty for the future.

Challenges Related to Biologics

Getting a Biologic

The journey of getting on a biologic that worked for them was reported to be fraught with 'trial and error' – what drug, what dosage, how long to wait to see if it worked or make a decision to change medication, when to discontinue the biologic, etc. and stability is a moving target as disease state and medication is a delicate balance. There was a perception that there was a lot of variability in how clinicians approached these decisions. Long periods of uncertainty were raised as an issue. Specifically, some respondents reported having to wait months to know if the new biologic would work or before a decision to discontinue it was made. Participants sometimes reported that they were ready to make decisions to start, change or stop biologics before their doctor, who usually adopted a more conservative and lengthier time frame for decisions. Of concern to a few participants was that extreme negative events like hospitalizations were sometimes the impetus for change among physicians.

Some said that they did not want to start on a biologic, but reported being persuaded even when they felt the side effects might be considerable and that a biologic might not be the right choice for them. Participants sometimes reported being concerned about cognitive or mental health side effects as well as physical effects. Among the people who had experienced several biologics, some expressed the perception that some of the biologics that they'd taken were of little or no help.

Cost of Biologics

Cost was a significant concern. Some participants reported having to fight to get their drug plan to cover a biologic; others reported having no or little difficulty. Some noted that they believed there was criteria for what medications had to be taken first. Even when the biologic eventually was covered, the wait for approval and reimbursement could be quite long. A change in the biologic was a concern as it could result in the person having to start all over again to get coverage.

“ . . .patients just want a treatment to control their disease and to be able to live their lives. It wouldn't matter to me if the drug cost ten dollars or ten thousand dollars as long as I could tolerate the side effects and it controlled my RA. For some reason I always get the impression that payers, both public and private, feel patients are pushing for the latest, greatest, most expensive drug, but I don't believe that's the case.”

Linda, living in the Atlantic Region

Once the coverage was approved, people reported having significant out-of-pocket payments due to plan caps or the requirement to pay up front and then wait for reimbursement.

Pharmaceutical company patient support programs were identified by a number of participants as key to getting coverage and additional information. However, in some cases, patient support program personnel were identified as barriers to access, especially because they did not return calls and requests for information. Physicians and family also were identified as sources of support in making decisions and in helping patients get coverage (e.g., insurance costs covered by a family member's policy).

Compassionate coverage was mentioned several times as being helpful, but there was concern that changes in the biologic or the compassionate program might eliminate this coverage.

Focus group participants told us:

We couldn't afford it. [Drug] is outrageously expensive and for a while my Dad's medical would cover a bit of it, but we'd still have to pay a majority of it.

Cost was a factor, I wasn't sure if it was going to be covered with my insurance, it was pretty seamless in the end.

My biggest worry is when I'm not covered anymore by the compassionate care program.

Focus group participants told us:

School and work are difficult, because you're always sick. I've lost jobs because I've been sick.

I was lucky – I didn't get it until I was 50 and I had a very active life up to then.

Pre-survey data:

- ✓ Majority not very/not at all confident in knowledge of biosimilars
- ✓ Less than half of the respondents would be somewhat comfortable/ very comfortable switching to a biosimilar.

Life Course and Roles

The stage of life at which the disease presented was relevant to a number of participants in terms of treatment, information and costs.

For example, the move from the paediatric to the adult health care system was sometimes noted as being problematic and there was limited information for some participants to guide the transition. A couple of younger participants commented that a chronic condition was more difficult to deal with psychologically for those at a younger age who were still establishing their identity. In addition, younger adults were often in the process of completing their education and entering the work force and wanting to start a family. During this period, drug coverage could be problematic as parental insurance coverage may end and no workplace benefits might yet be available. The uncertainty was reported as creating anxiety for the future.

Participants at the later stages of life also reported challenges related to employment ending, particularly early retirement, which may limit insurance coverage for some medication. Some participants also noted that they had a range of social responsibilities related to children, spouses, and work. Several mentioned considerable fatigue, needing time off work for appointments or treatments or to pick up medications. This made any difficulties with accessing medications and changing treatments especially challenging.

Biosimilars / Subsequent Entry Biologics

Some participants said that they were uncomfortable responding to focus group questions on biosimilars as they didn't know enough to be informed. (The brief video on biosimilars was shown immediately prior to the discussion on biosimilars). In some cases, even after showing a brief video, a number of participants reported that they had never heard about biosimilars/subsequent entry biologics. Some also expressed the opinion that, since biosimilars were so new, their physician likely did not know what a biosimilar was. Evidence for this was that most participants noted their physicians had never mentioned biosimilars to them.

Reactions to biosimilars were highly mixed. In general, however, the reaction was very negative to any efforts that might be undertaken to force a patient to switch to a biosimilar. In fact, a few participants felt that biosimilars were all about driving down costs and not delivering quality treatment. However, in the pre-survey the majority of respondents reported being very/somewhat comfortable with provinces requiring a physician to prescribe the less expensive biosimilar to patients not on the original biologic.

Some participants did not have negative reactions to biosimilars. They reported that they would be open to taking a biosimilar if it was approved by Health Canada. Others were willing to take them if there was research showing that they were safe or just as good as the original biologic.

“Biosimilars for biologic naive patients are a great option but not for stable patients who are doing well on their current medication.”

Gail, living in Toronto

Some participants were concerned that biosimilars might be unsafe. Perceptions included viewing biosimilars as generics or ‘knock offs’ with potentially different side effects that might arise as a result of ‘fillers’ in the ingredients. Some individuals questioned why anyone would bother switching a patient to a ‘generic’ version of the drug if the original biologic was not working. There was also concern that switching to a biosimilar might result in the loss of current supports and coordination received from pharmaceutical companies.

Some participants felt access to biosimilars might be easier and improve the wait time for coverage because they were cheaper. Conversely, others expressed concern that switching to the biosimilar might result in them having to start all over with the insurance company and take longer to access. Several participants indicated that they were willing to try a biosimilar if they could switch back if it did not work, and that switching back should be made easy to do.

“If I had not started the original biologic I would try the biosimilar for lower cost purposes. If my disease was stable on my current medication I would NOT be comfortable switching to a biosimilar due to cost.”

Corrie, living in the Prairies

Switching Biologics

Many participants reported having switched biologics more than two times and quite a few reported more than four biologic medication switches. A number of individuals also experienced many changes with a single medication, particularly dosage and schedule changes.

For many participants, changes in medication were seen as something to be avoided. Some reported feeling that a change was a setback in their treatment. Any change was reported as being disruptive. A new drug might have side effects or there might be a long wait to see if it would work or if it might fail. For many individuals there was concern that options were limited and each change meant they might run out of options. Some shared negative stories of the consequences of a switch, including hospitalization.

Focus group participants told us:

Don't know enough about the biosimilars.

This is the first I've heard of them.

If it's the same, shouldn't it be called 'biosame' instead of 'biosimilar?'

Good idea for sure.

Pre-survey data:

- ✓ 87% very important to be engaged in decisions
- ✓ 89% very / somewhat important for physician to approve any switch in biologic, including biosimilar

Focus group participants told us:

It's awful and I hate switching – old drug not working, not feeling well, and it takes awhile for the new drug to kick in. It's really difficult – I would like to never switch again.

Trust your doctor, but get a lot of information. Go on company websites, take time to read, look at [product] monographs.

Didn't have too much trouble and I am on biologic number six. Each one was an easier process than the last.

“Why switch medications if you’re okay with what you’re taking? . . . If someone asked me to switch medications and I was stable, I would ask why they suggested it, what the pros and cons are of the other medication, the side effects, and have a discussion with my doctor.”

Person living in Toronto

“When we finally find a treatment that works, after possibly failing (and all that is associated with using that word) on numerous drugs (and the hopes of a patient and their family that finally something will help being dashed time after time), the very idea of someone forcing a switch and risking their health is abhorrent. . . No one seems to acknowledge the stress all of this puts on the patient.”

Person living in Vancouver

Many individuals reported not feeling that they had any choice about making a change. Some participants reported believing that the change was necessary because the drugs were not working or they had experienced a negative response to them. Others reported that changes in biologics came about as a result of other treatments like surgery. Negotiating changes with physicians varied among participants. Some reported that changes were driven by their physicians and they went along with them reluctantly. Others reported that they had to fight with their physician to make changes to their biologic and that their physician was too conservative, wanted too much evidence and to ‘wait and see’ over prolonged periods despite the problems this created for them.

“It has been a challenge to get where I am now, it’s not perfect but switching drugs for any reason but a medical one is scary to me.”

Gail, living in Toronto

Some participants reported wanting more information and support related to the decision of whether to switch biologics. Practical support available as a result of a switch to a new biologic was reported as helpful, e.g. needle disposal and home delivery.

Cost saving was generally felt to be an unacceptable reason for a change. Rather, some participants said that quality of care should be the driving factor.

Supports Available

Support from Patient Support / Assistance Programs (Pharmaceutical Companies)

Not everyone had heard of patient assistance or patient support programs. In discussing patient support, some participants focused on support offered by pharmaceutical companies and others noted that a variety of patient support services were offered by health charities and other groups. A couple of participants also noted the support they received from their physician's secretary or nurse.

The perception of support from pharmaceutical companies' patient support programs varied, but was often positive. Some felt they served as a strong advocate and were very helpful in liaising with a variety of different people in order to enable access to biologics, especially with insurers and physicians. However, in some cases, patient support program personnel were identified as barriers to access, especially because they did not return calls and requests for information. Moreover, at times there were so many people involved in communications and approvals that participants reported they were left out and didn't know what was happening.

Other Supports

Most focus group participants identified the need to self-advocate for treatment and the need to keep up to date with information and do your own research to be informed so that you can advocate for yourself.

Many felt that their physician, especially their specialist, was a good advocate on their behalf and that they could be trusted. At the same time, some participants reported that family physicians were not always as knowledgeable as specialists, especially about biologics. Some participants also reported having to struggle to get a therapy change when their current treatment was not working.

Perceptions of the time needed to get a decision from insurers were also variable. Some participants reported that getting a decision was difficult and prolonged, but once a decision was made it was relatively easy to get renewals and access to the biologic. Having to change insurers was reported as creating difficulty.

Several participants felt that they could go to a pharmacist for information about biologics, but a couple of participants said they relied on their physician to make the final decision.

Across more than one group, the value of psychological support was identified. People felt that many of the issues they faced were traumatic and the decisions difficult. Support from others could help deal with the impact of living with a chronic condition.

For the most part, individuals recognized the value in talking to others who had experiences similar to oneself. However, some participants noted that support groups had limited availability or expressed concerns about confidentiality.

Focus group participants told us:

[They had a] patient support program, they took care of dealing with the contact with the (specialist) and the insurance company...I had to do very little, which was fantastic.

The support program from the pharmaceutical companies is helping with the drugs and managing the drugs. But I want the least amount of advice from them as possible – they have drugs to sell.

They are there for you if you need to call them for anything.

No phone call in 1.5 years...there has been no personal contact from [pharmaceutical company].

Frustrated with how the patient is not included in all communications. E-mails would sit in an admin person's inbox and wouldn't get approval quick enough.

Focus group participants told us:

I had to move to a larger city to get a good physician.

It's good to talk to people who have had it.

Don't go on (online) forums because often it's not the people who are having success who are on there. It's a lot of people who are depressed.

I would want psychologists and social workers.

Some participants felt that health charities were more trustworthy in providing information about biosimilars, as they were not trying to sell the drugs. Others felt they were disorganized in their support services and focused on fundraising. Some participants also noted that physicians lack awareness of health charities and do not advertise them to their patients.

Patient forums (online) were discussed in a couple of focus groups with mixed perceptions of their usefulness. A couple of participants reported valuing the opportunity to share and learn from others' experiences. Some participants were less enthusiastic. They felt forums did not provide a balanced perspective because they mostly included people for whom treatment didn't work. A preference for professional support from psychologists and social workers was mentioned by some.

Appendix 1

THE PROJECT PARTNERS

The Arthritis Society has been setting lives in motion for over 65 years, and is dedicated to a vision of living well while creating a future without arthritis. Founded in 1948 by Mary Pack and Dr. Wallace Graham, The Society is Canada's principal health charity providing education, programs and support to the over 4.6 million Canadians living with arthritis.

Vision

Living well while creating a future without arthritis

Mission

Provide leadership and funding for research, advocacy and solutions to improve the quality of life for Canadians affected by arthritis

Canadian Arthritis Patient Alliance (CAPA) is a grass-root, patient-driven, independent, national organization with members across Canada and supporters both Canadian and International. CAPA believes the first expert on arthritis is the individual who has the disease, theirs is a unique perspective. We assist members to become advocates not only for themselves but all people with arthritis.

CAPA facilitates links between Canadians with arthritis and their support systems through collaboration and partnerships with other organizations, representatives from all levels of government, researchers, and other individuals to help achieve CAPA's strategic priorities. The organization communicates the latest news on health policy issues, research, technology and emerging issues relevant to members through its website and Facebook pages. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

Canadian Psoriasis Network (CNP) has a goal is to improve the quality of life of all Canadians who are living with psoriasis and psoriatic arthritis while vigorously pursuing a cure. Our mission is to provide all current information on treatment and continuing care through education, outreach, research and leading by example.

Crohn's and Colitis Canada is a national, volunteer-based charity focused on finding the cures for Crohn's disease and ulcerative colitis and improving the lives of children and adults affected by these diseases.

We are one of the top two health charity funders of Crohn's and colitis research in the world, investing over \$94 million in research to date. We are transforming the lives of people affected by Crohn's and colitis (the two main forms of inflammatory bowel disease) through research, patient programs, advocacy, and awareness.

Mission

Crohn's and Colitis Canada will raise funds to:

- Invest in Crohn's and colitis research to foster advances in prevention, treatments, cures and health policy
- Educate patients, families, industry and governments about Crohn's and colitis
- Increase public awareness of these chronic diseases and our organization
- Advocate to governments and stakeholders on behalf of those affected by Crohn's and colitis

Gastrointestinal Society as the Canadian leaders in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the Gastrointestinal Society and the Canadian Society of Intestinal Research are registered charities committed to improving the lives of people with GI and liver conditions since 1976. They do this by supporting research, advocating for appropriate patient access to health care, and promoting gastrointestinal and liver health.

Appendix 2

The Six Diseases

Ankylosing Spondylitis (AS)

Ankylosing spondylitis, or AS, is a type of inflammatory arthritis that affects the spine and the sacroiliac joints which attach the pelvis to the base of the spine. Ankylosing means fusing and spondylitis means inflammation of the spine. As well as being a form of inflammatory arthritis, AS is also an autoimmune disease meaning the body's own immune system attacks healthy tissue. With AS inflammation, the immune attack targets the ligaments and tendons attached to bone in the joints of the spine. The bone erodes at these sites and the body tries to repair itself by forming new bone. The bones of the spine begin to fuse, or grow together, causing the spine to become stiff, inflexible and painful. Even though new bone forms, the original bone in the spine can become thin, increasing the risk of spinal fractures.

While spondyloarthritis is a form of inflammatory arthritis, it differs from rheumatoid arthritis, because people with spondyloarthritis do not have rheumatoid factor antibodies in their blood. They are known as seronegative whereas those with rheumatoid arthritis are seropositive.

Typically, the first symptoms of ankylosing spondylitis start in late adolescence or early adulthood between the ages of 15 and 30. Inflammation usually starts at the base of the spine, often in the sacroiliac joints around the pelvis. It can spread upwards to other parts of the spine and, in the most severe cases can involve the entire spine.

As well as the spine, AS can cause pain and stiffness in peripheral joints, such as the hips and shoulders. The stiffness is due to inflammation of the tendons surrounding the joints, called enthesitis. Some common spots for enthesitis are the back of the heels (Achilles tendonitis); the bottoms of the feet (plantar fasciitis); the outside of the hips (trochanteric bursitis); and along the breast bone (costochondritis).

When the immune system lacks the normal checks and balances, it can attack parts of the body other than the joints and tendons. In AS, this attack may cause inflammation in the eye, a condition called uveitis or iritis.

Inflammatory Bowel Disease (Crohn's Disease and Ulcerative Colitis)

- About one out of every 150 Canadians is living with Crohn's disease and ulcerative colitis. That's about 250,000 Canadians, including 5,900 children, one of the highest rates in the world
- Over 10,200 people every year are newly diagnose: 5,700 people with Crohn's disease and 4,500 with ulcerative colitis
 - Rates are rising
 - In children new cases of Crohn's disease has almost doubled since 1995
- Families new to Canada are developing Crohn's and colitis for the first time – often within the first generation
- Crohn's disease and ulcerative colitis can be diagnosed at any age, but has a typical age of onset in the twenties.

Crohn's and ulcerative colitis causes sections of the gastrointestinal tract to become severely inflamed and ulcerated. An abnormal response of the body's immune system plays a role in Crohn's disease (CD) and ulcerative colitis (UC). With CD, inflammation can occur anywhere in the GI tract but is usually present in the lower part of the small bowel and the colon. Patches of inflammation occur between healthy portions of the gut, and can penetrate the intestinal layers from inner to outer lining. UC only affects portions of the large intestine, including the rectum and anus and typically only inflames the innermost lining of bowel tissue. It almost always starts at the rectum, extending upwards in a continuous manner through the colon. CD and UC also occur in children and are increasingly being diagnosed in young children.

Patients with CD and IC experience symptoms such as abdominal pain, rectal bleeding, fatigue, vomiting, diarrhea, itchiness or irritation around the anus, flatulence, and bloating. Weight loss and anemia also pose significant problems. Additionally, the complications associated with CD and IC can affect a patient's bones (leading to osteoporosis), liver, skin, eyes, height and weight, and mental health (leading to depression or anxiety).

In the absence of a cure, current therapies are directed at achieving and maintaining freedom from symptoms. Most people require ongoing medication; when this fails, surgery is often required. These are lifelong diseases, usually starting in early adulthood in otherwise healthy, active individuals. CD and IC severely impact quality of life through ongoing debilitating symptoms, reduction in ability to work, social stigma, management of bathroom access issues, difficulty with physical intimacy, and restriction in career choices.

Psoriasis

Psoriasis is a chronic inflammatory condition that involves red elevated patches and flaking silvery scales on the skin. It can take on several different forms and appearances, and symptoms can range from mild to severe. The lesions can be painful and/or itchy and vary in size. Since plaques consist of dry, flaky inflamed skin, it may also crack and bleed. While lesions can appear anywhere on the body, the most common sites include elbows, knees, scalp, chest and lower back. Psoriatic lesions can make it difficult to sleep, dress or engage in various daily activities. The plaques tend to appear in the same place on both sides of the body. While it is not known exactly what causes psoriasis to develop, experts believe that the condition may involve malfunctioning of the immune system and the consequent production of inflammation.

Psoriasis has an impact that extends beyond the cosmetic or physical aspects. It negatively affects quality of life from the pain, discomfort and limitations to having a heavy emotional toll.

Psoriatic Arthritis (PsA)

- PsA is estimated to affect 0.3% – 1% of Canadians
- Between 10 – 30 per cent of people with psoriasis will get psoriatic arthritis
- PsA affects both men and women in equal numbers and usually appears between the ages of 20 to 50 years old
- PsA most commonly occurs in the age of 40 to 50 years old

PsA is a type of inflammatory arthritis and an autoimmune disease in the spondyloarthritis group of diseases. In PsA the joints are the target of the immune attack. This causes swelling, pain and warmth (inflammation) in the joints. PsA usually begins slowly, spreading to other joints over a few weeks to a few months. In rare instances, PsA can develop quickly and be severe. PsA is an unusual type of arthritis because it can look very different from person to person. Doctors have discovered five general patterns of psoriatic arthritis. PsA can also cause inflammation in tendons around the joints.

In most people, psoriatic arthritis starts after the onset of psoriasis. Yet having psoriasis does not mean you will have PsA. In fact, most people with psoriasis will never develop psoriatic arthritis.

There is no cure for PsA, but when you are diagnosed early and start the right treatment, you can take control of your disease and avoid severe damage to your joints. Most people with PsA can lead active and productive lives with the help of the right medication, surgery (in some cases), exercise, rest and joint protection techniques.

Rheumatoid Arthritis (RA)

- About one out of every 100 adult Canadians lives with RA. That's about 300,000 Canadians.
- RA affects women two to three times more often than men.
- RA can affect anyone of any age, although people are most commonly affected between the ages of 30 and 60.

In rheumatoid arthritis (RA) the inflammation occurs in the lining of joints that causes pain, swelling, and if not treated effectively, also results in joint damage and deformity. RA is systemic in that it does not just affect one part of the body – it may also involve other organs, such as the nerves, eyes, lungs or heart. The symptoms and course of RA can be very different from person to person. In many cases RA starts in a few joints then spreads to other joints over a few weeks to months. However, RA can also progress very rapidly; some people report that one morning they just could not get out of bed.

The earliest symptoms of RA can be non-specific, including feeling unwell or tired, soreness in or around joints, low-grade fever, and weight loss/poor appetite. As time goes on, RA can involve more and more joints on both sides of the body, often in a “symmetrical” pattern, meaning that it will affect the same joints on each side of the body.

Early diagnosis and prompt and aggressive treatment has been shown to help people avoid permanent joint damage to joints and allow people to lead active and productive lives. The approach to treating RA is to reduce inflammation and prevent joint damage. Managing pain is also important. Using medication to treat RA is extremely important and usually includes disease modifying anti-rheumatic drugs (DMARDs) and biologics. These types of medications can slow down RA's course, but they do not cure RA – there is no cure for RA at this time. Generally medication is required for life to control inflammation. You can think of this inflammation like a ‘fire’ burning in the joints. If the fire is left ‘burning,’ it can permanently damage the joint. Once a joint is damaged, it cannot be fixed other than to be replaced by surgery. Just as you would try to put out a fire in your home before it spreads, you want to put out the inflammation of RA as quickly and as safely as possible. When medication is stopped or for some reason no longer works well, the ‘fire’ flares up again.

Even with the best treatment, RA can be uncertain, with flares at times that can be painful and very debilitating. Flares can last for hours or weeks and are different from one person to another.

Because RA is unpredictable, sometimes medications need to be changed. Sometimes a medication that has worked well for years no longer does and needs to be switched; sometimes because a person has to stop their medication for a health reason the medication may no longer work after it is restarted; or sometimes for no apparent reason, a medication just stops working. Not knowing the course of your RA or what you will need to do to treat it can be very stressful.

Appendix 3

FOCUS GROUP RECRUITMENT COMMUNICATION TEMPLATE

Document shared with project partners as a template for their use.

Project overview

(May be most useful in replying to inquiries or for developing a more comprehensive communication.)

Help get the word out: Survey closes August 19th

Biologic medications have changed the treatment of inflammatory diseases, and as new biologic medications targeting inflammation become available in Canada, they are providing more choice for patients and their physicians. Some of the earliest biologic medications have reached the stage where their patents have expired.

To better understand the impact that changing biologic medications has on Canadians, we are participating in a joint project with other Canadian health charities and patient groups to conduct a series of focus groups asking Canadians about their experience taking and switching biologics for their chronic disease.

The focus groups will include representation from rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis. Discussion will focus on the issues relating to changes in biologic medications, especially a switch to a biosimilar, so people who have experienced or are facing a change in biologic medication are encouraged to consider participating in the focus groups.

The information from the project will help health charities and patient groups in their work, and will provide valuable information to other stakeholders including government leaders, physician organizations, and pharmaceutical organizations.

The health charities and patient groups that have joined together to make this project possible are:

- Canadian Arthritis Patient Alliance, <http://www.arthritispatient.ca>
- Canadian Psoriasis Network, <http://www.cpn-rcp.com/>
- Crohn's and Colitis Canada, <http://www.crohnsandcolitis.ca>
- Gastrointestinal Society, <http://www.badgut.org>
- The Arthritis Society (project lead), <http://arthritis.ca>.

The project is sponsored by:

- AbbVie, <http://www.abbvie.ca>
- Janssen, <http://www.janssen.com/canada>

Four in-person focus groups will be held in Halifax, Montreal (in French), Toronto and Vancouver. There will be one online focus group held in English. Each focus group will be approximately 1.5 hours long, and will involve 8 to 12 participants (slightly fewer in the online group).

Given the time commitment, focus group participants will receive a honourarium, plus reimbursement for reasonable out-of-pocket expenses incurred, e.g. travel, parking.

To ensure the project results in the best possible information to inform policies, programs and education, the focus group participants will be selected to capture a broad range of experiences and perspectives. To get the right mix, we are asking interested people to complete a brief survey to be considered for participation.

The privacy of personal information will be safeguarded. At the conclusion of the project all responses will be destroyed and the information in the report will in no way identify any one individual. If a person has any questions about the protection of personal information s/he can contact privacy@arthritis.ca

If the person wishes to be considered for participation, direct them to [here](#). The survey will close on August 19th.

Encourage people to share information about this project and to check your website (organization's website) in early 2017 for a report on the study findings.

Suggested Communication

Help Us to Help You. Your response is requested by August 19th

Are you are taking a biologic medication for rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis psoriatic arthritis or psoriasis? If you have changed or are facing a possible change in your biologic medication, please consider participating to help us understand your perspectives and needs.

Canadians who have taken more than one biologic medication, including a biosimilar are needed for five focus groups being held in September. The information from the project will help XXXX name of organization and other health charities and patient groups in their work, and as well provide valuable information to other stakeholders including government leaders, physician organizations, and pharmaceutical manufacturers.

Four in-person focus groups will be held in Halifax, Montreal (in French), Toronto and Vancouver. There will be one online focus group held in English. Each focus group will be approximately 1.5 hours long. If you are selected to participate, you will receive a honourarium, plus reimbursement for reasonable out-of-pocket expenses.

If you wish to be considered for participation in one of the focus groups, please take the survey below. The survey will be closed on August 19th.

[TAKE THE SURVEY TO APPLY]

This is important project will help us better understand the needs of Canadians in an ever-changing treatment landscape for chronic disease. Thank you for considering taking part! We encourage you to share information about this project, and to check back on our website (active link suggested) in early 2017 for a report on the study findings.

Tweet (126 characters)

Changed your biologic? Share your experience. We're hosting focus groups in Sept – take this survey to apply:
www.surveymonkey.com/r/transitionsbiologic

Biologic information

(Provided as background for use by partners at their discretion)

Biologic medications have changed the treatment of inflammatory diseases, and as new biologic medications targeting inflammation become available in Canada, they are providing more choice for patients and their physicians. Some of the earliest biologic medications have reached the stage where their patents have expired.

We are all familiar with generic medications, which are considered to be fundamentally the same as the original medication. A generic version of biologic medications is not possible due to the inherent complexities of using living organisms to manufacture biologics, and the size and complexity of the resulting molecules. Therefore, biosimilars (also called subsequent entry biologics) are similar but not identical to the original medication.

Over the past few years biosimilars targeting inflammation have been introduced. The first of these medications is now in use in Canada and others soon will follow. For more information on biosimilars go to <http://arthritis.ca/manage-arthritis/medication/subsequent-entry-biologics>. Partner organizations may prefer to refer to their organization's information.

Appendix 4

FOCUS GROUP PRE-SELECTION TOOL (SURVEY MONKEY)

We need your help to better understand the impact of changes to the biologic medication you take.

Thank you for taking the time to complete this brief survey.

The information requested in this survey is to help the project generate the best possible information for the use of health charities, patient groups and other organizations such as physician groups, government leadership and pharmaceutical companies. The project includes five focus groups (in-person in Halifax, Montreal (in French), Toronto and Vancouver, plus an online focus group). Each in person group will consist of 8 - 12 participants, with slightly fewer for the online group.

Participants must be at least 18 years of age or older.

The privacy of your personal information will be protected. At the conclusion of the project all responses will be destroyed and any information included in reports from the project will contain only anonymous information that can in no way be used to identify any one individual. If you have any questions about the protection of your personal information you can contact privacy@arthritis.ca.

1. How old are you?

_____ years old

2. Do you take your current biologic medication by: (choose one)

- 2.1. Injection
- 2.2. Infusion
- 2.3. Not sure (thanks and end)
- 2.4. Neither (thanks and end)

3. For which of the following conditions have you been prescribed a biologic medication (choose all that apply)

- 3.1. Rheumatoid arthritis
- 3.2. Ankylosing spondylitis
- 3.3. Crohn's disease
- 3.4. Ulcerative colitis
- 3.5. Psoriatic arthritis
- 3.6. Psoriasis
- 3.7. Not sure (thanks and end)
- 3.8. None of the above (thanks and end)

4. How long ago were you diagnosed with this condition(s)? (choose one)

- 4.1. Less than 6 months ago
- 4.2. More than 6 months but less than 2 years ago
- 4.3. Between 2 and 5 years ago
- 4.4. Longer than 5 years ago
- 4.5. Not sure
- 4.6. I have not had a diagnosis (thanks and end).

5. Is this the first biologic medication that you have taken for the conditions you identified above? (choose one)
- 5.1. Yes, this is the first
 - 5.2. No this is the second
 - 5.3. No, I have previously taken two or more different biologics
 - 5.4. Not sure
6. How long ago did you start on your first biologic medication? (choose one)
- 6.1. Less than 6 months ago
 - 6.2. Between 6 months and 2 years ago
 - 6.3. Between 2 – 5 years ago
 - 6.4. More than 5 years ago
 - 6.5. Not sure
7. Have you ever taken the biologic Inflectra (choose one)
- 7.1. Yes, currently receiving Inflectra
 - 7.2. Yes, but not currently receiving Inflectra
 - 7.3. No
 - 7.4. Not sure
8. Patient Support Programs are made available to people who take biologics. Have you had to change to a new Patient Support Program? (choose one)
- 8.1. Yes
 - 8.2. No
 - 8.3. Not sure
9. Would you be willing to participate in an online focus group?
- 9.1. Yes
 - 9.2. No
10. When would you be available to participate in an in-person or online focus group (choose all)
- 10.1. Weekday mornings
 - 10.2. Weekday afternoons
 - 10.3. Weekday evenings
 - 10.4. Weekend mornings
 - 10.5. Weekend afternoons
 - 10.6. Weekend evenings
11. During the period from September 12 - 30 are there any days when you would not be able to participating in a focus group (choose one)
- 11.1. Yes (please specify which days you would not be available)
 - 11.1.1. _____
 - 11.2. No, I would be available to participate on any day during that period
12. Where do you live?
- 12.1. City/town _____
 - 12.2. Province/territory (drop down box, if possible)

13. Would you feel comfortable expressing your opinions and engaging in discussion with a group of 8-12 strangers (choose all)

- 13.1. Yes, in English
- 13.2. Yes, in French
- 13.3. Yes, in English or French
- 13.4. No, in neither English or French

The following information is required so that we can contact you if you are chosen to participate in a focus group. This information will be used only for that purpose and will be destroyed at the end of the project. The information will not be used in any way to allow your responses in the survey to be connected to you personally.

15. What is your name

- 15.1. First name _____
- 15.2. Last name _____

16. Do you have regular and reliable access to email and internet most days of the week (choose one)

- 16.1. Yes
- 16.2. No

17. What is your contact information

- 17.1. Day time telephone # _____
- 17.2. Evening/weekend phone # _____
- 17.3. Email address _____

Thank you for taking the time to complete this survey.

We will contact you to let you know if you have been selected to participate in a focus group.

Appendix 5

INCLUSION/EXCLUSION CRITERIA

Characteristic	Priority (Mandatory, 1, 2 or 3)
Receives biologic medication by infusion or injection	M
Approximately equal distribution infusion/injection at every focus group	2
Biologic prescribed for rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriatic arthritis, plaque psoriasis	M
Representation from each disease at every focus group	3
No more than 4 of any one disease at any focus group	2
At least 6 from each disease included overall	1
Has received more than 1 biologic medication	1
Has taken Inflectra	1
Has been on a biologic for more than 1 year	2
Time since diagnosis	3
Age	3
Comfortable engaging in focus group in English or French as appropriate	M

Biosimilar Project Report

Appendix 6

Pre-Survey

The confidentiality of the information collected through this survey will be protected. The completed survey will be sent directly to an academic research group affiliated with an accredited university. No information will be reported or shared that can in anyway identify you or allow any of the information you provide to be linked to you.

1. How confident are you about your knowledge of biosimilars, also known as Subsequent Entry Biologics?
 - a. Very confident
 - b. Somewhat confident
 - c. Not at all confident
2. Have you ever taken Inflectra?
 - a. Yes, currently taking
 - b. Yes, in past
 - c. No
 - d. Unsure
3. Are you currently taking Remicade?
 - a. Yes
 - b. No
 - c. Unsure
4. How comfortable would you be taking a biosimilar?
 - a. Very comfortable
 - b. Somewhat comfortable
 - c. Not at all comfortable
 - d. Not sure

Please tell us why you feel this way.

5. A person taking a biologic for RA, AS, PsA, psoriasis, UC or CC should only be switched from that drug to its biosimilar if the switch was approved by their physician. How important is this requirement to you?
 - a. Very important
 - b. Somewhat import
 - c. Not at all important
 - d. Not sure/uncertain

6. How important is it for you to be adequately informed and fully engaged in any decision to switch your biologic, including to a biosimilar?
- a. Very important
 - b. Somewhat import
 - c. Not at all important
 - d. Not sure/uncertain
7. A biosimilar is less expensive than its original biologic. Therefore when a person is first prescribed a biologic some drug plans may fund only its biosimilar, where one has been approved by Health Canada. How comfortable are you with this?
- a. Very comfortable
 - b. Somewhat comfortable
 - c. Not at all comfortable
 - d. Not sure
8. How important to you is patient support program for the biologic you are taking?
- a. Very important
 - b. Somewhat import
 - c. Not at all important
 - d. Not sure what a patient support program is
 - e. Do not use the patient support program
9. How do you take your current biologic:
- a. Intravenously/infused
 - b. Injected
 - c. Neither

The following information has already been asked, but to allow you to complete this survey anonymously it is being asked again.

10. How old are you

11. Are you

- a. M
- b. F
- c. Other

12. How many years have you lived with your disease

13. What Province/Territory do you live in?

14. What disease(s) do you live with: (Please circle all that apply)

- a. RA
- b. AS
- c. PsA
- d. Ps
- e. UC
- f. CC

What is your name?

(Having your name will allow a more complete analysis of the study results, but you can choose to submit the survey anonymously)

Appendix 7

FOCUS GROUP MODERATOR GUIDE

INTRODUCTION/WARM UP

10 minutes

MODERATOR INTRODUCTION:

- Welcome everyone and thank for their time
- Explain group will last approximately 2 hours
- Explain audio/video recording / colleagues behind the glass
- Explain role as moderator / unbiased / neutral party, the importance of honest responses, no right or wrong answers etc.

EXPLAIN THE PURPOSE OF THE DISCUSSION:

- Statement about the project to be provided by The Arthritis Society

I want to begin by learning a little bit about you. While you are all here because you are all taking biologics for inflammatory disease, you may have different conditions that you are treating. Let's start by going around the room and talking a bit about who you are, describe your household, and the conditions you are treating.

JOURNEY TO STABILITY

20 minutes

I want to hear a bit about your journey to achieving stability in your treatment. (In other words, getting to the point where your symptoms are largely under control.)

- Have you achieved stable treatment? What does that mean for you in your life?
- How long did it take you to achieve stability in your medication? IF NOT STABLE, how long have you been seeking stability in your medication?
- What were the challenges in this process?
- Who / what did you lean on for support during this process? What did that support look like?
- Did you encounter any barriers to getting a biologic?
- Did you make use of any supports in getting a biologic?
- Were there any difficult decisions you had to make along this journey to stability? If so, please elaborate.

EXPERIENCE WITH SWITCHING

30 minutes

Now I'd like to hear about how your experience with switches to different biologic medications affected you.

- How many times have you had to make a change to your biologic?
- How did the change impact you? Do you feel you had a role in the decision to switch?
 - PROBE: Health, emotional, life, work, financial, etc.
- What were the reasons for the change?
 - PROBE MEDICAL REASONS: Disease progression, drug doesn't work as well anymore, side effects
 - PROBE NON-MEDICAL REASONS: Mode of delivery (IV, SC), drug coverage change, cost (private plan cap, co-pay cost, etc.), personal preference, location of infusion services
- How was the change managed by your doctor? Patient support program? Pharmacists?
 - PROBE: Tease out differences in how the change was managed based on the different reasons for the change.

- Who or what was the most helpful to you in managing the switch? What could have been better? Is there anything else that could have been available to help you through the switch?
–PROBE: Impact of support that was available or not available (emotional, financial, functional, information)

I would like to understand the factors that drove the decision to change biologics.

- WHITEBOARD ACTIVITY: What are all the factors that drove the decision?
–PROBE IF NOT MENTIONED: Efficacy, how quickly it starts to work, known safety / side effects, cost, reduction in number of other drugs required, injection vs. infusion vs. oral, frequency of dosing, patient support program, options if change does not work.
- What were the three most important factors? Least important factors?
PROBE IF COST NOT MENTIONED: Cost wasn't a key factor for all of you, why not? [trying to get at if cost is masked or distorted by a person's access to drug coverage, high/low/no co-pay, on compassionate program offered by drug manufacturer, cap, etc.]
- Have you ever felt forced to make a switch? Tell me about that experience.

BIOSIMILARS

15 minutes

Now, please raise your hand if you've heard of biosimilars? They're sometimes called subsequent entry biologics, or SEBs.

Before we go any farther, I'd like to show you a brief video that outlines biologics, biosimilars and how they differ. Understanding this will be helpful for our further discussion. Please note that this video was prepared for arthritis patients; however, the underlying science applies equally to biologics and biosimilars used for other disease types as well.

[PLAY VIDEO]

- What do you think about biosimilars as a potential medication option for you?
– PROBE: Negative or positive answers [cost effective addition to the existing options available vs. a way for governments to save money]
- Do you feel you know enough about them?
- Where would you feel comfortable learning more about biosimilars?
– PROBE: Is your physician adequately knowledgeable about biosimilars?
– PROBE: Pharmacists? Drug plan funders? Health charities? Patient groups? Others?

We were talking about switching before; now I'd like to explore the question of switching from a biologic to a biosimilar.

- For those of you that have experienced a switch in your biologic, how does the idea of switching to a biosimilar strike you?
- Would you think the process would be the same? Or different?
- Under what circumstances would you feel comfortable / confident switching to a biosimilar? Are there circumstances where you might feel uncomfortable switching to a biosimilar?

PATIENT SUPPORT PROGRAMS

20 minutes

Now let's discuss patient support programs (PSPs)...

- Let's start with what you know about these programs – can anyone describe what these PSPs do?
- Each biologic has its own PSP funded by the manufacturer of the biologic. Have you interacted with PSPs? If so, how?
- What was most valuable / useful for you about the PSP? What was least valuable / useful?
- When making a decision to take a biologic, were you made aware of the PSP?
 - If yes, where did you get the information?
- Have you noticed that there has been a change in the PSP when you've changed your biologic? How did that impact you?
- IF NOT MENTIONED IN THE EXPERIENCE WITH SWITCHING SECTION: When considering a change in biologic how important is the PSP to your decision?
- Have you noticed a change between PSPs between injected vs. infused biologics?

SWITCHING BIOLOGICS PT. II

If time allows

Circling back to our discussion on switching biologics...

- Did you feel fully engaged in the decision to make or consider a change?
 - Was it important to you to be engaged?
- If you could change anything about the switching experience, what would you have liked to be different?
- For those of you who have made one or more changes in your biologic, do you think you were better able to engage in decision-making in subsequent changes?
- What advice would you offer to people who are facing a first change?
- Do you feel your physician was able to adequately inform you about all available options and recommended the option that was right for you?
 - PROBE: Why or why not?
- If you were being switched to a biosimilar for medical reasons, what information would you want to know? (MEDICAL REASONS: Disease progression, drug doesn't work as well anymore, side effects)
- Would your information needs be different if you were being switched for non-medical reasons? If yes, in what way? (NON-MEDICAL REASONS: Mode of delivery (IV, SC), drug coverage change, cost (private plan cap, co-pay cost, etc.), personal preference, location of infusion services)
- Do you feel your physician was able to ensure you received the best medication for your needs?
 - PROBE: Why or why not?
 - PROBE: If it comes out naturally, probe on whether there should be other health professionals involved in making decisions about a change to your biologic.
- Do you feel that you had the right information and were given sufficient time to participate fully in the decision-making?
 - PROBE: Is there any information you wish you would have had?
- How did you get your information on the biologics being considered?
 - PROBE: Peers, Internet, Disease Associations/Groups, physician? Were these sources trustworthy?

CLOSING

- Moderator runs to back room to see if any additional questions.
- Moderator closes conversation.
- Thanks and dismisses participants.

Appendix 8

PROJECT SPONSOR COMMENTS

Achieving Stability

Comments made by project sponsors on the focus group findings:

- The unique nature of the journey experienced by individuals living with each of these diseases was felt to be of critical importance to understanding the perspectives expressed in the focus groups. The design of the project did not allow for exploration of differences or similarities across the diseases, age cohorts, gender, etc. However, the diseases do have similar impacts on people's lives. It is a long and often arduous journey for a patient to achieve stability, and once achieved, stability is fragile. Getting a diagnosis alone can often be a multi-year journey, and then you face a life-long need for treatments to manage the disease.
- There seems to be inconsistency in how terms are understood, e.g. remission and stability.
- Education is needed so that patients:
 - have a broader understanding of treatment options that are available to them;
 - can be more confident when speaking to their primary care physician (GP) and specialist (dermatologist, gastroenterologist or rheumatologist) to take more control of the treatment options available; and
 - can be more confident when speaking with their pharmacist (to better understand changes that could happen to their prescribed medications at the pharmacy counter).

Challenges Related to Biologics

Getting a Biologic

Comments made by project sponsors on the focus group findings:

- The advent of biologics has changed the face of these diseases. Previously, symptoms may not have been well managed, and people living with the diseases would often have to leave work and remain hospitalized. Biologics have allowed many people to lead more productive and satisfying lives.
- The relative ease for more newly diagnosed people to get biologics demonstrated the success of many years of advocacy and reinforced the need for continued advocacy.
- The focus group participants had considerable experience with taking biologics. Some had a good understanding of biologics, while others did not seem to have the same knowledge.

- Health Canada definition – ‘Biologic drugs are derived through the metabolic activity of living organisms and tend to be significantly more variable and structurally complex than chemically synthesized drugs.’ <http://www.hc-sc.gc.ca/dhp-mps/consultation/biolog/submission-seb-exigences-pbu-eng.php>
- Currently approved biologics –

Biologic	Approved for these diseases*
Abatacept / Orencia®	RA
Adalimumab / Humira®	RA, AS, PsA, CD, UC, Psoriasis
Anakinra / Kineret®	RA
Certolizumab pegol / Cimzia®	RA, AS, PsA,
Etanercept / Enbrel®	RA, AS, PsA, Psoriasis
Golimumab / Simponi®	RA, AS, PsA, UC
Infliximab / Inflectra®	RA, AS, PsA, Psoriasis
Infliximab / Remicade®	RA, AS, PsA, CD,UC, Psoriasis
Rituximab / Rituxan or Mabthera®	RA
Secukinumab / Cosentyx™	AS, PsA, Psoriasis
Tocilizumab / Actmera®	RA
Ustekinumab / Stelara®	PsA, Psoriasis, CD
Vedolizumab / Entyvio®	UC, CD

*physicians sometimes prescribe ‘off-label’

Cost of Biologics

Comments made by project sponsors on the focus group findings:

- It appeared that a number of the focus group participants had limited or faulty knowledge of how their medications were funded. The system is complex and the funding options often change depending on a person’s life circumstance and sometimes when a medication is changed.
 - Each province and territory offers coverage for prescription medications. Who qualifies for coverage, what drugs are covered and how much is paid varies. Most governments offer coverage for seniors and those on social support. Each plan has an application and re-application process that may vary by the medication.
 - Many workplaces provide health and drug coverage for employees. This is normally through a contract with an insurance company that is periodically renegotiated. In larger workplaces there may be different plans available to different categories of employees. What drugs are covered and how much of the cost is paid is unique to each plan. This results in a variety of out of pocket payments each employee is expected to contribute (co-payments, annual fees, deductibles, annual payment caps, etc.). Some adult children may be covered under their parent’s plan up to a defined age. Increasingly fewer workplace plans extend coverage past retirement.
 - Private insurance may be purchased by individuals directly from insurance companies or through associations such as CAA, CARP, etc. As for workplace insurance plans, the coverage under each plan and the cost to purchase it varies.
 - Compassionate and/or copayment coverage may be provided by the pharmaceutical company where an individual has been prescribed an expensive medication, like a biologic, but is unable to cover the cost, or one where access is limited for another reason. The conditions and duration of this coverage vary.
 - In some limited cases hospitals may extend compassionate coverage as well, typically with regard to a medication that is part of a treatment regime the individual is receiving through the hospital that falls outside provincial formularies.

Biosimilars / Subsequent Entry Biologics

Comments made by project sponsors on the focus group findings:

- More education is needed to ensure patients understand biosimilars/ subsequent entry biologics (SEB). The vast majority of focus group participants lacked knowledge of biosimilars. Viewing a short informational video did not markedly improve this knowledge. Some referred to biosimilars as ‘generics’ even after viewing the video.
- There also seemed to be a perception that physicians had limited knowledge of biosimilars, with the exception of some specialists.

Switching Biologics

Comments made by project sponsors on the focus group findings:

- The clinical guidelines on/rationale for switching between biologics, including to a biosimilar, were poorly understood by the focus group participants.
- The project sponsors have stated positions on the role of biosimilars, switching medications, and the need to ensure patient choice and safety, which can be viewed here:
 - <http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/AbbVie-Infographic-E.pdf>
 - <http://www.janssen.com/canada/about/healthcarepolicy/biosimilars>
- More advocacy is needed to ensure that patients are not forced to move to a biosimilar when their current biologic is successfully treating their disease.

Supports Available

Comments made by project sponsors on the focus group findings:

- There seemed to be a lack of knowledge and confusion as to what supports might be available, who provided them, what they offered and how to access.
 - Pharmaceutical companies make patient support programs available to individuals who have been prescribed a biologic. These programs are offered by an independent third party, in part to protect the individual’s confidentiality. Each program is different, but most provide assistance in accessing payment for the biologic, information on the biologic, support for the administration of the biologic, etc. Compassionate coverage for the cost of the biologic is usually available to qualified individuals until other arrangements can be made.
 - Disease charities and patient groups offer a range of supports, including information on the disease and treatments, and education on symptom management and living well with the disease. Some make peer support or online chat available.

About Biosimilars

What is a biosimilar/SEB – BIOTECCanada’s definition - Subsequent Entry Biologics (SEBs), also known as “biosimilars” or “follow-on biologics” in Europe and the USA, are follow-on versions similar to an original biologic drug, made by different manufacturers after the patent on the innovator drug has expired. SEBs are sometimes mistakenly called “generic” versions of innovative biologics. Unlike generics, which are identical copies of chemically synthesized drugs, SEBs are similar to, but not identical to the original innovator drug. This is due to the inherent complexities of large molecule drugs and their manufacturing process. <http://www.biotech.ca/policy-matters/health/subsequent-entry-biologics/>

What is the regulatory approval process for biosimilars/ SEBs in Canada? Institut national d’excellence en santé et en services sociaux (INESSS) statement - A subsequent entry biologic (SEB) is a biologic product that enters the Canadian market subsequent to a reference biologic drug and has a demonstrated similarity to this reference. Biologics are a class of drugs derived from living organisms that are more variable and structurally complex than chemically synthesized drugs. The regulatory approval process for SEBs therefore differs from that for generic drugs. In Canada, their approval is based not only on a demonstrated similarity between a SEB and its reference biologic in terms of biological and physicochemical factors, but also on a reduced set of clinical and non-clinical data in comparison to a brand name drug. In some cases, approval of a biosimilar for some indications may be based on extrapolation relative to the indications approved for the reference drug, i.e. once a biosimilar has been established as comparable to the reference drug for some indications, the biosimilar may receive approval for additional indications where the reference drug is also used. <https://www.inesss.qc.ca/en/activities/drug-products/frequently-asked-questions-about-prescription-medications/subsequent-entry-biologics.html>

More About Biosimilars

Health Canada’s guidance for biosimilars/subsequent entry biologics – ‘SEBs are not “generic biologics” and many characteristics associated with the authorization process and marketed use for generic pharmaceutical drugs do not apply. Authorization of an SEB is not a declaration of pharmaceutical equivalence, bioequivalence or therapeutic equivalence to the reference biologic drug. <http://www.hc-sc.gc.ca/dhp-mps/consultation/biolog/submission-seb-exigences-pbu-eng.php>

Other Comments

- Take advantage of opportunities to reach out to medical/health professional students to better educate them on:
 - options available to patients to help them access the best possible treatment for their disease, including treatment options, insurance/payer issues, and other options available to patients to help them access the best possible treatment for their disease; and
 - biologics and biosimilars.

CAPA Canadian Arthritis
Patient Alliance
experience · perspective · voice

Canadian
Psoriasis
Network  Réseau
canadien
du psoriasis

 Crohn's and
Colitis Canada
Crohn et
Colite Canada

 **badgut.org**
Gastrointestinal Society
Canadian Society of Intestinal Research


The Arthritis
Society