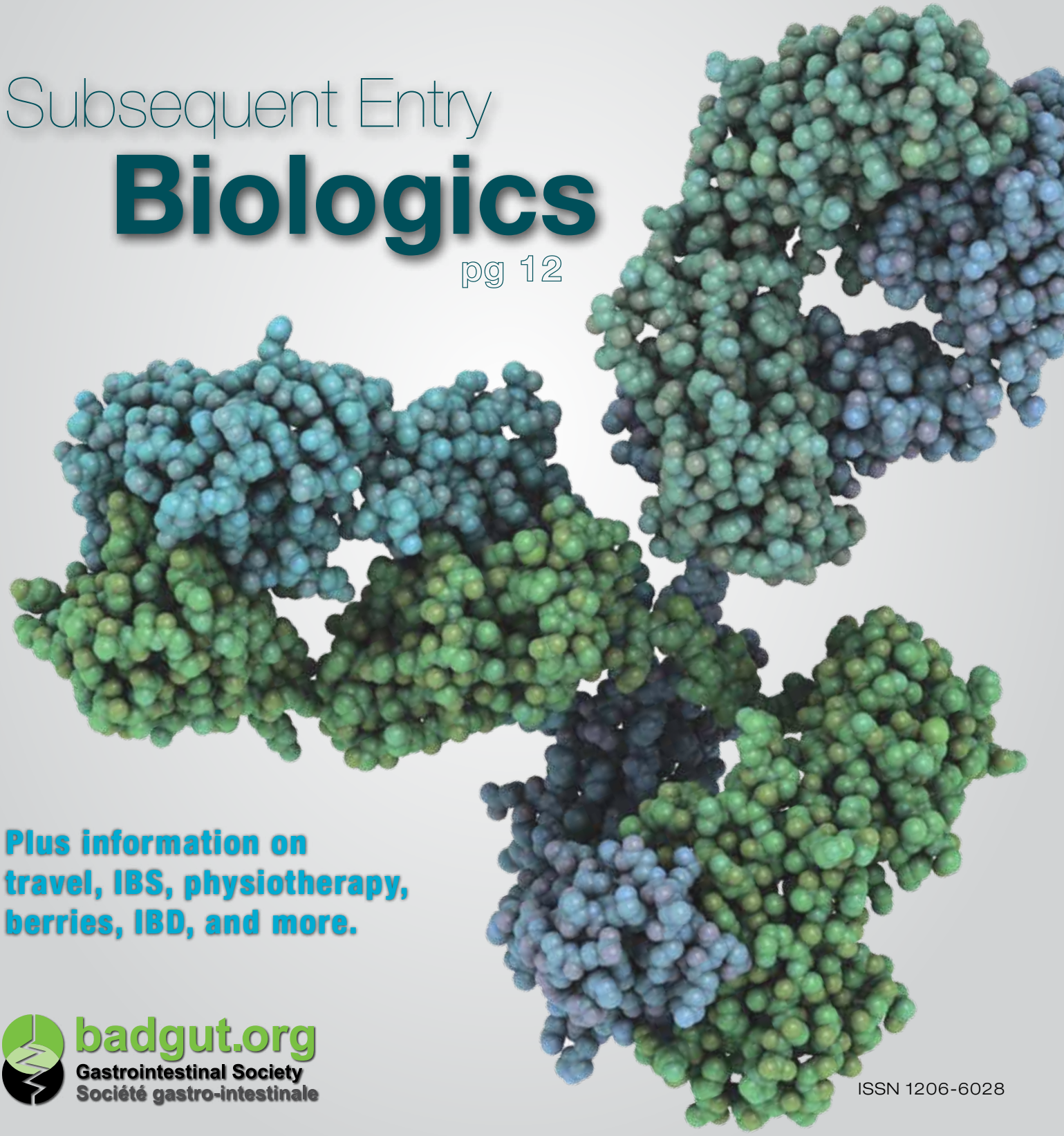
Inside Tract®

Canada's Gastrointestinal Disease & Disorder Newsletter

Issue 185 | 2013

Subsequent Entry Biologics

pg 12



Plus information on travel, IBS, physiotherapy, berries, IBD, and more.

badgut.org
Gastrointestinal Society
Société gastro-intestinale

ISSN 1206-6028

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Gail Attara	**Chief Executive Officer**
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Morgan Amber	**Communications Assistant**
Jesse-Ann Demanche	**Office Assistant**

Phone	604-875-4875
Toll-Free	866-600-4875
Fax	604-875-4429
Toll-Free Fax	855-875-4429
Email	info@badgut.org
Website	www.badgut.org

Mailing Address
Gastrointestinal Society
855 West 12th Avenue
Vancouver, BC V5Z 1M9

Office Location
700 West 10th Avenue, 212
Vancouver, BC V5Z 1L5

Ontario Staff

Melanie Chapman	**Executive Director**
Toll-Free	855-848-4875

Quebec & Atlantic Canada Staff

Gary G. Fabian	**Executive Director**
Toll-Free	855-600-4875

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Follow the Gastrointestinal Society on

About Us

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI Society is committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to health care, and promoting gastrointestinal and liver health.

Our core knowledge transfer programming includes a comprehensive series of patient education pamphlets called BadGut® Basics, the BadGut® Lecture Series, online resources at www.badgut.org, and *The Inside Tract*® newsletter.

The GI Society was built in 2008 on the foundation of its partner organization, the Canadian Society of Intestinal Research (CSIR), a registered charity since 1976, and now these two organizations collaborate on many initiatives. The GI Society (Société GI) is also carrying on the legacy of L'Association des maladies gastro-intestinales fonctionnelles (AMGIF) and providing programs and services in the French language for all diseases and disorders of the GI tract.

We have printed resources available on these topics, and even more information online:

Celiac Disease
Colorectal Cancer
Constipation
Crohn's Disease
Diverticular Disease
Functional Dyspepsia
GERD (Reflux Disease)
Hemorrhoids
Hepatitis B
Hepatitis C
Hiatus Hernia
Inflammatory Bowel Disease
Intestinal Gas
Irritable Bowel Syndrome
Non-Alcoholic Fatty Liver Disease
Ostomies
Pancreatitis
Stress Management
Ulcer Disease
Ulcerative Colitis
Ulcerative Proctitis

President & CEO Report

Gail Attara

Along with other members of the GI Society and CSIR teams, I returned recently from the annual Canadian Digestive Diseases Week (CDDW) conference, which took place this year in Victoria, BC. This important national event, hosted by the Canadian Association of Gastroenterology, brings together gastroenterologists, researchers, health care industry leaders, and a variety of GI organizations from across the country for crucial knowledge sharing and networking.

We are collaborating with the Crohn's and Colitis Foundation of Canada on a number of projects this year. The GI Society and CSIR are bringing the Giant Colon to their Gutsy Walk event in Vancouver on June 9. The Giant Colon is an educational display promoted by the Colorectal Cancer Association of Canada, which invites Canadians to experience walking through an eight-foot tall colon, educating them on the signs and symptoms of colorectal cancer and other diseases of the colon.

Recently developed protease inhibitor medications have changed the face of treatment for individuals infected with the Hepatitis C virus. Late last year, Merck Canada Inc.'s Victrelis® (boceprevir) and Vertex Pharmaceuticals Canada Ltd's Incivek® (telaprevir) each received a prestigious Prix Galien Canada Innovative Drug Product award, and I had the pleasure of watching the award presentation in person at the Prix Galien Foundation event in Toronto. The Foundation recognizes products and agents in medical science that improve the human condition. Congratulations, Merck and Vertex!

Victrelis and Incivek were the first two direct acting antivirals available in Canada for the treatment of chronic genotype 1 hepatitis C infection. Current medication prices and government formulary restrictions can make them economically inaccessible for many patients, something the GI Society hopes to see changed through its ongoing advocacy work on behalf of patients.

Save the dates! Our Inside Affair fundraising and networking evenings return this fall with dynamic events in Vancouver on October 21, Montreal on October 24, and in Toronto on October 28. Sponsorships and tickets for these sure-to-be-packed events are available now.

The **Inside Tract**®

This quarterly newsletter is a primary tool of the Gastrointestinal Society (GI Society) for delivering up-to-date medical information, in lay terms, to the Canadian public. Readership includes a mix of patients and their family, friends, and caregivers; health care professionals; and business professionals who are interested in the wellness of their employees. To subscribe for a low annual fee of $20 ($30 outside Canada), please visit our website, or complete and submit the form on page 23.

The GI Society does not endorse the products or services contained in this newsletter. Opinions expressed by the authors are their own and not necessarily those of the GI Society. Members of our medical advisory council or other professionals write or review all articles contained herein. In the interest of space, we usually do not publish references but will provide them upon request. We do not intend that this newsletter replace the knowledge or diagnosis of your physician or health care team and we advise seeking advice from a medical professional whenever a health problem arises.

Preparation and printing of *The Inside Tract*® newsletter is possible due to financial contributions from individuals, the Province of British Columbia, AbbVie Corporation, Aptalis Pharma, Ferring Pharmaceuticals, GlaxoSmithKline Inc., Hoffmann-La Roche Ltd., Janssen Inc., Medical Futures Inc., Merck Frosst Canada Inc., Optimer Pharmaceuticals Inc., and Takeda Canada Inc. This newsletter contains advertising.

Contributors

Gail Attara	**Editor**
Susan Mersereau	**Assistant Editor**
Kwynn Vodnak	**Design**
Morgan Amber	
Jesse-Ann Demanche	
Dr. James Gray	
Claire Maisonneuve	
Kimberly Skulsky	
Laura Werner	

Translation Services Provided by:
Transvision Plus
416-524-8182
transvisionplusjosee@gmail.com

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Gastrointestinal Society
855 West 12th Avenue
Vancouver, BC V5Z 1M9


Photo: © Saskia Hemman

Guts

THIS NEWSLETTER IS ALSO AVAILABLE IN FRENCH

IBS What Would You Risk for a Cure?

April marks another Irritable Bowel Syndrome (IBS) Awareness Month in Canada. Affecting 13-20% of the population, this diverse condition can have a drastic impact on a person's life. How drastic, you ask? Enough that many patients say they would even risk death for a chance at a cure, according to a surprising study published last summer by *The American Journal of Gastroenterology*.[1]

Despite decades of research, there is still no cure for IBS, which is a chronic condition for most diagnosed individuals, frustrating both patients and physicians. Health care providers offer individualized treatments for the varied symptoms associated with IBS, which include abdominal pain or discomfort, bloating, diarrhea, and constipation. Some individuals respond well to treatments, while for others, IBS is an ongoing battle against relentless symptoms.

Perception and Perspective

In this study, the researchers started by developing a unique survey to evaluate IBS patients' experiences with IBS, perception of the risks associated with medications used to treat IBS, and willingness to accept hypothetical medication risks for a chance of complete cure. The study included 186 IBS patients, aged 18 years and older, who met the Rome III criteria for IBS.

There is no evidence for a relationship between IBS and an increased risk of colorectal cancer, but 49% of the study's participants believed that there was an increased risk, and 54% of them held the belief that their IBS symptoms would never go away. About 30% of the participants were also convinced that IBS would affect their lifespan, even though this does not correlate with current evidence. Health care providers can help patients with unwarranted fears around the long-term consequences of IBS by reassuring them about the condition. The researchers also compared the participants' perception of their own IBS symptoms with their rating on a validated IBS severity scoring system. It showed that patients have a slight tendency to underrate the severity of their IBS symptoms. This is an important finding, the study authors say, because of the concern that some health care providers might think that IBS patients exaggerate their symptoms.

No Ordinary Gamble

The final part of the survey implemented a tool called the Standard Gamble, which asks patients to choose between different percentages of risk of death and chances for a cure from their disease or ailment. In this study, the researchers asked participants about a hypothetical medication that would cure all of their IBS symptoms without the need for further IBS medications. The participants claimed that they would accept a median 1% risk of immediate death for a 99% chance of a total cure. The median level of risk patients were willing to take was the same for all subtypes, such as IBS-Constipation and IBS-Diarrhea. Factors such as age, gender, general risk-taking behaviour, duration of IBS symptoms, current medication use, and prior side-effects from medications did not appear to affect the participants' willingness to risk all for a possible cure from their IBS symptoms. As the study authors explain, "This remarkable willingness to risk sudden death illustrates how significantly the burden of IBS symptoms compromises the quality of patients' lives."

In reality, of course, there is no perfect cure, and no magic answer to chronic disease. If you or someone you care about is affected by IBS, do not lose hope and do not give up on finding effective treatment. A vast amount of research is still dedicated to this area and practitioners introduce new or improved treatments for the symptoms of IBS regularly. About 40% of individuals with IBS never seek treatment, which means they are living with ongoing disruptive, possibly painful, symptoms without the benefit of available treatments. If you think you may have IBS, or if you received a diagnosis years ago but gave up on treatments, talk to your health care provider. There are several and varied therapies that many individuals find helpful. These include over-the-counter and prescription medications, diet and lifestyle modifications, psychological counselling, and even physiotherapy treatments specifically aimed at helping individuals with IBS (see Pelvic Floor Dysfunction article on page 20).

APRIL IS IBS AWARENESS MONTH!

BERRIES

bursting with health benefits

The health benefits of berries are plentiful. These small, versatile fruits come in many varieties and forms, making it easy to incorporate them into your diet year round. Did you know that Canada is the second largest producer and exporter of blueberries in the world, after the US, and that more than 200 species of berries grow in this country?[1] Since these fine fruits are indigenous to North America, we naturally edge out other areas of the world in production.

Whether eaten fresh, frozen, dried, or in juice form, berries provide a big dose of important vitamins and minerals that are rich in antioxidants. Often given superstar status for their nutritional content, below we review a few of the many health benefits of these mouth-watering, colourful fruits.

Vitamins and Minerals

You may be surprised to know that approximately one cup of fresh strawberries provides more vitamin C than a small orange! This water-soluble vitamin is necessary for several body processes, including the synthesis of collagen – a protein found in skin, bones, tendons, and cartilage. Strawberries are also one of the richest natural sources of folate, an essential micronutrient important in health promotion and disease prevention.[2]

Beta-carotene is a substance naturally present in many fruits, including berries, which can convert into vitamin A in the body (a provitamin). It plays key roles in cell development and immune function. Considering their small size, berries pack a hard punch when it comes to providing the body with important nutrients. This, along with the fact that they are low in calories, makes them a great addition to your daily diet.

Antioxidants

Antioxidants are substances (e.g., beta-carotene, lycopene, vitamins A, C, and E) that reverse oxidation (see sidebar), which is associated with aging, inflammation, and the development of such conditions as cancer, heart disease, and arthritis.[3] Berries, along with other fruits, vegetables, legumes, nuts, and whole grains, all contain some form of antioxidant. The type of berry, climate and soil conditions during growth, degree of ripeness, and the method of processing all affect the antioxidant level in a specific berry.[4]

The Department of Nutrition at the University of Oslo in Sweden created an Antioxidant Food Database listing the total antioxidant capacity of many fruits, vegetables, beverages, spices, and herbs. They procured samples from countries worldwide and determined their total antioxidant content using a method known as the ferric reducing ability of plasma (FRAP) assay. Table 1 lists the results of some of the berries and berry products. The average antioxidant content of berries and berry products ranked high compared to the other food groups studied.[5]

Table 1[6]

Product with antioxidant content in mmol/100g	
Berry, raw	
Blackberry	4.02
Cranberry	3.29
Raspberry	2.33
Strawberry	2.16
Blueberry	1.85
Gooseberry	1.45
Juice	
Fruits & Berries	1.69
Grape Blend	1.62
Cranberry	1.00
Cran-Apple	0.71
Berries, dried	
Goji berries	4.31
Cranberries	1.64
Blueberries	1.32

Fibre

Dietary fibre can help to control blood sugar (glucose) levels, avoid constipation, reduce some symptoms of irritable bowel syndrome, maintain a healthy body weight, and avert diverticular disease. Berries, both in fresh and dried form, are a very good source of fibre. Including a serving of berries each day will help you reach the recommended daily fibre intake of 25-38g. (See Table 2.)

With all of their water removed, dried berries have an extended shelf life. They are also higher in calories,

carbohydrates, fibre, and other nutrients per serving compared to their fresh counterparts.[7] This is important to keep in mind if you are trying to lose weight or if you are monitoring your sugar intake. One downside of dried fruits is that processing destroys their water-soluble vitamins (e.g., B and C), although many manufacturers do add these nutrients back in at the end, so read the label to be sure.

In fact, reading the labels on products is a good habit, and doing so when selecting fruit juices could guide you to varieties containing added vegetables, omega 3s, fibre, calcium, and probiotics, making them healthier options over other products. It's also good to look for juices with no added sugar.

Berries really do live up to all their hype. They are delicious, versatile, packed full of vitamins and minerals, and a good source of fibre. When incorporated into a balanced diet, these juicy fruits contribute to a healthy body and a healthy digestive tract. Eat them often and enjoy their wide-ranging benefits!

OXIDATION & ANTIOXIDANTS

Oxidation is a chemical reaction that occurs during regular cellular processes, such as metabolism and inflammation. It increases with exposure to environmental toxins such as pollution, cigarette smoke, ultraviolet rays, strenuous exercise, and alcohol use. Simply put, oxidation creates highly reactive, unstable molecules (free radicals) which can cause DNA damage and destruction of cells and tissues. Antioxidants are substances that prevent and manage these free radicals and their damaging effects. The body produces its own antioxidants, but external sources help aid in the body's defense. Although Health Canada has not set a recommended dietary allowance for antioxidants, following *Canada's Food Guide* will ensure a balanced diet that includes a variety of foods and beverages, including those containing antioxidants. Be sure to speak with your health care provider before taking any supplements that boast antioxidant claims.

Table 2

Fibre (g) per 100 g	
Raspberry	6.5
Blackberry	5.3
Cranberry	4.6
Gooseberry	4.3
Blueberry	2.6
Strawberry	2.2

IBD Patient Stories

Over the past thirty-six years, we have offered this newsletter as a forum for our members/subscribers to share their personal stories about living with gastrointestinal (GI) conditions, including inflammatory bowel disease (IBD). As knowledge and treatment options have expanded for IBD, we wondered how the patient experience has changed. Through our recent BadGut® Lectures across the country, patient roundtable discussions, and public calls for feedback, we have been asking patients, "What is it like to live with IBD in Canada right now?" Recent research suggests that IBD currently affects about 233,000 Canadians. Here we present two of their voices.

Paul

Paul, who lives in Ontario, received his Crohn's disease (CD) diagnosis in 1993 at the age of 46, and he underwent a colon resection the next year. Today, surgeons will sometimes remove severely diseased portions of the digestive tract, but this is only as a last alternative, usually in cases of failed medical management and/or complications. An unfortunate feature of CD is that there is a high recurrence rate, even after surgical removal of all visible and microscopic disease. Throughout the late nineties, Paul experienced various levels of remission while taking 5-ASA medications, including Pentasa® and Asacol®, which are still widely used today.

In 2001, Paul underwent a second surgery. In CD, an abnormal, tunnel-like connection between the intestine and the skin (fistula) may occur near the opening of the rectum, between loops of intestine within the abdomen, or between the intestine and the abdominal wall, particularly following surgery. Paul developed a fistula in 2006, which was the beginning of what he describes as "a very painful episode" that included more fistulae and many surgeries. Eventually, his health care team determined that removal of more intestinal tissue was required, and that an ileostomy (a surgical procedure in which the end of the small intestine is brought through an opening in the abdominal wall) was the best option for controlling Paul's disease activity.

He told us, "A month or two after I came home, [my gastroenterologist] started me on Remicade. This worked well for me and within a few months I had healed well enough to have the ostomy reversed." Remicade® is a powerful biologic medication first introduced in Canada in 2001. Today, both Remicade® and another biologic, Humira®, are available to treat moderate to severe Crohn's disease.

Paul explained, "Since that very dark period I have been fortunate to have healed completely and now have a very good quality of life. I have developed antibodies to Remicade, which causes a mild reaction at each infusion, but I remain relatively healthy and again enjoy a full life."

Mary Anne

Mary Anne's journey with IBD began in 2008, when she received a diagnosis of ulcerative colitis (UC). Unlike Crohn's disease, UC involves only the colon and always begins at the anus, with disease activity continuously progressing upward; inflammation involves only the inner mucosa (as opposed to Crohn's disease, in which inflammation can extend through the entire thickness of the bowel wall). However, UC can be severe for some patients, as it is for Mary Anne, who requires regular Remicade® infusions to control disease activity. In addition to fears about her future and the long-term effects of treatment, Mary Anne is very concerned about access to medications. She travels over 120km every few weeks to receive a Remicade® infusion. "Not only is access to the drug for rural residents challenging," she explained, "but access to specialists is as well." She must travel several hours to see her GI specialist and incurs travel and accommodation costs for each visit.

Biologic medications such as Remicade® and Humira® cost considerably more to develop and produce than previous classes of IBD medications, and can therefore be very expensive for patients, especially since drug formulary coverage varies from province to province. In BC, where Mary Anne lives, patients must meet specific criteria in order to receive coverage through BC PharmaCare for Remicade®, and while having some kind of eligibility criteria is typical, these criteria vary widely across jurisdictions in Canada. Mary Anne asked, "Why should some be entitled to access to medication when others are not? I have been approved for financial assistance for a year, but what happens when I am up for review and possibly am not approved? Do I get taken off the drug? Is that fair? Should fairness even come into play when we are talking about health care?"

you could win an iPad!

The GI Society Wants Your **IBD Tales of Triumph**

The GI Society invites you to tell us in your own words what it's like to live with inflammatory bowel disease (IBD). Do you live in Iqaluit, Nunavut; St. John's, Newfoundland; Montreal; downtown Toronto; or in Ucluelet on Vancouver Island? Wherever you reside in this beautiful and diverse country of ours, we want to hear your story of living with IBD.

What are the biggest barriers you've faced while living with IBD and how did you overcome them? What makes your story unique? How might sharing your story help other Canadians with IBD?

A panel of readers will choose a selection of the submitted stories for publication in *The Inside Tract*® newsletter and online at www.badgut.org. We will also enter each contributor in a random draw to win one of several brand new iPads. The draw will take place on **July 31, 2013** and we will announce the winners in this newsletter. Don't delay – put pen to paper and send your story in right away.

We welcome submissions from patients, caregivers, family members, or anyone with a close connection to someone affected by IBD.

A maximum 600 words of prose or poetry, please. Are you more of a talker? Send us a 2-3minute video instead! If selected, we will feature your video at www.badgut.org.

Please send your submission (Word, PDF, or common video file attachments) along with a high-resolution photo of yourself to info@badgut.org with the subject heading, "IBD Tales of Triumph."

Please note: Our editorial team will copyedit published stories for spelling, grammar, format, and style/tone. By submitting your story or video, you give the GI Society the right to publish your story, poem, or video and author photo in *The Inside Tract*® newsletter, online at www.badgut.org, and (in whole or in part) for other GI Society awareness initiatives.

The GI Society thanks Janssen Inc. for its generous contribution in support of this independent initiative that benefits IBD patients across the country.

janssen

Would you like to **join one of our Boards**?

We are a community of individuals who care, and we're going places. Do you want to be a part of a dynamic, innovative team that is a precious community resource for patients, physicians, and other health care stakeholders?

The GI Society became a registered charity in 2008, founded by key leaders of the Canadian Society of Intestinal Research, its allied registered charity, established in 1976. In 2011, we also absorbed a Quebec-only registered charity, AMGIF.

As grassroots organizations caring about GI and liver patients' needs, we focus on open, honest dialogues about GI and liver diseases and disorders. We are also dedicated to initiatives that aim to improve how the complex pan-Canadian health care systems meet the needs of Canadians affected by these serious conditions. As mission-based organizations, our impact is far reaching.

We are looking for board members for both the GI Society, which is national in scope, and for CSIR, which focuses its efforts on BC initiatives. There are currently openings for both general and executive board members from a variety of professional backgrounds and geographical locations. We encourage younger individuals to apply, who might not have tons of board experience but are proactive and have the drive to learn and get things done. We also want experienced members, who can add value and context to good governance and ongoing activities.

We need forward-thinking leaders who are willing to roll up their sleeves and work together with staff in finalizing and approving some governing policies and strategizing ways to grow. We need individuals with a keen interest in fundraising to help plan and support the GI Society's many community activities, including events happening this fall in Vancouver, Toronto, and Montreal.

As this is part of a larger recruitment initiative, we have many initiatives on the go and we will train those who are interested in patient/consumer advocacy issues.

We have a long, respected, history – join us for an exciting future!

5-ASA Victory for BC Patients and Physicians

The GI Society was alarmed to learn that BC PharmaCare, as well as the provincial formularies in Nova Scotia, Manitoba, and Ontario, had recently announced that they would only cover the cost of generic 5-ASA when a physician prescribed Asacol® 400mg (5-ASA) for the treatment of ulcerative colitis. We were extremely concerned that those decisions, which would allow pharmacists to substitute generic 5-ASA for Asacol 400mg (5-ASA) without asking or even informing the prescribing physician, had the potential to adversely affect patient care. Some provinces have set the generic price as the highest amount they will pay, which effectively means that if patients want to stay on the medications that are keeping their disease under control, then they will have to pay the difference between the generic and brand prices or accept substitution with the generic medication.

As an organization, we know there is a role for generic medicines; however, this situation is unique, and we had to stand up for ulcerative colitis patients whose health this could affect.

Why the concern? The main difference between generic 5-ASA and Asacol 400mg (5-ASA) is that they have different enteric coatings, which means they might release the active ingredient into different areas of the digestive tract. This is crucially important because, unlike many other types of drugs taken in pill form for non-gastrointestinal diseases, 5-ASA is an internally topical medication, delivering the active ingredient to the precise location of disease activity within the intestine. If patients are responding well to treatment with Asacol 400mg, then it is vital that they have continuity of medication supply. Switching to the generic might mean that the active ingredient would release in the wrong area of the digestive system and miss the area with active disease. Additionally, if physicians don't know which medications (generic or brand) their patients are actually receiving at the pharmacy, they might conclude that the 5-ASA treatment is not working and then move their patients to the next level of treatment, with medicines that could have higher risk profiles and greater costs.

When we heard the announcements, we took immediate action, writing letters to all four provincial formularies, and we are pleased to announce that BC PharmaCare has favourably modified its earlier decision.

What does this mean? This decision ensures that, as of October 23, 2012, Asacol 400mg tablets will continue to be a paid benefit under the BC PharmaCare Program as long as a gastroenterologist writes the original prescription. PharmaCare will also cover Asacol 400mg fully if a general practitioner writes refill prescriptions. However, this decision is not retroactive and therefore does not affect prescriptions written or filled prior to October 23, 2012. If your physician has prescribed Asacol 400mg, then make sure you are receiving the specific product prescribed for you. You may need to receive a new prescription from your gastroenterologist in order to receive coverage for Asacol 400mg. Of related interest, Asacol® 800 (800mg tablets of 5-ASA) continues to be fully reimbursed for any prescriptions.

While we are relieved to hear that BC has modified its decision, ulcerative colitis patients and their physicians in NS, ON, and MB are still suffering from a lack of treatment choice and we truly hope that those jurisdictions will follow BC PharmaCare's decision so that patients across the country can have equitable access to the medications they need.

The GI Society continues to forge strong relationships with health care professionals, patient associations, governments, businesses, the insurance industry, and with decision-makers in our community, so we can focus on improving our health care systems while empowering, encouraging, and educating persons living with GI and liver conditions, as well as their friends and families.

We conduct surveys of patients' experiences and provide patient input submissions to provincial and federal government bodies regarding medication listings and other issues important to the GI and liver patients we represent. We are currently seeking patient, family member, and caregiver perspectives on Crohn's disease, ulcerative colitis, *C. difficile* infection, and chronic constipation. Visit www.badgut.org for more information, or to become involved.

WOMEN AND IBD

In recognition of **International Women's Day**, which is marked each year on March 8th, we present some recent research on the extra challenges faced by women with Crohn's disease and ulcerative colitis.

Work and Romance

A recent study from Sweden found that, compared to men with Crohn's disease, women with the disease were more likely to experience long-term sickness, be on a disability pension, and be single.[1] Based on the health-related quality of life (HRQL) scale – a standard for measuring individuals' beliefs about how a disease affects their lives – the women in the study also perceived a more negative impact on their lives from Crohn's disease than did the men in the study.

The study included 505 Crohn's disease patients and, for comparison, also collected data from 300 ulcerative colitis patients. Men with Crohn's disease reported a similar level of HRQL as that reported by women with ulcerative colitis, but men with ulcerative colitis reported their disease as having only a very minimal impact on their quality of life. In terms of objective disease activity, there were no significant differences between genders in either Crohn's disease or ulcerative colitis, though women with IBD are more likely than men to experience extraintestinal IBD symptoms and to also have irritable bowel syndrome (IBS). This may go some way toward explaining the discrepancy, but not entirely. This study's authors speculate that differing coping strategies between genders or societal inequalities may also play a role, such as increased pressure on women to fulfil their daily functional roles – as mothers, employees, etc. – regardless of disease symptoms.

IBD Flare or Regular Menses Symptoms?

Researchers in Manitoba explored the relationship between gastrointestinal (GI) symptoms and menses in IBD. Their study's findings, published in *Alimentary Pharmacology and Therapeutics,*[2] showed that women with IBD have very similar symptoms before and during menses as those of women without IBD (e.g., bloating, fatigue, and mood changes). However, women in the study with Crohn's disease had increased premenstrual diarrhea compared to women with ulcerative colitis and those in the control group.

Both the Crohn's disease and ulcerative colitis groups were more likely to experience diarrhea during menses than the healthy control group. The researchers suggest studies like this one, which help elucidate the cause of specific GI symptoms, may help gastroenterologists in making treatment recommendations for premenopausal women with IBD.

Pregnancy Update

In *The Inside Tract*® Issue #180, we described the special factors that women with IBD must consider around pregnancy. A new literature review from researchers at the University of Toronto makes a number of updated recommendations for gastroenterologists.[3] At the top of their list is proactive counselling for female IBD patients who are of reproductive age. These pregnancy-related discussions should include nutrition factors, vitamin and mineral supplements, smoking and alcohol cessation, and achieving and maintaining remission before becoming pregnant (if possible). The review also indicates that some medications, such as biologics, can be used safely during pregnancy for longer than was previously thought.

Another recent study, evaluating how well women with IBD understand pregnancy-related issues through a validated questionnaire called Crohn's and Colitis Pregnancy Knowledge (CCPKnow), found that nearly half (45%) of the 145 women in the study had poor knowledge of pregnancy-related issues in IBD, 28% had adequate knowledge, 17% had good knowledge, and only 10% had very good knowledge of these issues.[4] Many women with IBD report that they avoid becoming pregnant out of fear (e.g., infertility, medication risks, and possible birth defects) that is out of proportion with current scientific evidence. The researchers are also concerned that women with IBD who do choose to become pregnant could stop taking their IBD medications during pregnancy out of unwarranted fear that the medication puts her fetus at risk. As described in our previous article, ongoing research continues to show that the best pregnancy outcome occurs when the disease stays in remission during pregnancy and that, with few exceptions, most drugs used to treat IBD are safe for pregnant and breastfeeding women. However, we strongly urge women to have a thorough discussion with their gastroenterologists about the particular risk/benefit ratios for all medications and supplements taken during pregnancy.

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SMALL MOLECULE

LARGE MOLECULE

Subsequent Entry **Biologics**

Gail Attara, President & CEO, Gastrointestinal Society

In the last issue of *The Inside Tract*® newsletter, in the article entitled Understanding Research, I promised to expand on the topic of subsequent entry biologics (SEBs). There are a number of concerns around SEB efficacy, patient safety, and regulatory expectations, but before we look at *subsequent entry* biologics, let's look at *innovative* biologics. Below are some complex and intricate issues that, with your grace, I will condense and simplify in this article.

Canadians have been using biologics for more than two hundred years, initially in the form of rudimentary vaccines for smallpox as far back as 1796. Another significant and widely used biologic medicine came from Canada in 1921, when Dr. Frederick Banting and Dr. Charles Best extracted the hormone insulin from pigs for use in humans to treat diabetes that, up until that time, had always been a fatal disease.

On a personal note, during the late sixties, Dr. Best was a frequent visitor to my family's home after he heard of my brother's case – a fifteen-month-old baby who, with a few initial injections of insulin, went from near death to thriving. Dr. Best would sit chatting with the adults and us older children while watching my small brother's growing strength and mischievous playfulness, knowing that it was his (and others) direct efforts that helped this little boy survive. I ended up acing a middle-school project on insulin – with none other than Dr. Best as my mentor!

Some other examples of state-of-the-art targeted biologics are blood and its components, human growth hormone, interferon, and monoclonal antibody (mAb) technology, such as Remicade® (infliximab) and Humira® (adalimumab) used to treat Crohn's disease and/or ulcerative colitis via the anti-tumour necrosis factor-alpha (anti-TNF-α) mechanism of action. For some of the 233,000 inflammatory bowel disease (IBD) patients in Canada, issues around the safety and availability of biologics and these new SEBs will be just as important to them and their families as life-saving insulin was for my brother.

Biologic medicines are not new, but they have evolved into very intricate medicines that continue to improve health outcomes drastically for patients in a number of serious disease areas.

How Biologics Differ From Other Drugs

Biologics are large molecule medicines, but this refers more to their complexity than to their size. These medicines have complex ways of working within the body. They are intricate structures that manufacturers specifically develop using unique processes. Let's look at the basic differences between small and large molecule medicines.

SMALL MOLECULE

Simply put, most common medicines, including dietary supplements, are small molecules created by compounding

organic and/or inorganic chemical substances, which we take orally. About 90% of the medicines on the market are small molecule medications.

LARGE MOLECULE

These molecules are structurally elaborate agents grown through a complex biologic process using diverse human, animal, and/or microorganism (e.g. bacteria, yeast) sources, and are often produced using recombinant DNA (rDNA) technology. (See sidebar.) More than 1,000 process steps could be necessary to assemble a complex medicine and this information is proprietary.[1] We have to inject or infuse biologics, because if we take them orally, we'll digest them.

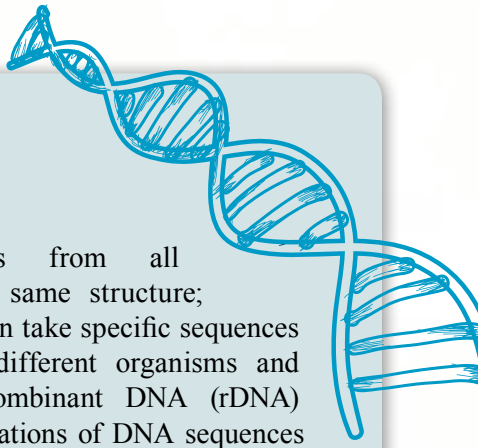
These complex biological structures can contaminate easily and even a slight change to the equipment used to produce these medicines can result in a clinically different medication, the implications of which could range from minimal impact, to a less effective response, and all the way to a severe adverse reaction. Biologics are also vulnerable while they travel through the supply chain (manufacturer-wholesaler-pharmacy/hospital-patient), as they require continual refrigeration.[2] Due to their complex manufacturing process, regulatory hurdles, and handling requirements, biologic medications are more expensive than traditional, small molecule drugs.

Most medicines are small molecule chemical compounds that are relatively simple to produce and copy. In contrast, large molecules such as biologics are complex, distinctly variable structures that are impossible to reproduce accurately without using the exact base components and then knowing and following an exact manufacturing process. This process is legally protected information belonging to the company whose innovators first developed it.

Innovators vs. Copies

SMALL MOLECULE

When patent protection ends for small molecule medications, generic companies jump in and create their own cheaper medications using the same active chemical compound, known by its international nonproprietary name (INN). Using this naming convention is helpful because medications often have different brand names in different countries. Health Canada, our drug regulator, assesses new generic products on healthy volunteers and when it approves them for use in Canada, it deems them to be equal (bioequivalent) to the innovator (brand), even if they might look slightly different. Public and private drug plans then generally consider the originator and generic products interchangeable for drug coverage. This leads to substitution from the brand to generic medication frequently at the pharmacy level, typically without consequence. (There are exceptions to every practice.)



rDNA

DNA molecules from all organisms share the same structure; therefore, scientists can take specific sequences from one or more different organisms and combine them. Recombinant DNA (rDNA) molecules are combinations of DNA sequences that bring together genetic material from multiple sources, creating sequences that do not occur naturally together. Scientists have also found a way to use chemical synthesis to create completely new DNA sequences that do not occur anywhere in nature and incorporate these into recombinant molecules. For use as medicines, these structures are multiplied (grown) through multiple steps.

LARGE MOLECULE

Copying the large molecule processes is not as simple as copying a chemical, so a completely new set of challenges has arisen as manufacturers are creating what Health Canada deems to be subsequent entry biologics (SEBs) and many other jurisdictions around the world deem to be biosimilars. Health Canada has stated, "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 or therapeutic equivalence to the reference biologic drug."[3]

Once a patent expires, other manufacturers may legally combine the same ingredients to make a similar medicine, but the innovator company is not obliged to share its manufacturing processes. For small molecule medications, the processes are relatively simple, which makes it easier for generic manufacturers to create versions of the brand medication that have the same active ingredient and clinical behaviour, making them interchangeable. This is not true of biologics, where the manufacturing process is integral to creating the medication.

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Patient Safety/Naming Issue

Patient safety is paramount and we will advocate alongside other patient groups to ensure there is no confusion between innovator and SEB medications when used in the community. For example, it is very important to make sure that the international nonproprietary names are completely different from each other, so that the real world usage data attaches to the applicable medicine throughout the world when physicians prescribe medications, pharmacists dispense them, and if patients report adverse reactions. Safety is an important issue that we – as a group representing patients – must monitor.

We support a more distinct naming convention to differentiate these medications more clearly in the health care system and recommend that there be a unique INN for each SEB, because they are not bioequivalent nor interchangeable with the originator medicine.

There is a strong regulatory need in Canada for distinguishable INNs between the innovator and SEB medications. The GI Society will continue to liaise with government bodies as new SEB medications enter Canada and as regional policies to cover these medications develop. These include protecting physicians' authority to prescribe the exact biologic or SEB that is right for each patient, and insisting on distinct INNs to ensure that safety information regarding these new SEBs is not confused with existing biologics.

Evidence Collection and Extrapolation

SMALL MOLECULE

Typically, when a generic medication comes to market, Health Canada does not require population studies because the generic manufacturer can prove its medication's bioequivalence just by using the same active ingredient as in the innovator medication. Therefore, if the brand works for various conditions, then it's a good bet that the generic will work for all of the same conditions (indications).

LARGE MOLECULE

Since SEBs are not equivalent, but only similar to the originator biologic, we cannot assume an SEB will work in exactly the same way as the originator, nor can we assume it to be effective for all of the same indications as the originator without proper clinical trials. For example, if an innovator medication earns indications (by conducting clinical trials with positive results) to treat rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis, and yet clinical trials using the SEB have only been done in rheumatoid arthritis, we should not expect the SEB to automatically receive an indication for the other diseases that the innovator has earned.

The other factor is that patients might not react to the SEB in the same way they've reacted to the brand medication and we want to be certain that interchangeability or substitutions won't occur. Biopharmaceutical manufacturing, packaging, distribution, storage, and quality assurance are all factors in the degree to which a medication provokes an unwanted immune response (immunogenicity), which could lead to a different clinical response or even a severe adverse reaction.[4] Since these medications are unique, it is possible that for some individuals, the SEB will work better for them than the innovator medication, offering new hope to those who have not found an ideal treatment.

Generic medications are bioequivalent and typically interchangeable with brand medications, but biosimilars/SEBs are only similar and never bioequivalent. Therefore, public and private drug plans must never assign biologics/SEBs interchangeability status or direct patients whose illness is under control while on one biologic to switch to another, innovator or SEB, as this could endanger patients, whose immune systems might react adversely to the different medication.

SEBs should go through rigorous testing for safety and efficacy for every disease group expected to benefit from the new medicine. In other words, it should not be as easy for SEBs to expand indications to treat a condition as it has been for small molecule generic medications.

Patient Engagement

As with all areas of health care in Canada, we strongly support an environment of patient engagement. It's our belief that the patients, as the end users of these medications, have vital knowledge about the disease processes and the potential value these medications could add to their lives.

Since these medications – both originator and those that come to the system later – are intricate and specialized, patients need to be involved in many stages along the way. We will continue to work with the health jurisdictions, and encourage the authorities and the pharmaceutical industry to engage patients throughout all the stages of medication formulation and development of policies for its use.

It was a rare opportunity for me as a young girl to get to know a biologic pioneer and I am forever grateful for the experience. For me, the most inspiring thing I remember about Dr. Charles Best was how he cared so profoundly for the patients he could help with innovative science. I think he would be interested in how far we've come in almost a century and in how far there is yet to go.

Let's Talk
Lecture Spotlight on GERD

Last fall, the GI Society held a BadGut® Lecture on gastroesophageal reflux disease (GERD). We were not surprised by how popular this packed event was, since recurring GERD symptoms affect 13-29% of Canadians. We spoke with some of the attendees afterward, who shared with us how the lecture, presented by Dr. James Gray, a gastroenterologist in Vancouver, helped them in a number of ways. Many people, for example, have trouble explaining GERD to others because it can sound like regular heartburn – which almost everyone will experience at some point. As one attendee explained, "It's not occasional heartburn or a sore throat – it's a diagnosable chronic disease."

Those diagnosed with GERD know that it is a much more serious condition that can affect their long-term health and quality of life. In normal digestion, a specialized ring of muscle at the bottom of the esophagus called the lower esophageal sphincter (LES) opens to allow food to pass into the stomach and then quickly closes. The LES can malfunction, allowing contents from the stomach, such as hydrochloric acid, to push up into the esophagus. In GERD, this backflow is recurring.

Attendees told us that Dr. Gray's presentation provided them with reassurances about their biggest fears around GERD – scoping procedures, accepting it as a chronic disease, the slight possibility of cancer and Barrett's esophagus, and the potential for having to take a medication for life. One attendee told us about her experience taking a proton pump inhibitor (PPI) to control her GERD symptoms. PPIs work by blocking an enzyme necessary for acid secretion. She told us she doesn't like the idea of taking a medication over the long term, but recognizes that it is the only medication adequately controlling her symptoms and improving her quality of life, even if there is no cure for her condition.

A recent article published in *Southern Medical Journal* reviewed the use of PPIs.[1] The goal of PPI therapy in GERD is twofold: control symptoms and heal esophageal mucosa. PPIs are powerful medications and research is ongoing into possible complications and risks associated with the long-term use of high doses of PPIs, including osteoporosis, low magnesium levels (hypomagnesemia), increased risk for *Clostridium difficile* infection, and others. PPI medications are not for the individual who experiences the occasional bout of heartburn or incident of reflux, and some GERD patients are able to manage their symptoms effectively through other treatments. For some of our recent lecture attendees, however, who have recurring, debilitating GERD symptoms, PPI medication is the treatment they require daily in order to keep their disease activity under control.

Unfortunately, many other individuals with GERD – almost one third – do not seek help from physicians because they mistakenly believe their own GERD symptoms to be due to food or behavioural choices alone and they try to self-medicate, usually without success. Treatment can vary among individuals and might include diet and lifestyle modifications, over-the-counter treatments, prescription medications, or (in rare cases) surgery. If you think you might have GERD, it is important to see your physician to receive a correct diagnosis and support. If your physician has recently diagnosed you with GERD, please contact our office to receive our free GERD patient information package.

GI Society Support Groups

VANCOUVER, BC

Inflammatory Bowel Disease Group

7:00pm third Wednesday of each month
Raven Song Community Health Centre, Rm 101
2450 Ontario St, V5T 4T7

TORONTO, ON

Irritable Bowel Syndrome Group

7:00 pm fourth Tuesday of each month
Trinity Recreation Centre
155 Crawford St (Queen and Ossington)

Photo: (top) © Cunliffe/Bigstockphoto.com, Les Cunliffe/Bigstockphoto.com, Pierre Giard

Caring for your Gut while Travelling Abroad

There are several infectious illnesses a traveller could experience, especially while visiting developing regions where health and sanitation conditions are different from North American standards. This article will focus on two conditions that affect the digestive system: travellers' diarrhea, and infectious hepatitis (A and B).

Travellers' Diarrhea

Travellers' diarrhea (TD) afflicts 20-50% of people travelling from industrialized countries to high-risk developing ones. The most common mode of transmission is through ingesting food contaminated by feces that contains viruses, pathogenic bacteria, or parasites. These infectious organisms colonize the small and/or large intestine. Most of them produce toxins that increase the flow of water and electrolytes into the bowel (secretion). An infection-related fluid imbalance can cause large and uncomfortable increases in stool production (i.e., diarrhea).

Most TD cases occur within 2 weeks of arriving at a destination and could still occur within 2 weeks after returning home.[3] The most common cause of travellers' diarrhea is infection with enterotoxigenic *Escherichia coli* (ETEC), a pathogenic bacterium; however, other organisms can cause travellers' diarrhea and most people never learn the specific contaminant that infected them. TD is a self-limiting disease usually lasting less than 7 days.[2] However, 20% of TD sufferers are confined to bed, 8-15% remain unwell after a week, and at least 1% become hospitalized.[4] In addition, an episode of TD does not provide protection against future attacks and an individual can experience more than one episode in a single trip.[3]

Mild travellers' diarrhea involves the passage of three or more loose stools over a 24-hour period, with at least one other symptom: abdominal cramping, the sensation of having to go immediately (urgency), painful rectal spasms associated with the strong urge to pass stool even though little stool is present (tenesmus), and nausea or vomiting.

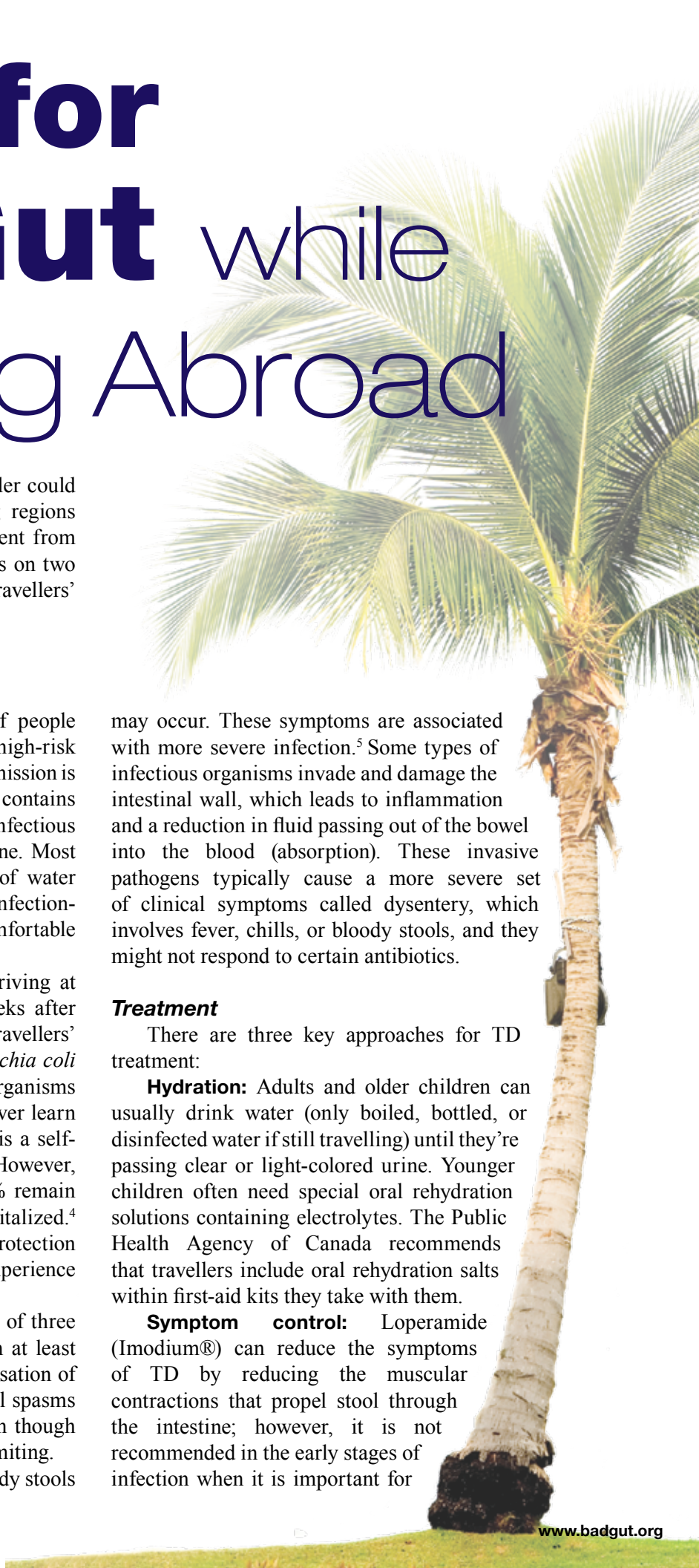
In 10% of effected travellers, fever and/or bloody stools may occur. These symptoms are associated with more severe infection.[5] Some types of infectious organisms invade and damage the intestinal wall, which leads to inflammation and a reduction in fluid passing out of the bowel into the blood (absorption). These invasive pathogens typically cause a more severe set of clinical symptoms called dysentery, which involves fever, chills, or bloody stools, and they might not respond to certain antibiotics.

Treatment

There are three key approaches for TD treatment:

Hydration: Adults and older children can usually drink water (only boiled, bottled, or disinfected water if still travelling) until they're passing clear or light-colored urine. Younger children often need special oral rehydration solutions containing electrolytes. The Public Health Agency of Canada recommends that travellers include oral rehydration salts within first-aid kits they take with them.

Symptom control: Loperamide (Imodium®) can reduce the symptoms of TD by reducing the muscular contractions that propel stool through the intestine; however, it is not recommended in the early stages of infection when it is important for



the offending organisms to evacuate the body. Loperamide is not for infants younger than two years old or travellers with fever or bloody stools.[6]

Antibiotics: Antibiotics kill the harmful bacteria and/or parasites causing the infection, reduce the amount of stool passed, and decrease the duration of symptoms by about half. Some studies suggest that antibiotics combined with loperamide are more effective than antibiotics alone.[7]

Complications

Although rare, TD can lead to serious complications or initiate chronic bowel problems. Studies indicate that post-infectious irritable bowel syndrome (PI-IBS) affects about 10% of those who experience TD. PI-IBS involves long-lasting abdominal discomfort or pain that is associated with a change in bowel habits. It usually involves prolonged diarrhea for at least three days out of every month, though it can also manifest as constipation. Symptoms typically persist for several years, slowly improving over time.

Guillain-Barré syndrome, a very rare complication of TD, is a neurologic disorder that causes weakness and sometimes numbness in the extremities; it can last from months to years. Another rare but serious complication is reactive arthritis, which involves mild to severe joint inflammation that typically affects the lower extremities and can persist for months.

Prevention

Careful dining habits and good personal hygiene practices will help prevent infection. While travelling in high-risk areas:

- Drink only boiled, bottled, or carbonated beverages. Alcohol also presents a low risk of contamination. Do not mix any beverages with juice or ice, as these could be a source of contamination and freezing does not kill most microorganisms. Check that bottled beverages are factory-sealed.
- Avoid raw vegetables and fruit unless they have a skin that you can peel (apples, kiwi, etc.).
- Eat only thoroughly and recently cooked meat or fish.[8] Food served by street vendors is at a high risk for contamination. Restaurant food is usually safer, but water used to clean food and cooking tools can be a

source of contamination. Home-cooked meals are the safest, although nothing is foolproof.
- Wash hands with soap and water before eating. Waterless alcohol-based hand sanitizers might also be effective if hands are not visibly dirty.[8]

Prophylactic Treatments

Even careful travellers occasionally make a mistake or a risky dietary choice, and some individuals (such as those with blood group O or certain genetic backgrounds) are more susceptible to infection with particular bacteria than the general population. Those who take stomach acid-suppressing medications, such as proton pump inhibitors (PPIs) for GERD, and travellers with chronic diseases, including kidney disease and diabetes, are at a higher risk for TD or for more severe consequences.[7] Fortunately, there are some prophylactic treatments available:

Vaccination: Dukoral® is an oral vaccine (taken by mouth) that helps prevent travellers' diarrhea caused by ETEC in adults and children 2 years of age and older. It also protects against cholera, another bacterial infection that affects some developing regions. In a field trial, the Dukoral® vaccine demonstrated 67% protection against certain ETEC strains for three months. In a second trial of tourists from Finland visiting Morocco, efficacy against any ETEC diarrhea was 52%. Protective efficacy for all TD will vary depending on the prevalence of ETEC in the travel region or season.[11]

Bismuth subsalicylate: One trial found that this substance, the active ingredient in Pepto-Bismol®, reduced the rate of TD from 40% to 14%, a 65% rate of protection. The protective effects occur with frequent, regular doses (usually 2 tablets taken up to four times a day) for the duration of a trip. However, bismuth subsalicylate has a range of potential side effects and it is not recommended for everyone, including children and pregnant women.[9]

Probiotics: Probiotics are living microorganisms, typically bacteria or yeast, taken orally to maintain a healthy microbiome in the colon and prevent colonization by harmful microorganisms. They are effective in treating some diarrheal disorders and probiotic research is ongoing. In particular, a study of *Saccharomyces boulardii* (Florastor®), a probiotic yeast, showed that it has a protective effect against travellers' diarrhea. Limited evidence supports the effectiveness of certain other probiotic strains against TD and suggests that probiotic efficacy varies widely depending on the travellers' destination.[10] If you do choose to use probiotics while travelling, look for ones that contain a sufficient quantity of microorganisms to confer a health benefit and that do not require refrigeration.

Evidence suggests that certain antibiotics also have a preventative effect against travellers' diarrhea, but specialists in this area do not recommend prophylactic antibiotics unless an individual is at a higher risk of TD or its complications (e.g., individuals whose immune system is suppressed).

Book an appointment with your family physician or local travel clinic well in advance of travel to high-risk areas in order to obtain personalized advice, medications, or immunizations. Similarly, don't wait until you're travelling to buy prophylactic products as they might not be available in the country you're visiting – prepare in advance to avoid disappointment.

Infectious Hepatitis

Hepatitis A

Hepatitis A (HAV) spreads when a person ingests food or beverages, including water, contaminated with stool containing the virus. Obvious symptoms are more common in adults and older children, and they can be mistaken for the flu. These include fatigue, fever, abdominal pain, nausea, and loss of appetite.[1] Other symptoms include dark urine and jaundice.

Most patients recover within two months of infection, but 10-15% of patients will experience a relapse within the first six months of their initial infection. HAV causes the liver to swell, but it does not become chronic or cause permanent liver damage.

If you suspect HAV, contact a physician for a proper diagnosis and avoid spreading the illness to others by taking careful hygiene precautions such as frequent hand-washing. Treatment usually involves rest, plenty of fluids (no alcohol), and regular meals. Once you have contracted HAV, your immune system makes antibodies so that you will never get it again.

Fortunately, you can avoid ever getting hepatitis A because there are vaccines available to prevent HAV infection. It is unusual for individuals to contract HAV in North America unless it is through a household member who is suffering from the illness after returning from travels to a high-risk area. Vaccination for hepatitis A is not part of the publicly funded immunization program in Canada, but you can purchase the vaccine at most travel clinics or through your family physician. Twinrix® is a vaccine that provides immunization against both hepatitis A and hepatitis B (see below). If you have already received

vaccination for hepatitis B, there is also a vaccine for hepatitis A alone.

Hepatitis B

Hepatitis B affects more than 350 million people worldwide and is quite common in Asia, Africa, the South Pacific Islands, and much of the Middle East, Eastern Europe, and Central and South America.

After exposure to the hepatitis B virus, infection begins as acute hepatitis B. Less than 5% of adults who get acute hepatitis B develop chronic hepatitis, but up to 90% of infants and children infected with hepatitis B become chronically infected. Researchers estimate that 0.7-0.9% of Canadians have chronic hepatitis B. Worldwide, 500,000-700,000 people die from hepatitis B each year due to complications of severe scarring of the liver (cirrhosis) and/or liver cancer.

Symptoms and Spread

Some infected individuals experience nonspecific symptoms, such as mild fatigue or discomfort in the abdomen, but many people do not have any symptoms and may not know that they have the disease. Hepatitis B often does not manifest noticeable symptoms until it has advanced, so individuals could unknowingly live with hepatitis B for years, resulting in liver damage and the infection of others.

Hepatitis B spreads when blood or another bodily fluid (salivary, seminal, or vaginal) from a person infected with the virus enters the body of someone who is not infected. High-risk activities include sexual contact with an infected person, having multiple sexual partners, getting a tattoo or body piercing using unsterilized instruments, or sharing contaminated drug paraphernalia. Blood-to-blood contact may occur through sharing of personal hygiene items (such as razors and toothbrushes) and through contact with open wounds. Hepatitis B does not transmit through casual contact, such as coughing, sneezing, hugging, or sharing food.

While chronic hepatitis B is not curable, there are excellent treatments available, as well as clear strategies to prevent and decrease complications, and to avoid further spread of this disease.

Vaccination

If you were not vaccinated as a child or teenager through a routine vaccination program, visit your family physician or local travel clinic and receive a vaccination well in advance of travelling to any high-risk areas (at least three weeks prior to travelling). You may save some time and money by getting Twinrix®, a safe and effective vaccine that provides life-long immunity from both hepatitis A and B.

Pelvic Floor Dysfunction

Laura Werner, BKin MPT Registered Physiotherapist
Dayan Physiotherapy and Pelvic Floor Clinic

If you have irritable bowel syndrome, chronic constipation, or chronic diarrhea caused by inflammatory bowel disease or an ongoing *C. difficile* infection, you could have developed a pelvic floor dysfunction. Those who have constipation-predominant symptoms might have pelvic floor muscular incoordination (dyssynergia/anismus) while those who have diarrhea-predominant symptoms might experience bowel urgency and/or incontinence of loose stools. Physiotherapists with specific training in these areas offer treatments that can help.

The pelvic floor consists of muscles that help control defecation. A successful bowel movement requires the coordination of gentle deep abdominal muscle contractions with simultaneous full relaxation of the pelvic floor. The puborectalis muscle acts like a sling that, when relaxed, increases the angle between the rectum and anus and aids in defecation. The external anal sphincter, located just past the anus, helps keep stool safely inside the rectum until a person makes the conscious decision to have a bowel movement. The external anal sphincter relaxes with the puborectalis, allowing defecation.

Pelvic Floor Dyssynergia

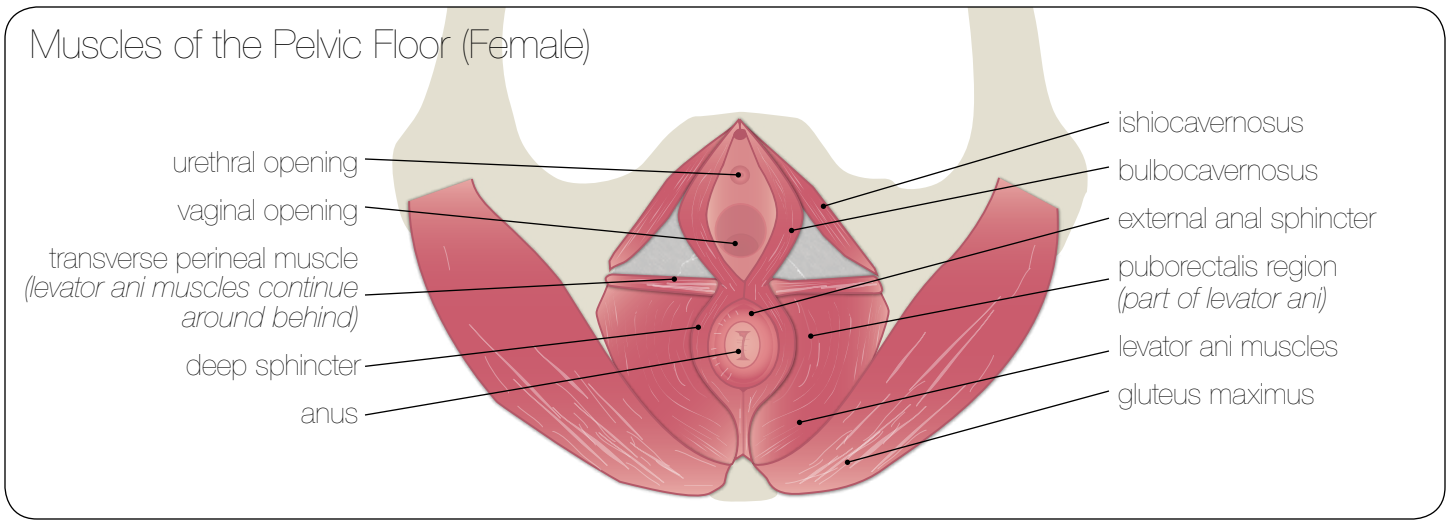
If you have chronic constipation, you might inadvertently develop an ineffective habit when moving your bowels, which involves bulging (distending) the abdominal muscles while contracting the pelvic floor – leaving you straining in vain to move stool through a firm muscular wall. Symptoms can include passing only a small amount of stool at one time, typically leading to repeated trips to the toilet within a short period while attempting to evacuate the remaining stool. Residual stool in the rectum might slowly leak out, leading to bowel incontinence.

Ineffective habits typically involve straining/pushing for stool to evacuate while holding your mouth tightly closed (i.e., attempting to exhale against a closed airway), and this can produce or worsen pelvic organ prolapse. A pelvic organ prolapse occurs when the rectal wall, for example, moves from its original position. If the wall between the rectum and the vagina bulges into the vagina, this is called a posterior vaginal wall prolapse (rectocele), or if the wall protrudes from the anus, it's called a rectal prolapse.

How Physiotherapy Can Help

A physiotherapist with training in pelvic floor rehabilitation can conduct a thorough evaluation of pelvic organ prolapse, and evaluate strategies to evacuate stool. Examination may include a digital vaginal exam (for women), a digital rectal exam, observation and touching (palpation) of the perineum and abdominal wall, and electromyographic (EMG) biofeedback assessment. In EMG biofeedback, the physiotherapist shows you your own physical responses to various stimuli or cueing using computerized instruments.

The goal of treatment is to develop your ability to relax the pelvic floor completely while simultaneously allowing gentle propulsive forces from deep abdominal muscles to evacuate the bowel fully. A physiotherapist will provide education in pelvic floor anatomy and function, pelvic floor dysfunction and dyssynergia, bowel control mechanisms, and physiotherapy treatments. Your physiotherapist will also review healthy bowel habits, including positioning,



time spent on the toilet, and facilitating good bowel patterns. Your physiotherapist will help you address diet-related problems contributing to constipation, and might ask you to keep a diary of your physical activity, fibre consumption, and fluid intake. You might find it helpful to discuss any significant dietary modifications with a registered dietitian.

Through your physiotherapist's feedback and EMG biofeedback, you can retrain motor control and the way your body automatically responds to stimuli related to pelvic floor contraction and relaxation. Your physiotherapist will also suggest management strategies for any prolapse that might be present.

Electromyograph (EMG) Biofeedback

Surface electrodes (internal or external) placed by the physiotherapist detect muscle contraction and relaxation. The information picked up from the biofeedback unit is displayed on a screen for both you and your physiotherapist to view. Internal electrodes are either vaginal or rectal probes. External electrodes may be placed on either side of the anus. An advantage to external electrodes is that you can move or change position (e.g., to sitting or standing) without having to adjust your posture to hold the electrode in place, facilitating a more realistic scenario. EMG biofeedback is a safe treatment with very few contraindications.

Bowel Urgency and/or Incontinence of Loose Stool

Pelvic floor muscles should tighten at the right time to hold stool so that you can reach the toilet to evacuate. The involuntary loss of stool (fecal incontinence) can occur if your pelvic floor muscles lack strength, endurance, and functional control. Physiotherapy for bowel urgency and/or incontinence of loose stool also includes education (e.g., pelvic floor anatomy and function, bowel control mechanisms, physical therapy treatment) as well as pelvic floor proprioceptive and motor control exercises. Your physiotherapist might use EMG biofeedback therapy, and will teach you specific pelvic floor exercises that you can integrate into daily activities, such as coughing, sneezing, lifting, rising from sitting, standing, exercising, and so on.

Finding a Registered Physiotherapist

You can find a physiotherapist through your regional physiotherapy association. Search for a registered physiotherapist who has incontinence or pelvic floor interest and training. Before making your appointment, ask about the physiotherapist's experience in treating either pelvic floor dyssynergia or fecal incontinence. In some regions, there are whole clinics that focus on pelvic floor dysfunction. Unless your extended medical plan requires it, you usually do not need a physician's referral to see a physiotherapist.

Welcome New Staff

Melanie Chapman, BSc, MSc
Executive Director Ontario

Melanie Chapman graduated from Brock University with a BSc (Hons) in Neuropsychology in 2008 and with an MSc in Neurobiology & Physiology in 2010. She is a twice-published co-author in *Behavioral Brain Research*.

Through her time at the Xerox Research Centre of Canada in Toronto, she has honed her customer relations, event planning, business administration, marketing, and communications skills, offering a unique set of skills to her role in Ontario.

Melanie's passion for the GI Society's patient-focused mandate comes from seeing first-hand the debilitating effects of several gastrointestinal illnesses, and from learning how the nervous system connects so intricately with many of these disorders. Melanie is looking forward to bringing her leadership skills and high energy to this dynamic team, helping to fulfill the GI Society's mandate through strategic development in Ontario.

Call for Crohn's Disease Participants for Clinical Trial

Qu Biologics is currently seeking Canadian participants for their Health Canada-approved clinical trial in Vancouver. The Crohn's disease treatment they are developing, QBECO, is a site-specific immunomodulator (SSI) that targets an organ's innate immune response. The researchers are recruiting 60 adults with active, uncontrolled, moderate to severe Crohn's disease. The main purpose of this randomized, placebo-controlled, double-blind study is to test whether this investigational treatment is safe and potentially effective for the treatment of Crohn's disease. Potential participants can learn more about the trial and complete an online pre-screening questionnaire to assess their eligibility by visiting www.qucrohnstrial.com.

Qu biologics

Healthy Breathing
for the Mind, Body, and Gut

Claire Maisonneuve, Registered Clinical Counsellor
Director, Alpine Anxiety & Stress Relief Clinic

Research has found associations between anxiety or depression and the development of some gastrointestinal (GI) conditions and related symptoms. Many symptoms of anxiety and stress are due to the way an individual breathes. There is a huge difference between a deep breath and a big breath. Most people with anxiety, fear, and panic tend to take big, restricted, effortful breaths rather than deep, satisfying, relaxing breaths. As a result, they suffer from upper chest breathing (disordered breathing), a dysfunctional way of breathing in which you breathe too fast, too shallow, and too high in the chest. Disordered breathing leads to a low-grade habit of hyperventilation, which provokes and maintains symptoms of anxiety by keeping the body tense and the heart racing.

While looking in the mirror as you take in a deep breath, watch to see if your upper chest and torso move up. Do your shoulders lift and your abdominal area contract as you inhale? Do your shoulders drop on the exhale? If this happens, then you have witnessed disordered breathing.

If you struggle to take a deep, satisfying breath in, find it hard to catch your breath at times, or experience attacks of breathlessness (even at rest), then you should work on improving your breathing patterns. Some of the symptoms of disordered breathing include:

- dizziness
- light headedness
- poor concentration
- erratic heartbeats
- pounding heart
- chest pains
- tingling, prickling, or pins and needles in the hands, feet, and lips
- regular sighs or sniffing
- repeated throat clearing
- tension in the neck, shoulder, and upper back
- sleep disturbances

Healthy breathing resembles that of a newborn baby. When you inhale, the abdominal area inflates and the shoulders barely move. If you were to place one hand on your belly and one hand on your upper chest, you would feel your belly move more than your upper chest.

Rapid upper chest breathing is a normal response to a sudden threat and it is one of the reactions of the fight or flight response, which is an instinctive, adaptive internal response to danger. In some people with anxiety and stress, this upper chest breathing has become an ongoing pattern. They breathe as if they are in imminent danger or as if something bad is going to happen at any moment. This keeps the body in a state of hyper-arousal or hyper-vigilance. Studies show that this type of constant stress or anxiety has a negative effect on the functioning of the GI tract.

For some people, this way of breathing could have started early on in life, especially if they grew up in an environment that was unpredictable, volatile, and chaotic, or filled with conflict or criticism. Other individuals report a distinct change in their breathing pattern after a surgery, car accident, or significant loss. Daily negative thought patterns of worry, nervousness, and fear, such as, *"What if I fail? What if they don't like me? I should..., I could..., I must...,"* all contribute to sustain disordered breathing.

Although events from the past originally created this habit and current fearful thoughts might exacerbate it, you must change your body's breathing habit in order to experience relief from anxiety and discover a sense of calmness. You might do this with the help of a therapist who works with the breath, by practicing specific breathing exercises and relaxation techniques, or by getting regular exercise at a level that is right for you.

While research is ongoing into the relationship between anxiety and GI conditions, stress management is an important and recognized component of GI health and treatment. If detrimental breathing patterns are so powerful that they can produce a range of negative symptoms, then it is reasonable to believe that healthy breathing patterns can produce positive experiences. Learning how to re-establish proper breathing habits can help to calm your mind, relieve anxiety symptoms, and possibly thwart or better manage a GI disease or disorder.

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Gastrointestinal Society
855 West 12th Avenue
Vancouver, BC V5Z 1M9

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