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Dietary Fibre

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Gastrointestinal Society
Canadian Society of Intestinal Research

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ABOUT US

WHO WE ARE

The GI (Gastrointestinal) Society and the Canadian Society of Intestinal Research (CSIR) are registered Canadian charities committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to healthcare, and promoting gastrointestinal and liver health.

THE INSIDE TRACT®

The *Inside Tract®* newsletter is our primary tool for delivering up-to-date medical information, in lay terms, to the Canadian public in English and French. Subscribe now for a low annual fee of $20 on our website www.badgut.org or complete the mail-in form on page 23.

KEY TOPICS

We've been providing information to the public since 1976 and have a very wide range of free resources, articles, and tools online and in print on:

- Aging Digestive Tract
- Biologics & Biosimilars
- Celiac Disease
- *Clostridium difficile* Infection
- Colorectal Cancer
- Colorectal Polyps
- Constipation
- Crohn's Disease
- Diverticular Disease
- Dysphagia
- Eosinophilic GI Disease
- Functional Dyspepsia
- Gastroparesis
- GERD (reflux & heartburn)
- Hemorrhoids
- Hepatitis B & C
- Hiatus Hernia
- Inflammatory Bowel Disease
- Intestinal Gas
- Irritable Bowel Syndrome
- Lactose Intolerance
- Medical Cannabis
- Non-Alcoholic Fatty Liver Disease
- Pancreatic Exocrine Insufficiency
- Pancreatitis
- Short Bowel Syndrome
- Ulcer Disease
- Ulcerative Colitis
- Ulcerative Proctitis

FREE PRINTED INFORMATION

Contact us today to request some specific free information, or check us out online and on our social media platforms for the latest digestive health news. Healthcare professionals can order these pamphlets in bulk online.

SPONSORS

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President & CEO Report

Gail Attara, Gastrointestinal Society

For much of this fall, we have been focused on advocacy related to the new switching policy that the BC government released on September 5. In Phase 2 of their Biosimilars Initiative, they are forcing patients in BC who have Crohn's disease or ulcerative colitis taking a biologic medication (Remicade®) to switch to a biosimilar (Inflectra® or Renflexis®) in order to maintain PharmaCare coverage. On September 30, the GI Society hosted a forum about this policy, in which patients could learn more from healthcare experts and ask questions of two PharmaCare pharmacists. We highlight the events of this forum on page 18. On October 31, I met with government in Edmonton because the Alberta Health Services is also making coverage changes to innovative biologics and biosimilars. If you have been affected by any policy change, we want to help. We believe that patients, in consultation with their physicians, have the right to choose the therapy that is best for them. Contact us to share your biosimilars story. We anticipate other jurisdictions across the country to announce some form of biosimilars policy in the coming months as well.

We also brought our well-loved fundraiser, the Inside Affair networking event, back to Vancouver and Toronto this November. Go to page 4 to learn more about these events.

I continue to attend meetings with the Better Pharmacare Coalition once a month to help advocate for better access to medication for all patients.

On September 9, I met with healthcare experts at the Navigating Toward HCV Elimination in Canada conference in Montreal, where we discussed Canada's role in supporting the World Health Organization's goal to eradicate hepatitis C by 2030. For more information, go to page 22. As a reminder, if you were born between 1945 and 1975 and have never been tested for hepatitis C, please go to your doctor to get tested.

We are also hosting two surveys right now, one about the unmet needs in the treatment of IBD and the other about biosimilars in Canada. You can find more details about these surveys on page 17. If you qualify, please complete these surveys online; your responses help shape our advocacy.

Inside Affair 2019

The Inside Affair networking events in Vancouver and Toronto this fall allowed business, healthcare, and patient communities to come together to show support for the Gastrointestinal Society's charitable work. For these events, we focused on honouring the past, considering the present, and looking to the future of gastrointestinal research, science, and healthcare.

The high point of the event in Vancouver was a heartfelt thanks to Dr. James R. Gray, including a video showcasing his 27 years of support of the Canadian Society of Intestinal Research (CSIR) and the Gastrointestinal Society.

Serving as Chairperson for our Medical Advisory Council since 1992, Dr. Gray co-founded the Gastrointestinal Society in 2008, with the late Dr. Frank Anderson and our CEO, Gail Attara. Dr. Gray has continued to serve both the CSIR and the GI Society throughout the past years, generously providing his medical knowledge and connections. He is also the vice president of the CSIR board of directors.

Dr. Gray volunteers his time to review our quarterly *Inside Tract*® newsletters, all patient information pamphlets, our BadGut® lectures, and video scripts for medical accuracy. He

Reid Jamieson Band

Evan Carter

has also delivered more than 30 of our BadGut® Lectures and is the voice of our educational videos.

Gail Attara recognized Dr. Gray's tremendous contributions with an award, but jokingly presented him a poop emoji award at first. This was paired with a scrumptious and creative fondant cake. Guests not only enjoyed eating the cake, but they also expressed admiration for its detail and artwork.

Ron Goetz, chair of our Board of Directors, emceed our first Inside Affair of the year on November 5 at the Delta Hotels Conference Centre in Burnaby, right on the Vancouver border.

We were fortunate to have Mitch Moneo, Assistant Deputy Minister, Pharmaceutical Services Division in the BC Ministry of Health speak at this event. He reflected on the rigorous and vital work of the GI Society in providing input and collaboration on a number of issues and highlighted the challenges the Pharmaceutical Services Division has grappled with over the years. He noted how the Society placed access to treatments and patient-focused care at the forefront, with a value of inclusion in bringing various patient groups to the table. In many ways, he acclaimed, it has made a remarkable transformation in partnerships between the government and patient communities.

Attendees enjoyed music from the Reid Jamieson Band, Vancouver's very own singer and song-writing duo. Reid Jamieson performed with his wife and creative song-writing partner, Carolyn Victoria Mill.

Nicole Mittmann

On November 18, in Toronto we had our second Inside Affair networking event at the Fermenting Cellar in the Distillery District, where we have held many Inside Affairs over the years. Robert Kulik, a director on the GI Society Board was the emcee at this event. The night featured a talk by Nicole Mittmann, MSc PhD, Chief Scientist and Vice-President of Evidence Standards, CADTH, about the current challenges in the area of health technology assessment and management to ensure patient access to valuable medications and devices. Entertainment was by musician Vincent Soars and renowned comedian Evan Carter.

Guests received a GI Society digestive tract themed pen (either in the shape of intestines or a stomach), and a range of delectable goodies to take home. Toronto guests also enjoyed our own rendition of mousse brownie poop emojis. All of these treats demonstrated that we can talk freely about digestive functions; it doesn't have to stay quietly in the shadows, causing those with digestive diseases to suffer in silence.

Both Inside Affairs were powerful events, where old friends connected, new friendships were forged, and networking occurred naturally throughout the evening.

We thank all of our speakers and appreciate them taking the time to share vital knowledge and insights with the attendees. We are also grateful for the organizations and individuals who recognized the work of the GI Society by sponsoring these events, purchasing tickets, or volunteering. We could not have done it without you! Our major event sponsors were AbbVie, Allergan, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, the Dr. Rogers Prize, Gilead, Innovative Medicines Canada, Janssen, LifeScan, Pfizer, Sanofi, and Takeda. Special thanks to amazing volunteer, Laurie Middleton-Crump.

Everything in moderation?
Focusing on ultra-processed foods

We all know what processed foods are, but what about ultra-processed foods? It doesn't take too long to find them at the grocery store; all you need to do is read the ingredient list on a packaged food item. If you wouldn't use these ingredients for cooking at home, then they're likely an ultra-processed food. You might find high fructose corn syrup, invert sugar, modified starches, hydrogenated oils, and colourings, as well as de-foaming, bulking, and bleaching agents on the food label. These are just a few examples of ultra-processed food ingredients.

This article focuses on ultra-processed foods, their effects on health, and how we consume them in Canada. One of the best things you can do for your health in the coming year is to eat more unprocessed food and less ultra-processed foods. Yes, food manufacturers aggressively market these very addictive products, and I certainly don't blame anyone for eating or wanting to eat them. That said, I think it's time to aggressively market real food instead, which is why I'm writing this article. For many people, the more unprocessed food you eat, the less you'll crave the artificial stuff as time goes on. Trust me, I've been there too.

Ultra-Processed Foods

The term comes from the *NOVA* food classification system, a system created to classify foods based on how they are processed and for what purpose (extending shelf life, fortifying with vitamins and minerals, creating ready-to-eat or ready-to-heat foods, etc.).[1] They classify food into four groups: unprocessed or minimally processed foods, processed culinary ingredients, processed foods, and ultra-processed foods. Ultra-processed foods are defined as "formulations of several ingredients which, besides salt, sugar, oils, and fats, include food substances not used in culinary preparations, in particular flavours, colours sweeteners, emulsifiers, and other additives used to imitate sensorial qualities of unprocessed or minimally processed foods and their culinary preparations or to disguise undesirable qualities of the final product".[2] I can't imagine ever having to disguise undesirable qualities of the final product of something that I'm cooking at home, unless something has gone terribly wrong with the recipe.

NOVA Food Classification Examples*

Unprocessed or minimally processed foods

- vegetables and fruits (fresh or frozen)
- dried fruits with no added sugar, honey, or oil
- grains and legumes (chickpeas, lentils)
- meat, poultry, fish, seafood, eggs
- milk without added sugar
- plain yogurt with no added sugar
- nuts and seeds
- spices and herbs
- tea, coffee, water

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1 Moubarac J-C. *et al.* Consumption of ultra-processed foods predicts diet quality in Canada. *Appetite.* 2017; 108: 512-520.
2 Martinez Steele E. *et al.* Ultra-processed foods and added sugars in the US diet: evidence from a nationally representative cross-sectional study. *BMJ Open.* 2016; 6.
3 PAHO. Ultra-processed food and drink products in Latin America: Trends, impact on obesity, policy implications. Washington, D.C.I Pan American Health Organization. 2015.
4 Ricker, M. et al. Anti-Inflammatory Diet in Clinical Practice: A Review. *Nutrition in Clinical Practice.* 2017; 32: 318-325.
5 WHO. Guideline: Sugars intake for adults and children. 2015.

Processed culinary ingredients

- iodized salt
- salted butter
- sugar and molasses from cane or beet
- honey extracted from combs
- syrup from maple trees
- vegetable oils crushed from olives or seeds
- butter and lard from milk and pork
- starches extracted from corn and other plants
- vegetable oils with added anti-oxidants
- vinegar with added preservatives

Processed foods

- canned vegetables, fruits, and legumes
- fruits in syrup
- salted or sugared nuts and seeds
- salted cured or smoked meats
- canned fish
- artisanal breads and cheese

Ultra-processed foods

- pop and fruit drinks
- sweetened yogurt
- sweet or savoury packaged snacks (e.g., cookies)
- candies and cake mixes
- mass-produced packaged breads and buns
- margarines and spreads
- breakfast cereals
- cereal and energy bars
- energy drinks
- instant soups, sauces, and noodles
- poultry and fish nuggets, hot dogs
- many ready-to-heat products: pre-prepared pies, pasta, and pizza dishes

*Adapted from PAHO 2015[3]

Nutrition and Inflammation

Ultra-processed foods are less filling and raise our blood sugars higher than minimally processed foods. They are generally higher in calories and sugar, lower in protein and fibre, and are associated with obesity.[1] They are nutritionally inferior and eating them replaces healthier nutrient-rich foods that you could be eating instead (crispy veggies and hummus instead of pop and chips). Many of them are snack foods and promote mindless eating, replacing the need or desire for a real meal. Not only that, they contain pro-inflammatory ingredients, such as refined sugars (carbohydrates), and unhealthy fats, like corn oil.[4] I recommend avoiding pro-inflammatory foods to my clients, especially for those with inflammatory conditions such as inflammatory bowel disease (IBD) and obesity, or digestive health conditions like irritable bowel syndrome (IBS) and diverticular disease.

Refined sugars (carbohydrates), such as high fructose corn syrup, are one of the primary dietary factors that affect inflammation.[4] They can be hard to avoid when they are found in so many foods at the grocery store, especially when they're hidden in foods you wouldn't suspect (e.g., coconut milk). The World Health Organization (WHO) recommends limiting free sugar (also known as added sugar) intake to no more than 10% of total energy intake, and ideally less than 5% of total energy intake for greater health benefits (this amounts to approximately 25 grams, or six teaspoons of sugar). One cup (250 mL) of regular Coca-Cola has 27 grams of added sugar. That's more than enough for the day if you're not looking to exceed the 5% limit.[5]

Consumption in Canada

The United States wins first place for largest buyers of ultra-processed foods and drinks in the world and, sadly, Canada comes in second.[1] . A study released in 2017 looked at the consumption of ultra-processed foods and diet quality in Canada. They found that 48% of calories consumed by Canadians came from ultra-processed foods such as soft drinks, packaged juices, fast food, and mass-produced breads.[1] Their data was from the Canadian Community Health Survey. The people who had the highest intake of ultra-processed foods were those of a younger age and males. Compared to other high-income countries, such as France and Italy, Canada and the United States still consume significantly more of these products. Food processing has not always been a factor in measuring diet quality, but it should be.

Bottom Line

Ultra-processed foods are everywhere. They are addictive, nutritionally void, and contain pro-inflammatory ingredients that we should avoid. So how can you eat less of them? I suggest adding real food back into your diet, one meal or snack at a time. This could mean simply replacing your afternoon snack with some grapes and walnuts, instead of a packaged granola bar. Cooking at home is a great proactive way to eat less ultra-processed foods. If you're not used to cooking, no worries, it takes time to develop this habit, and I suggest starting small, like making one batch meal on Sundays. You may find you actually enjoy the time you spend and many find that cooking helps reduce and minimize stress too. How would *you* benefit from eating fewer ultra-processed foods? It's something to think about.

Celebrating the Growth and Resilience of Complementary and Alternative Medicine and Research

On the evening of September 26, staff and board members of the GI Society and CSIR attended the 2019 Dr. Rogers Prize for Excellence in Complementary and Alternative Medicine Gala Award Dinner, compliments of the Dr. Rogers Prize organizers.

Guests were treated to delectable gluten-free cuisine and illuminating knowledge from keynote speaker, Dr. Alessio Fasano, Professor of Pediatrics at Harvard Medical School and Director of the Mucosal Immunology and Biology Research Center (MIBRC) at the Massachusetts General Hospital for Children. He spoke about what few only dare to share: the despairing realities of trial and error involved in research. Humorous, poignant, yet serious and highly informative, Dr. Fasano walked us through his growth and indirect discovery – 'serendipity' as he described it – of the protein zonulin and its relationship with celiac disease and intestinal permeability.

The gala concluded with the announcement of the 2019 Recipient of the $250,000 Dr. Rogers Prize: Dr. Bonnie J. Kaplan, a professor emerita of the Cumming School of Medicine at the University of Calgary. She is recognized for her work in psychiatric research and the role of nutrition in mental illness and brain disorders, particularly in demonstrating evidence on the use of a particular set of micronutrients for the treatment of bipolar disorder and attention deficit hyperactivity disorder. Her efforts are currently focused on participating in international lectures and managing two charitable funds to support research and clinical trials in micronutrient therapies.

The $250,000 Dr. Rogers Prize for Excellence in Complementary and Alternative Medicine recognizes individuals whose research has contributed to significant progress in complementary and alternative medicine and captures the legacy of the late Dr. Roger Hayward Rogers. Dr. Rogers was appointed the Order of British Columbia in 2001 for his work in complementary cancer care. The Prize is held and awarded in Vancouver, BC every other year and is made possible by contributions from the Lotte and John

Photo: © Brian Demnehy

Standing (L to R): Shereen Low, Dr. Bruce Vallance, Brittany Moretti, Dr. Ganive Bhinder, Ciara Regan
Seated (L to R): Dr. Alan Low, Gail Attara, Dr. James Gray, Jane Gray, Jaymee Maaghop

Photo: © Brian Dennehy

Dr. Alessio Fasano and Gail Attara

Hecht Memorial Foundation. To learn more, please visit www.drrogersprize.org.

A colloquium followed the next morning, which featured a panel on emerging studies in the microbiome and nutrition in autoimmune diseases. Dr. Fasano began with a review of the increasing roles of lifestyle and environmental factors in the gut microbiome in relation to genetics and/or genetic predispositions. He shared that personalized preventative treatments focused on nutrition and lifestyle are at the forefront of research and development.

Dr. Jeremy P. Burton, BSc, MSc, PhD, dBA, the Miriam Burnett Chair in Urological Sciences in the Division of Urology, Department of Surgery of the Canadian Centre for Human Microbiome and Probiotics, shared his work in using fecal microbiota transplantation (FMT) in treating autoimmune diseases. He spoke on the use of FMT to treat *Clostridioides difficile (*formerly *Clostridium difficile)* infection and in multiple sclerosis patients' microbiome. He noted that there is a shift in developing a less invasive procedure for FMT, such as the use of oral capsules.

Dr. Kaplan, recipient of the 2019 Dr. Rogers Prize, enlightened attendees on nutrient research, illustrating how every enzymatic step in the brain requires certain vitamins and minerals to produce necessary chemicals, such as serotonin. This, among others, established the foundations for her approach in research using broad spectrum micronutrients as opposed to single nutrient research.

The GI Society thanks the Dr. Rogers Prize organizers for their thoughtful invitations to both the gala award dinner and colloquium. We look forward to hearing about future recipients and their work in advancing complementary and alternative medicine!

C. difficile Gets a Name Change

You've probably heard of *Clostridium difficile*, the bacterium that can cause a devastating illness known as *Clostridium difficile* infection (CDI) in vulnerable individuals. However, the name of the bacterium is currently undergoing some changes. Recently, the Clinical and Laboratory Standards Institute (an international not-for-profit organization dedicated to fostering excellence in laboratory medicine) has decided that the name of the bacteria should be *Clostridioides difficile*, which is a more accurate taxonomic classification than the old name. Since then, other science and healthcare groups have also been making the name change. This transition period might be a bit confusing to patients, but the similarity between the two names means that the old short forms, such as *C. difficile*, *C. diff*, and CDI, are still correct.

Photo: © Tyrannosaurus | Bigstockphoto.com

Support Group

Please call the Gastrointestinal Society office to check if the support group you are interested in attending is running for the month.

Inflammatory Bowel Disease (IBD)
7:00 pm, third Wednesday of each month
231-3665 Kingsway, Vancouver, BC

Photo: © Rawpixel.com | Bigstockphoto.com

Blood-Based Biomarkers for Diagnosing IBS-D

When patients present with symptoms of chronic diarrhea, physicians often determine it to be either irritable bowel syndrome with diarrhea (IBS-D), inflammatory bowel disease (primarily Crohn's disease and ulcerative colitis), and/or celiac disease. While highly accurate testing for celiac disease and inflammatory bowel disease (IBD) is available, screening for IBS lags behind as it relies on symptom-based diagnostic criteria and elimination of other diagnoses, which can be less accurate and take longer than a diagnostic test.

However, researchers have made advancements in developing alternative methods to diagnose IBS and further uncovering its pathogenesis. For instance, in our previous newsletter we discussed a urine-based biomarker test.[1] In this edition, we return with an overview of another biomarker test for this condition. After identification, validation, and enhancement, a group of scientists have successfully established blood-based biomarkers that can differentiate irritable bowel syndrome with diarrhea (IBS-D) from inflammatory bowel disease (IBD).

IBS is a chronic disorder with symptoms ranging from abdominal pain and bloating, to constipation and/or diarrhea. It is the most common gastrointestinal condition suffered by individuals worldwide. There are three main subtypes of IBS: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), and IBS with both constipation and diarrhea (mixed) (IBS-M). Lifestyle and dietary modifications greatly aid in symptom management, while some prescribed and over-the-counter medications are also useful.

IBD is a term that primarily refers to two diseases of the intestine: Crohn's disease and ulcerative colitis. In Crohn's disease, inflammation occurs in any part of the digestive tract and any depth of the bowel wall. In ulcerative colitis, on the other hand, inflammation is limited to the inner mucosa of the large intestine, beginning at the anus and spreading upward into the colon. The most common symptoms of IBD are diarrhea, abdominal pain, fever, rectal bleeding, weight loss, and anemia. Physicians typically diagnose IBD via endoscopy and treat it with a variety of strong medications.

While IBS and IBD are two distinct gastrointestinal conditions, many individuals mistake them for each other. With that said, it is clear to see how confusion arises between IBS-D and IBD when they both have diarrhea as a common symptom.

Implications of Validated Biomarkers for IBS

With the identification of two biomarkers called anti-vinculin and anti-cytolethal distending toxin B (anti-CdtB) from blood testing,[2] researchers from the study built on their findings in a later analysis,[3] significantly improving on the accuracy of the test. Not only do these biomarkers distinguish IBS-D from other digestive conditions with symptoms of chronic diarrhea, but they also aid in the diagnosis of IBS-D in new patients. Interestingly, their findings also provided some evidentiary basis for questioning the dominating viewpoint that IBS is a functional disorder caused by hyper-sensitivity to the nervous system, gut bacteria, and psychological factors (i.e., stress). They hypothesize that the condition – or at least a subtype – is rooted in biological interaction, signifying directions for therapeutic treatment.

The results of their studies address a critical gap in clinical practices for IBS, potentially transforming current diagnosing methods to blood sampling. This presents great opportunities

in reducing healthcare costs derived from exclusionary tests for IBS, as well as patient fatigue. These biomarkers can also be crucial for patients with both IBS and IBD, where ongoing chronic diarrhea may actually be a result of IBS, and may be concealing recovery in IBD.

Studies have increasingly found that gastroenteritis is a likely cause for a subset of IBS, called post-infectious IBS (PI-IBS), which affects as many as 5-32% of those who have had gastroenteritis.[4] The primary trigger for gastroenteritis, an inflammation in the stomach and intestines, is infection with bacteria such as *Campylobacter jejuni*, *Escherichia coli, Salmonella,* and *Shigella*. A common toxin among these infections is cytolethal distending toxin (Cdt). Cdt has three subunits called CdtA, CdtB, and CdtC. Researchers focused on CdtB because this toxin interacted with a host protein called vinculin, which translates and regulates the essential movements of biochemical properties between the receptors of the cell and its cytoskeleton, constantly interacting with the cell's inside and outside microenvironment.[2]

Scientists found that anti-CdtB and anti-vinculin were significantly elevated in IBS-D patients compared to participants who were healthy and did not have any history of digestive illnesses, participants with IBD (Crohn's disease and ulcerative colitis), and participants with celiac disease. Meanwhile, these biomarkers were equal and/or similar between healthy controls, IBD patients (Crohn's and colitis), and celiac disease patients, presenting no statistically meaningful differences.

It is important to note that these biomarkers are not found in all IBS-D patients. However, this subgroup of patients and further understanding of the specific pathogenesis for IBS can lead to the development of therapies to aid patients in their management of chronic diarrhea.

Increasing Diagnostic Power

The researchers conducted a follow-up study in 2019,[3] during which they noticed that the biomarkers' epitopes are easily subject to damage due to sensitivity to environmental changes such as heat and pH levels. These damages make it difficult to identify and, in some cases, hide the biomarkers in blood samples. To address this, they added a step to the biomarker testing process by stabilizing the epitopes (proprietary epitope stabilization). This greatly enhanced the test by increasing its specificity and sensitivity to a probable accuracy of greater than 98% in diagnosing IBS and more than 90% in distinguishing IBS and IBD patients.

Implementation in Clinical Practice

The researchers acknowledge that there are demographic limitations (such as the lack of inclusion from seniors greater than 65 years of age and Asian populations) encountered in their studies that need to be addressed in future research. However, this should not stray from the significance of their findings as well as the fact that other studies have confirmed the value of the biomarkers anti-CdtB and anti-vinculin since its validation in the 2015 study. In addition, researchers posit that the path forward is to assess the feasibility of implementing the test in clinical practice by conducting cost-analysis between current diagnosing methods and real-world application of the test.

How You Can Get Tested for IBS

The blood test for irritable bowel syndrome is now available in Canada and the US under the name ibs-smart™. To learn more, visit their website at www.ibssmart.com. If you reside in Canada, you can find a patient-directed process at www.ibssmart.com/canada. You can order the test online, priced at $285 USD. The ibs-smart™ kit and requisition form must be completed by your treating physician, and then shipped to labs for analysis. They send the results to your physician within four business days of receiving the blood samples.

1 I Spy IBS in Your Urine. *Inside Tract*® newsletter issue 211 – 2019.

2 Pimentel M *et al*. Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects. *PLoS ONE*. 2016;10(5):1-12.

3 Morales W *et al*. Second-Generation Biomarker Testing for Irritable Bowel Syndrome Using Plasma Anti-CdtB and Anti-Vinculin Levels. *Digestive Diseases and Sciences*. 2019.

4 Thabane M *et al*. Post-infectious irritable bowel syndrome. *World Journal of Gastroenterology*. 2009;15(29):3591-6.

Dietary Fibre

What you need to know to maintain a healthy gut.

What is Dietary Fibre?

Fibre is a type of carbohydrate that we cannot digest. With other types of carbohydrates, such as sugars and starches, our digestive system breaks them down into absorbable simple sugars, which our bodies use as energy. Fibre, on the other hand, passes through into the colon undigested, where it adds bulk to stool and, in some cases, becomes food for the beneficial bacteria colonizing the gut. The health benefits from fibre are numerous, but not enough people meet their daily fibre needs. Throughout this article, we will explain everything you need to know about fibre, including tips on how to add more of it into your diet.

Recommended Daily Amounts of Fibre

The amount of fibre you need to consume in a day can vary largely depending on your sex, age, digestive health, and specific nutritional goals. While there is no official maximum intake for dietary fibre, eating too much, especially by drastically increasing your intake over a short period of time, can lead to unpleasant side effects, such as gas and bloating. To avoid these side effects, gradually increase the amount of fibre in your diet and be sure to consume plenty of fluids. If you have certain digestive diseases or troublesome symptoms, you might need to limit your fibre intake. See our section on a fibre restricted diet for more information.

This chart shows the approximate intake you should be aiming for, based on age and sex.[2]

Age in Years	Female	Male
1-3	19 g	19 g
4-8	25 g	25 g
9-13	26 g	31 g
14-18	26 g	38 g
19-50	25 g	38 g
50+	21 g	30 g
Pregnant (any age)	28 g	-
Breastfeeding (any age)	29 g	-

Types of Dietary Fibre

We generally talk about fibre as if it is one specific thing, with a focus on reaching certain goals for total fibre intake. For many individuals this is adequate, as most types of fibre will generally benefit an otherwise healthy individual. However, there are actually many types of fibre, and some are more effective for relieving symptoms of specific digestive ailments. For practical purposes, we can sort these into two groups: soluble and insoluble fibre. Most plants contain a mix of the two fibre types, although some have higher concentrations of one or the other.

The Importance of Water

When you are trying to increase the amount of fibre you consume, it is important to also monitor your water intake. If you eat more fibre but don't drink more water, your stools can become too dry, causing or worsening constipation. Make sure to drink plenty of fluids to prevent this. If you have diarrhea, you might be tempted to drink less water to reduce the looseness of your stools. However, experiencing regular diarrhea puts you at risk of dehydration. If you are losing a lot of liquid through diarrhea, an electrolyte beverage might be more beneficial for you than plain water.

High-Fibre Foods

- whole grains (whole wheat products, oats, barley, popcorn, wild rice, etc.)
- legumes (beans, lentils, peas, edamame)
- nuts/seeds (chia seeds, flaxseed, pumpkin seeds, almonds, pistachios, walnuts, etc.)
- fruits (most varieties)
- vegetables (most varieties)

Soluble Fibre

These are fibres that are soluble in water. The primary types of soluble fibre include pectins (veggies, fruits), gums (gum Arabic), mucilages (guar, carrageenan), and some hemicelluloses. These fibres are especially beneficial for individuals with diarrhea, as they help slow down transit time. Soluble fibre also helps delay glucose absorption and lowers blood cholesterol. Sources include:

- fruits (especially apples and citrus)
- flaxseed
- oats
- barley
- legumes
- psyllium

Insoluble Fibre

Unlike soluble fibre, insoluble fibre does not dissolve in water. The main types of insoluble fibre include cellulose (primary material of plant cell walls), many hemicelluloses (cereal fibres), and lignins (non-polysaccharide). This is the best type of fibre for constipation, as it helps draw water into the stool to soften it and can help speed up transit time. It also increases fecal weight, which improves bowel movement consistency, and delays glucose absorption. Sources include:

- woody parts of vegetables
- small seeds (strawberries)
- wheat bran and corn bran
- whole grain breads and cereals
- vegetables (cabbage, carrots, Brussels sprouts)
- legumes

Resistant Starch

While not actually a type of fibre, resistant starches behave similarly to fibre in the gut. Like fibre, resistant starches do not break down into sugar and are not absorbed via the small intestine. While they are technically starches, they make it

Benefits of Fibre

- **improves gut microbiome[1]**
- **reduces digestive symptoms such as constipation and diarrhea[2]**
- **helps regulate blood sugar[3]**
- **lowers cholesterol levels[4]**
- **reduces risk of diverticular disease[5]**
- **reduces risk of colorectal cancer[6]**
- **increases satiety of meals, leading to better weight control[7]**

through the digestive system intact and ferment in the large intestine. They can help feed beneficial gut bacteria and improve the balance of the microbiome.[8] Sources include:

- starchy foods coated with seeds or germ (unprocessed whole grains, legumes such as soybean seeds, beans, lentils, and dried peas)
- naturally resistant starchy foods (uncooked potatoes, green banana flour, and high-amylose corn flour)
- retrograded starch, which occurs in starchy food that has been cooked and then cooled (potatoes or pasta cooked and cooled for a salad, sushi rice, etc.)
- starchy foods that manufacturers chemically modify so that they are resistant to digestion

Tips to Add More Fibre to Any Meal

- replace white starches with whole grain versions
- fill up half your plate with vegetables
- eat your veggie peels (if they are safe to eat), since most of the fibre is often found there
- try using avocado instead of mayonnaise or cheese on a sandwich
- sprinkle nuts or seeds on your salad
- try a vegetarian meal with beans or lentils instead of meat
- opt for whole fruits/vegetables instead of juice
- add fresh, frozen, or dried fruit to yogurt, cereal, and oatmeal
- snack on veggies dipped in hummus or guacamole, air-popped popcorn, and fresh fruit

Commercially-Prepared Fibre

Fibrous foods tend to be high in many other nutrients and are often inexpensive, which is why it is generally ideal to increase the amount of fibre in your diet by changing what you eat. However, you can also increase your fibre intake by taking commercial supplements. You might find it simpler to just add a supplement instead of overhauling your diet, or perhaps you are already eating a decent amount of fibrous foods, but need a little help to reach your fibre goal. Fibre supplements also take the guesswork out of gradually increasing your fibre intake, since you can easily adjust the amount you take.

Get-it-going Spread

This spread is great on a whole wheat English muffin or scone as an alternative to jam. Use it sparingly at first, to see how your digestive tract reacts.

Ingredients

½ cup pitted prunes
½ cup raisins
½ cup pitted dates
¼ cup orange juice
⅓ cup prune juice
⅛ tsp cinnamon
pinch of clove

Method

- blend all the ingredients in a food processor until smooth
- refrigerate up to 2 weeks or freeze for longer periods

Photo: (top) © Faschinadora | Bigstockphoto.com

Fibre Superstars

If you want to give your fibre intake a boost, find room for some of these foods in your diet:

Food Item	Fibre Content	Serving Size
bran (oat or wheat)	10-12 g	30 g
chia seeds	10 g	30 g
flaxseed	8 g	30 g
artichoke	10 g	1 medium (128 g)
beans and lentils	6-9.5 g	½ cup, cooked (85 g)
avocado	7 g	½ average (100 g)
raspberries	8 g	1 cup (120 g)

Types & Common Brands

There are many types of commercial fibre supplements available, and the exact types you can find will vary on your location. Some common products include:

- psyllium (Metamucil®), soluble and insoluble fibre
- inulin (Benefibre®), soluble fibre
- methylcellulose (Citrucel®), soluble fibre

How to Start

As with fibre from food sources, it is important to increase the dose gradually and drink plenty of fluids. Follow the recommendations on the product label or instructions from your doctor or dietitian for more details on how to use a specific product.

Does Fibre Help Digestive Illness?

Fibre is great for overall health, but is it really a viable treatment for those affected by GI illnesses? Here we review some of the areas where fibre is effective, as well as those where fibre just isn't enough. Always remember to consult your healthcare team before changing your treatment plan and for further information on these topics, search www.badgut.org.

Constipation & Hemorrhoids

Fibre is generally considered the first-line approach for treating constipation as well as hemorrhoids that result from constipation. For many who are constipated, consuming more insoluble fibre and plenty of water is enough to relieve symptoms. It's the simplest, safest, and often most effective treatment for this common symptom. However, sometimes fibre is not adequate for individuals with chronic constipation or constipation-predominant irritable bowel syndrome, who might require a more intensive treatment plan.

Diarrhea

Whether or not fibre is effective for treating diarrhea often depends on the cause. If you have diarrhea from an infection with a bacteria or parasite, severe diarrhea-predominant irritable bowel syndrome, or you are experiencing a flare-up of Crohn's disease or ulcerative colitis, it is unlikely that fibre will be enough to slow things down. However, if you have mild diarrhea-predominant irritable bowel syndrome, or experience occasional diarrhea without a known cause, increasing the amount of fibre, particularly soluble fibre, into your diet can often help reduce symptoms.

Irritable Bowel Syndrome (IBS)

IBS is a chronic, often debilitating, functional gastrointestinal disorder with symptoms that include abdominal pain, bloating, and altered bowel behaviours, such as constipation and/or diarrhea, or alternating between the two. Fibre can be very effective for many individuals with IBS. For constipation-predominant IBS, focus on eating more insoluble fibre. For diarrhea-predominant IBS, focus on soluble fibre and avoid consuming too much insoluble fibre (particularly bran) as this might increase diarrhea. If you have mixed-type IBS, try increasing your fibre intake in general. But a warning to those with IBS, it is extra important to be cautious and patient when increasing your fibre intake. Don't make sudden drastic changes to your diet, and ensure you drink plenty of fluids, because your gut might be extra sensitive to a sudden increase in fibre. However, a high-fibre diet isn't ideal for everyone with IBS. If your symptoms are mild to moderate, fibre can often be a great treatment. If your IBS is severe, fibre might make your symptoms worse. Speak with your healthcare team before making changes to your IBS treatment plan.

Inflammatory Bowel Disease (IBD)

Inflammatory bowel disease is a term that primarily refers to two diseases of the intestines: Crohn's disease and ulcerative colitis. Both diseases involve inflammation in the digestive tract, although the location and extent of inflammation are different. IBD symptoms, which include diarrhea, abdominal pain, fever, anemia, and weight loss, can be severe and greatly affect quality of life. When individuals with IBD are doing well, eating enough fibre can help keep things working in the digestive system. Above and beyond the standard regulation of bowel movements, fibre might help those with IBD by encouraging favourable changes in the gut microbiota. Research shows that eating more fibre can help modify the balance of gut bacteria by increasing the beneficial strains and decreasing the harmful ones in some individuals with IBD. However, during a flare-up, those with IBD will likely need to go on a fibre-restricted diet to give their bowel time to heal.

Slow-It-Down Smoothie

If diarrhea is a problem for you, this smoothie can help slow down your digestion and lead to bowel movements that are better formed. It is also a good source of potassium and magnesium, important nutrients that diarrhea can deplete.

Ingredients

1 cup of water or milk (nut, oat, dairy, soy depending on your tolerance)
1 cup of frozen bananas
honey (or sweetener of choice) to taste

Method

- blend all the ingredients in a high-speed blender until smooth
- serve immediately

Diverticular Disease

In diverticular disease, small sac-like out-pouchings of the colon lining (diverticula) bulge through the outer colon wall. Some studies show that individuals who eat diets higher in fibre are less likely to develop diverticular disease.[4] However, if you have diverticular disease and experience a flare-up (diverticulitis), then you might need to avoid fibre to give your bowel time to heal.

Fibre-Restricted Diets

While fibre is generally great for your digestive and overall health, there are some cases where you need to limit the amount of fibre in your diet. Your physician might recommend that you follow a fibre-restricted diet if you are having a flare-up of a digestive illness, such as Crohn's disease, ulcerative colitis, diverticular disease, or irritable bowel syndrome, or if you are recovering from a surgery in the digestive tract. In these cases, a fibre-restricted diet can help lower the amount of work for the digestive system so that it can heal and reduce symptoms caused by high fecal volume passing over irritated or inflamed digestive tissues. To maintain a fibre-restricted diet, you will need to reduce the quantity of foods high in fibre in your diet and fill up on foods that are low in fibre.

Food That Has No Fibre/Very Little Fibre

As fibre is a plant-based carbohydrate, animal products, including meat, fish, eggs, and dairy, contain no fibre naturally. However, manufacturers might fortify certain products, such as some yogurts, with fibre. In addition, some heavily processed plant foods, such as white flour, are very low in fibre, and some, such as sugar and oil, contain no fibre at all. Foods low in fibre include:

- meat (beef, chicken, pork, lamb, etc.)
- fish and shellfish (salmon, tuna, shrimp, oysters, crab, etc.)
- eggs
- tofu
- dairy (milk, cheese, sour cream, yogurt, etc.)
- milk alternatives (soymilk, almond milk, rice milk, coconut milk, etc.)
- sweeteners (white and brown sugar, honey, syrups, artificial sweeteners, etc.)
- oils and fats (butter, ghee, lard, olive oil, canola oil, coconut oil, etc.)
- fruit and vegetable juice without pulp
- white bread, white pasta, white rice
- cereals and baked goods made with white flour
- liquid meal replacements (Ensure®, Boost®, etc.)

Tips for Fibre-Restricted Diets

- avoid fruit and vegetable peels, as these often contain high amounts of fibre
- make sure to cook vegetables well, as this makes them easier to tolerate
- choose canned fruits and vegetables over fresh
- eat white bread or white rice instead of the whole grain versions
- choose versions of foods that don't have chunks (e.g., yogurt without fruit added, juice without pulp, jelly instead of jam, yellow mustard instead of Dijon, etc.)
- opt for meat, eggs, or tofu instead of beans for protein
- avoid other foods that can irritate the digestive system, such as spicy foods, alcohol, and caffeine (coffee and tea)
- you might also need to avoid dairy, if you are sensitive
- read food labels to find out the fibre content if you aren't sure how much they contain
- contact a registered dietitian for tips on getting the nutrition you need while avoiding many foods

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8 Gopalsamy G *et al*. Resistant Starch is Actively Fermented by Infant Faecal Microbiota and Increases Microbial Diversity. *Nutrients*. 2019;11(6).

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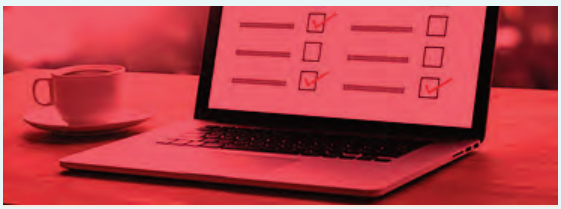
Surveys

We will use information from these surveys anonymously and in aggregate to shape future programming and to inform community members, healthcare professionals, and health policy decision-makers.

IBD Patients: What's Missing in Your Care?

We invite you to take part in this survey about what it's like to have inflammatory bowel disease (IBD). To complete this survey, you must have been diagnosed with IBD (Crohn's disease, ulcerative colitis, ulcerative proctitis, microscopic colitis, etc.).

www.badgut.org/ibd-survey-2019



Biosimilars Patient Survey

Take this survey if you receive a biologic medication to treat inflammatory bowel disease (Crohn's disease or ulcerative colitis), diabetes, rheumatoid arthritis, cancer, osteoporosis, psoriasis, HIV, multiple sclerosis, or growth deficiencies. Caregivers of a person who has one of these diseases are also welcome. We have designed this survey to help us understand your opinions and outlook regarding biosimilar medications. We did a similar survey in 2015 and are now asking for your current views.

www.badgut.org/biosimilars-survey-2019

BC Biosimilars Policy and Advocacy Update

(Maybe Coming to Your Province Soon)

On May 27, 2019, the Government of BC introduced Phase 1 of its new **Biosimilars Initiative** policy for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and type 1 diabetes, which requires these patients to switch their biologic medication. Phase 2, which launched on September 5, 2019, requires inflammatory bowel disease (Crohn's disease and ulcerative colitis) patients currently using originator infliximab (Remicade®) to switch to biosimilar infliximab (Inflectra® or Renflexis®), in consultation with their prescriber, to maintain PharmaCare coverage (with some exceptions). Each phase has a six-month timespan for completion. The GI Society has been working on a number of initiatives to ensure we are providing information and support to patients who will be affected by this policy. In addition, we continue to stay engaged with government as we monitor and track the impact of this policy on individuals in BC and likely beyond. This update provides a report on recent activities, an analysis of the impact to date of this initiative, and some potential patient-focused alternative solutions.

Biologic drugs are highly complex: Biologic drugs come from living organisms or from their cells. They are generally larger and more complex in composition than chemically produced pharmaceutical drugs.[1] They have transformed the way we treat many complex conditions, including Crohn's disease, ulcerative colitis, diabetes, rheumatoid arthritis, cancer, osteoporosis, psoriasis, HIV, multiple sclerosis, growth deficiencies, and many more.

Biosimilars are not the same as generic drugs: A biosimilar is a biologic drug that is highly similar to a biologic drug that was already authorized for sale. Generic drugs are small molecules that are chemically synthesized and contain identical medicinal ingredients to their reference products. A biosimilar and its reference biologic drug can be shown to be highly similar, but not identical.[21]

Canadian Association of Gastroenterology & Crohn's and Colitis Canada

On October 24, 2019, the Canadian Association of Gastroenterology and Crohn's and Colitis Canada announced a joint statement that has been accepted for publication in the *Journal of the Canadian Association of Gastroenterology*.[3] The paper, entitled **Joint Canadian Association of Gastroenterology and Crohn's and Colitis Canada Position Statement on Biosimilars for the Treatment of Inflammatory Bowel Disease**, was co-authored by Canadian gastroenterologists including: Drs Paul Moayyedi, Eric

Benchimol, David Armstrong, and Grigorios I. Leontiadis.

Using the GRADE approach, authors reviewed evidence comparing biosimilars (available in Canada) to originator biologics for the treatment of patients with inflammatory bowel disease. They evaluated efficacy, safety, cost, and acceptance by patients. GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses. Ultimately, this important joint statement made the following recommendations:

- patients may be started on a biosimilar if they have active disease and have not been exposed to that biologic previously; this is with the understanding that the price differential between the originator biologic and biosimilar is significant
- non-medical switch is not recommended for patients stable on biologic treatment
- automatic substitution from a biologic to its biosimilar is not recommended

Dr. Paul Moayyedi, Audrey Campbell Chair of Ulcerative Colitis Research at McMaster University said "there are a number of position statements from various organizations but none of these provide an explicit literature search or assessment of the quality of evidence of a defined clinical question according to GRADE criteria. We felt that this was critical in demonstrating the evidence base for our joint position."

"Gastroenterologists across Canada and indeed government and private payers need to understand the evidence, or lack of evidence on this topic. Based on what we learned, we cannot recommend a non-medical switch policy for patients stable on biologic treatment," added Dr. Grigorios Leontiadis, Associate Professor of Medicine, Division of Gastroenterology at McMaster University.

Crohn's and Colitis Canada released their own Position Statement in early September. "Opposition to a non-medical switch policy affecting patients with Crohn's and colitis has been irresponsibly characterized as an emotional reaction to change. This work invalidates this portrayal and firmly indicates to policy makers that non-medical switch is not in the best interest of patients as this may result in worsening of disease in some patients," says Mina Mawani, President and CEO of Crohn's and Colitis Canada. "We are hopeful that this joint statement gives government pause and opens up discussion toward alternate policy interventions."

Biosimilars Patient Forum Summary

On September 30, 2019, the Gastrointestinal Society and the Canadian Society of Intestinal Research (CSIR) hosted a patient forum in Vancouver funded entirely by the CSIR from bequest revenue. Representatives from the GI Society, the CSIR, the Better Pharmacare Coalition, and the Pharmaceutical Services Division (PSD) of the BC Ministry of Health presented.

Dr. Eric Lun, Executive Director, Drug Intelligence Outcomes and Strategy, Pharmaceutical Services Division (PSD), Ministry of Health, provided the rationale behind the **Biosimilars Initiative** and the public policy context around how they developed BC's policy. He explained that of the top 10 most expensive drugs that PSD funds, three of them are biologics (infliximab, adalimumab, and etanercept). The total annual cost for those three drugs is around $185.57 million, or roughly 17% of total PSD expenditures, placing significant financial pressure on PSD.

Overall, Canada's early uptake of certain biosimilars was much lower (roughly 8%) than the average for Organisation for Economic Co-operation and Development (OECD) countries. The policy has two key objectives: to provide better support for patients by improving the sustainability of our healthcare system and to offer additional savings to allow funds to be used for other medications. Health Canada expects no differences in both efficacy and safety following a change of routine use between a biosimilar and a reference product. The BC Ministry of Health also looked at what other provinces are doing and how they view biosimilars. The provinces formed a negotiating alliance in 2010, called the panCanadian Pharmaceutical Alliance (pCPA), which supports the use of biosimilars and seeks to improve the uptake as much as possible. Lots of consultation took place; however, not all of those consulted agreed with the policy.

Tijana Fazlagic, Executive Director, PharmaCare Benefits Branch, PSD, provided a roll-out of the Biosimilars Initiative and described follow-up efforts to monitor and evaluate its impact. PSD launched Phase 1 of the Biosimilars Initiative on May 27 with the goal of switching patients using originator biologics to their biosimilar versions by November 25, including:

- Enbrel® (etanercept) for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis to Erelzi™ or Brenzys® (biosimilar etanercept)
- Remicade® (infliximab) for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis to Inflectra® or Renflexis™ (biosimilar infliximab)
- Lantus® (insulin glargine) for diabetes to Basaglar™ (insulin glargine biosimilar)

In Phase 2 (September 5, 2019 - March 5, 2020), the Initiative will switch patients using Remicade® (infliximab) for Crohn's disease or ulcerative colitis to Inflectra® or Renflexis™ (biosimilar infliximab). During the switch period,

PSD will cover both biologic and biosimilar versions of the affected drugs, to allow time for patients to discuss the switch with their prescriber. After the switch periods end, PSD will cover only the biosimilar versions of etanercept, infliximab, and insulin glargine for the affected indications. Based on the evidence available and on the Health Canada position, no difference is expected between efficacy and safety of biologics and biosimilars. In the event that there are medical reasons for which a patient may need to remain on the originator product, the Ministry is allowing an opportunity for a physician to submit an exceptional coverage request (special authority).

For both phases of the Initiative, PSD introduced prescriber and pharmacist fees of $50 and $15 respectively to support the patient having an extra conversation with each of these healthcare practitioners about the switch, but the fee is not dependent on the patient actually switching.

Monitoring and evaluation is in place to look at the number of patients being switched, what kind of requests are being submitted for exceptional coverage, and to see what develops. Physician and ER visits and hospitalizations will also be tracked. Ongoing Health Canada monitoring will take place under its adverse drug reaction reporting, but it's important to keep in mind that Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions.

If you experienced an adverse reaction when switched from an originator biologic to a biosimilar (or from any other medicine), we encourage you to report it to Health Canada. Speak with your healthcare team for advice and more information, or report directly to Health Canada by phoning the Canada Vigilance National Office at 1-866-234-2345 or report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.

As of September 15, 2019, the total number of patients switched to a biosimilar was about 4,000, with the majority for the diabetes and inflammatory arthritis indications, and there were 400 requests for special authority for the patient to not switch, but PSD could not say whether these were approved or denied.

PSD expects to save about $96 million over three years, with the savings being directed to provide drug coverage and to improve patient care, including coverage for Jardiance® (empagliflozin) for diabetes patients, adding Taltz® (ixekizumab) for psoriatic arthritis, and adjustments to coverage for patients with rheumatoid arthritis.

Phase 2 includes a nursing support fee for gastroenterologists when a nurse is present in the care of IBD patients. The gastroenterologist can bill the extra fee for nursing (and then pay the nurse for his or her assistance); this is $60 per patient, billable every six months. Phase 2 also provides coverage for a fecal calprotectin test, which is used to monitor intestinal inflammation in IBD patients.

Patient Discussion

The following is a summary of the key concerns expressed directly by patients at the recent policy forum along with the transcript response from PSD, where applicable:

1. **Grandfathering of existing patients**: new patients who are starting a biologic for the first time could start on biosimilars to save costs rather than getting patients who are stable on originator biologics to switch.
   PSD Response: we actually tried that first and didn't get the [hoped for] amount of uptake [and it] was too low and based on the data and the experience of other countries, switching is safe and there's no problems with that.
2. **Immunogenicity:** why force someone to mess with a treatment that is working? Especially when switching back and forth may lessen the long-term effectiveness of the original biologic.
   PSD Response: the evidence to date suggests that this isn't a concern for most patients but that is why having exclusions is so important – for patients that shouldn't be switched. Also, even originator biologics change slightly with every batch manufactured so there are changes over the years in what a patient receives.
3. **Monitoring**: a lot of the studies have been done in Europe; however, Canada and BC specifically have unique populations. Also, there are very few studies in ulcerative colitis.
   No response.
4. **Health risk:** why take the risk to switch a patient who is stable and using a biologic that is effective? What if they are anxious and upset and nervous about switching – would that be a reason for their doctor to not switch them?
   PSD response: that would be taken on a case by case basis.
5. **Exceptions:** what if you are a patient who is one of those exceptions to the rule? It is no comfort to a patient who does not do well with the switch to tell them that they are the exception. There are no defined exemption criteria.
   PSD response: special application can be made if there is a specific reason to make an exception.

6. **Exceptions:** why are there so few exceptions? Are physicians being pressured to switch their patients?
   PSD response: physicians are not being pressured.
7. **Multicultural make-up of BC:** BC is very multicultural and has people from around the world living here – how do we know studies from Europe will be applicable?
   PSD response: BC looked at studies from around the world – not just Europe. And special authority is available if needed.
8. **Cost:** ultimately, this is really about saving money, not about providing better care.
   PSD response: BC will be able to pay for more drugs and provide more services for IBD patients with the money that is being saved.

Preferred Policy Options

There are previously established options that BC could have implemented, such as:

1. **Negotiating a lower, confidential net price for the originator biologic:** this would allow physicians and patients the option to either switch or remain on their current biologic at the same (or less) cost as the biosimilar, thereby achieving savings for the government equal to or greater than the biosimilar and avoid mandatory switching of stable patients. **We believe this is the best patient centric option and that it will result in the required cost-savings**.
2. **Manitoba's tiered biologics reimbursement policy:** on August 15, 2018, Manitoba Health, Seniors and Active Living implemented a tiered biologics reimbursement policy that only applies to new patients (biologic naïve) and existing patients that have previously been trialed and deemed unresponsive to biologic therapy. MB had already provided a model that BC could have adopted but chose not to.

For more information on biologics and biosimilars in Canada, visit www.badgut.org/biosimilars and www.biosimilaroptions.ca.

1 Health Canada: Biosimilar biologic drugs in Canada: Fact Sheet. www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html#a3

2 To lean more, the Joint Statement is available here: https://crohnsandcolitis.ca/News-Events/News-Releases/Joint-Statement-from-the-Canadian-Association-of-G

Did your biologic medicine get switched?
We want to help! Share your story with us online at www.badgut.org/contact-us, by email at info@badgut.org, or by phone at 604-873-4876 or 1-866-600-4875.

Our Recommended Approach for the Use of Biosimilars

We strongly urge all provinces to reject non-medical switching and commit to a patient-focused, evidence-based approach that ensures the best possible outcome for everyone. Preferred policy options exist that can achieve similar savings targets without forcing stabilized patients to switch biologics.

Patient-Physician choice must be respected and preserved. Recent surveys show that patients strongly believe that the biologic medicine used to treat their disease should be a clinical decision made in consultation with their physician, on an individual patient basis.

We support fair, responsible, and patient-focused policy for funding biosimilars. We recognize that biosimilars present a valuable opportunity for cost-savings in public drug budgets, and as such support their uptake in a responsible, patient-centred, and evidence-driven manner; however, there are alternatives that protect continuity of patient care that can also achieve cost-savings.

Patient support continuity must be protected. Forcing patients to switch to a biosimilar without appropriate information and support can lead to sub-optimal outcomes and responses to treatment. This is an especially important consideration in disease areas with limited therapeutic options upon potential failure of switching treatment to a biosimilar. It is further perpetuated in Canada by an associated change in healthcare professionals delivering their medications and training through proprietary patient support programs.

A robust monitoring system must be in place to capture a patient's response after switching, as well as to accurately capture any adverse reactions or changes in disease activity in the following months/years. A streamlined system to ensure that patients who experience loss of disease control after switching have timely access to the therapy that is right for them is essential. Monitoring should review overall impact to the healthcare system including resource utilization and impacts on patients which may affect their out of pocket expenditures and additional visits to healthcare practitioners, etc.

Globally Eradicating HCV by 2030

The World Health Organization (WHO) has set an initiative to eliminate hepatitis C by 2030.[1] They are calling on countries around the globe to achieve a reduction rate of new viral hepatitis infections by 90% and mortality by 65%.[2,3] There are different types of viral hepatitis infections, including A, B, and C; however, hepatitis C has high incidence rates and is yet to have a vaccine.

Hepatitis C affects more than 150 million people worldwide, with a mortality rate of 500,000 per year.[4] The main challenges preventing the eradication of hepatitis C are a severe need for public awareness and education, and accessibility of treatments. Hepatitis C can inflict serious damage to the liver and manifests in two forms, acute and chronic, with differing severity in symptoms. Acute hepatitis C usually passes without consequence, but for those who develop chronic hepatitis C, years of infection could result in significant damage to the liver, including cirrhosis and liver failure, and can even present an increased risk for the development of liver cancer.[5] Hepatitis C virus (HCV) is spread via blood-to-blood contact but it is not transmissible through hugging, kissing, or sharing eating utensils. Hepatitis C often presents no symptoms, and if so, they are generally nonspecific (i.e., fatigue or discomfort in the abdomen). However, blood tests are available for screening. Treatment of the disease includes a combination of lifestyle modifications, such as limiting alcohol intake, and curative therapies of oral antiviral medications. In fact, recent advancements have boosted cure rates to greater than 95% for nearly all individuals.

Challenges

Regardless of the availability of cost-effective prevention methods, diagnostic tools, and curative therapies for hepatitis C, there remains high incidence rates due to a number of barriers that inhibit timely access to treatment, such as a lack of education and awareness, stigma, monitoring issues, and availability. Researchers and advocates have called for the addition of HCV testing in patients' continuum of care. This consists of guidelines for clinical practice, with appropriate triage of care for **high risk populations, such as anyone born between 1945 and 1975 and individuals who use drugs, are in prison, or are of indigenous descent**.

Canada's Efforts

Healthcare experts have established models of care to address these roadblocks. These include integrated care in the community (i.e., substance use disorder treatment programs), and partnerships between healthcare professionals to encourage streamlined care, such as the ability of non-specialists to deliver treatment for most cases of hepatitis C. Complex cases may require support from a specialist. Of considerable note is the *Blueprint to inform hepatitis C elimination efforts in Canada*, published by the Canadian Network on Hepatitis C (CanHepC).[6] They designed this document to assist provinces and territories in the development of action plans for their jurisdictions, filled with options and flexibility for demographic, geographic, societal and cultural contexts from prevention and screening, diagnosis, care, and treatment. In addition, the Public Health Agency of Canada released guidelines for all healthcare stakeholders. *Reducing the health impact of sexually transmitted and blood-borne infections in Canada by 2030* aims to provide ways in which multidisciplinary partnerships between healthcare practitioners, members of the public and private sectors, and all levels of government can collaborate to meet the global 2030 target of eliminating HCV.[7]

The GI Society will continue to raise awareness and work with all healthcare stakeholders to promote education about HCV. If you'd like to learn more about this disease, we have a wide range of resources at www.badgut.org.

References available upon request.

Want to do your part?
Ask Your Doctor About
a **Hepatitis C** Test Today.

SUPPORT US

WAYS TO DONATE

We need your ongoing support to continue to help the millions of Canadians who live with gastrointestinal and liver diseases and disorders, and for those who want to maintain a healthy digestive tract.

The GI Society guards donor dollars rigorously, ensuring maximum yield. We are frugal and efficient, spending far less than the national charitable average on governance and administration. Your donations help to support:

- high-quality, up-to-date printed information and educational materials for patients and their families, and for healthcare professionals
- BadGut® Lectures throughout Canada
- advocacy to encourage governments to put digestive health on the agenda and implement policies that will improve quality of life

DONATING NOW

Visit our secure website www.badgut.org and complete your payment online or send a gift by filling in the form on this page and sending it to our office.

GIVING MONTHLY

Contact us to set up an automatic monthly donation.

GIVING IN HONOUR OR IN MEMORY

For gifts in honour of a special occasion or in memory of a person, provide us with your name and address, as well as that of the honouree or bereaved and decedent, so we can send a card advising of your gift on his or her behalf. We don't share the amount of your gift unless you ask us to do so.

BEQUESTS

Naming the GI (Gastrointestinal) Society or CSIR as a beneficiary in your will ensures your funds continue to support this important work.

SPONSORSHIP

Your business can collaborate with the GI Society on special projects or ongoing activities and receive recognition through a variety of avenues. Contact our CEO at the head office for details.

WORKPLACE GIVING

Does your place of work pool donations for charitable giving? Why not select the GI Society as the beneficiary? Sometimes all it takes is someone to suggest us. We'd be happy to send you some promotional literature to assist you in this task and, in many cases, can offer speakers.

DOUBLE THE DONATION

Want to make your donation go twice as far? An easy way to double your contribution is through the Double the Donation employee match program. Go to www.badgut.org/double-the-donation to learn more and find out if your employer will match your donation.

GI SOCIETY REGISTERED CHARITY 817065352RR0001
CSIR REGISTERED CHARITY 108090374RR0001

SUBSCRIPTION & DONATION FORM

Subscribe now! Your annual subscription fee of only $20 supports the GI Society's activities and includes quarterly issues of the *Inside Tract®* newsletter that we mail to you.

Please sign up online at www.badgut.org or fill in and submit this form by mail to:

GI Society | 231-3665 Kingsway | Vancouver, BC V5R 5W2.

PURCHASE INFORMATION

☐ I enclose a donation of $ _____(eligible for a tax receipt).
☐ I enclose a $20 annual subscription fee ($30 outside Canada)
Total $_____

PERSONAL INFORMATION

_____
Name (Mr./Mrs./Ms./Dr.)

_____
Company Name (Optional)

_____
Street Address

_____
City, Province, Postal Code

_____
Phone Number(s)

_____
Email(s)

☐ Patient ☐ Friend/Family Member ☐ Professional

Diagnosis/Area of Interest:
(This optional information helps us to determine which topics might be of interest to you and is kept confidential.)

_____

Would you like more information? Please list your topics:

_____

☐ Check this box if you would like to volunteer

PAYMENT METHOD

- Cheque (payable to GI Society)
- Credit Card and bank debit purchase is available on our secure website www.badgut.org.

The GI (Gastrointestinal) Society respects your privacy. We never sell, trade, or loan your information to any other organization. We will use your information only for follow-up contact, statistical purposes, evaluation of our services, and to process and recognize your contributions. We disclose your information only to our own employees and agents and only to accomplish these purposes. If at any time you no longer wish to be contacted by the GI Society, please call 604-873-4876 (Toll Free 1-866-600-4875) or email info@badgut.org and we will promptly remove you from our list.

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Gastrointestinal Society
Canadian Society of Intestinal Research

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