EFCCA MAGAZINE

European Federation of Crohn's and Ulcerative Colitis Associations February 2020

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www.oemccv.at

Belgium
CCV: www.ccv.be
Crohn-RCUH: www.mici.be

Bulgaria - BCUCA
www.babkuk.org

Croatia - HUCUK
www.hucuk.hr

Cyprus - CYCCA
www.cycca.org

Czech Republic - Pacienti IBD
www.crohn.cz

Denmark - CCF
www.ccf.dk

Estonia - EPSS
www.ibd.ee

Finland - CCAFIN
www.crohnjacolitis.fi

France - AFA
www.afa.asso.fr

Germany - DCCV.e.V.
www.dccv.de

Greece - HELLESCC
www.crohnhellas.gr

Hungary - MCCBE
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Iceland - CCU
www.ccu.is

Ireland - ISCC
www.iscc.ie

Israel - CCFI
www.ccfi.co.il

Italy - AMICI
www.amiciitalia.org

Luxembourg - ALMC
www.afa.asso.fr/luxembourg

Lithuania - CCLA
www.draugija.info

Malta - MACC
www.macc.org.mt

Montenegro - CUKUK
http://www.cukuk.me

Netherlands - CCUVN
www.crohn-colitis.nl

Norway - LMF
www.lmfnorge.no

Poland - J-elita
www.j-elita.org.pl

Portugal - APDI
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Romania - ASPIIR
www.aspiir.ro

Serbia - UKUKS
www.ukuks.org

Slovakia - SCC
www.crohnclub.sk

Slovenia - SAIBD
www.kvcb.si

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www.accuesp.com

Sweden - MOT
www.magotarm.se

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www.smccv.ch
www.asmcc.ch

Turkey - IBHDYD
www.ibhportali.com

UK - Crohn’s and Colitis
www.crohnsandcolitis.org.uk

Associate Members:

Argentina - Mas Vida
www.masvida.org.ar

New Zealand
Crohn’s and Colitis
www.crohnsandcolitis.org.nz

Brazil - DII Brasil
www.facebook.com/diibrasil

Kazakhstan - FPVZK
http://vzk.kz

Content

Making IBD work

As we are approaching a new year, I cannot help but take a moment to look back. It was exactly one year ago when we met with the EFCCA Board to discuss how we can best capitalize on our previous work and how we can include the needs and priorities of our members into a strategy for the coming four years that will shape our plan of action and reflect our mission and values.

I was proud to present this new strategy to our General Assembly in Prague and we are now taking steps to implement the proposed activities and to focus on the priority areas outlined in our strategy.

One priority area for EFCCA is networking with the aim to promote and encourage the exchange of information, knowledge and practices and to collaborate with other international organizations and key players of the IBD community.

For example, our participation at medical congresses such as ECCO and UEG WEEK are an important element of our networking activity and you can see from the article in this magazine on UEGWEEK Barcelona (October 2019) the benefits and potentials of such a collaboration.

Our CEO was invited to participate in a Faculty Talk of the UEG educational programme, giving EFCCA and the patient community an excellent opportunity to be more visible and having our perspectives heard at such an important medical meeting.

Being at UEG WEEK also enabled us to connect with many stakeholders and healthcare providers working on latest innovative IBD treatments and research. And this year, our networking efforts are bearing more fruits.

We are pleased to announce that we will be part of the official programme during the ECCO Congress to take place in Vienna from 12-15 February 2020.

Our Symposium will bring together patients, healthcare providers and other stakeholders in order to start discussions on how digital health and big data can contribute in delivering more personalised care and offering a higher quality of life of patients with IBD.

This is a very important event for EFCCA and reflects our mission to give people with IBD a louder voice and be more visible.

It also confirms our role as an active player within the IBD community committed to improving the quality of life of people with IBD and bringing their concerns and needs to strategic discussions.

> **“Considering that IBD is mainly affecting young people of working age the impact it has on a person’s professional life is an important challenge in particular for policy makers and employers.”**

Furthermore, in this issue you will find information about our plans around awareness raising and advocacy in particular for World IBD Day 2020. This year, within the framework of our strategy plan, our priority theme will be on the subject of Work and IBD.

Considering that IBD is on the rise and mainly affecting young people of working age the impact the disease has on a person’s professional life is an important challenge for society at large and in particular to policy makers and employers.

There are many solutions for solving this challenge and several of our members have already worked on this topic and developed useful material and guidelines.

We aim to make these resources available worldwide and to bring the discussion on Work and IBD to European policy makers.

You will find more examples of the work we are doing such as the survey on *the Impact of perianal fistulae on a Crohn’s disease patient’s quality of life* or our involvement in the *ECCO UC Treatment guideline project.*

Please also take a look at the news section of our members. It is always very inspiring and encouraging to read about the many activities and efforts our members are undertaking to support people with IBD in their countries and worldwide.

As you can see, we have some exciting months ahead. It will require a lot of efforts and working together to achieve our objectives set out in the strategy, but we are confident that we will succeed as we have a dedicated team behind as well as the support from our members and supporters.

United We Stand!

Salvo Leone
EFCCA Chairman

Digestive health in Europe and beyond - UEG Week 2019

UEG WEEK 2019 took place in Barcelona from 19-23 October 2019 and was attended by over 13 000 delegates (online and onsite). UEG Week together with the ECCO Congress are the major GI meetings in Europe bringing together world class scientific researchers, physicians, nurses and other key stakeholders in the GI field.

As usual, EFCCA was invited and represented at UEG WEEK and our information booth near the educational and scientific programmes area allowed us to be in close contact with many of the delegates to explain EFCCA's mission and main areas of work.

Of course, this was also the moment to connect with many of our stakeholders and to discuss common objectives and potential areas of collaboration.

Among the scientific highlights of UEG WEEK was the presentation of the EVOLVE study that aimed to compare the real-world clinical effectiveness and safety of vedolizumab (VDZ), a gut-selective anti-α4β7-integrin, and anti-tumour necrosis factor (TNF) agents in biologic (bio)-naïve ulcerative colitis (UC) patients.

The study involving more than 1,000 people with IBD reported that vedolizumab significantly reduces the risk of serious adverse events (SAEs) and serious infections (SIs) compared with antiTNF treatment.

On the "hot topic" of microbiome a study carried out by scientists from Groningen in the Netherlands have suggested that dietary manipulation could one day become a viable treatment strategy for people with inflammatory bowel conditions, such as IBD.

The team investigated the effects of 160 dietary factors on the gut microbiome in four cohorts representing the general population, Crohn's disease, ulcerative colitis, and IBS (N=1,425).

Stool samples from study participants were analysed alongside Food Frequency Questionnaires, with microbiota composition evaluated using shotgun metagenomic sequencing.

A UK study presented by researchers from Sandwell and West Birmingham hospitals NHS trust and the University of Birmingham revealed that the number of people suffering from IBD is three times higher than previous estimates, with sufferers also at a higher risk of developing colorectal cancer (CRC).

The research examined IBD cases from the beginning of the century to attain accurate data on ulcerative colitis (UC) and Crohn's Disease (CD) prevalence in the UK.

Previously, only limited or old data existed, but by utilising data from the Health Improvement Network (THIN), a nationally representative UK primary care database, this new evidence demonstrates that IBD prevalence is three times higher than previously reported, with UC and CD prevalence increasing by 55% and 83% respectively, between 2000 and 2017.

The study also showed that IBD prevalence is predicted to rise by almost a quarter from 2017 to 2025.

For more information on the scientific programme please visit: www.ueg.eu/week/programme

UEG Research Prize

EFCCA would like to congratulate ECCO President Silvio Danese who was awarded the UEG Research Prize for his project “The gut virome as a trigger for IBD: from metagenomics to pathogenesis”. The study is investigating how viral proteins may intervene in IBD etiogenesis. If the hypothesis is confirmed this would open doors for alternative therapies that seek for causes to be ‘switched off’ representing a real breakthrough in the IBD field.

“Early-diagnosed IBD patients, once assessed for the presence of the mucosal viruses, might be treated with specific siRNAs or antiviral drugs that directly and specifically inhibit initial phases of inflammation. This would avoid immune suppressive treatments and provide innovative protocols for patients. I’m sure we will obtain promising results in the very near future and will provide novel, striking insights that will improve current knowledge in IBD clinical and basic practice” said Professor Silvio Danese on receiving the award.

Professor Silvio Danese during his acceptance speech
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Patient Perspective at UEG WEEK

EFCCA CEO, Luisa Avedano, was invited to talk at one of the UEG WEEK faculty conference on the topic of “integrating modern approaches into daily practice for IBD treatment”. She presented the challenges and opportunities of apps/health data collection defining the needs and priorities and the role that patients can play in this process.

From a patient perspective big data are the future and collection of health data could ultimately lead to better personalized healthcare including the anticipation and prevention of flares, decreasing hospitalization, improving and facilitating communication between patients and health care providers and overall improving patient's quality of life.

An important issue to consider in the discussions around health data and collection is the need for interoperability between quality of care and quality of life data and to be able to combine in a meaningful way clinical data with Patient Reported Outcomes (PROs). Last but not least patient data privacy and data ownership and data analysis are an important aspect in this process.

Luisa Avedano, EFCCA CEO, during a UEG WEEK faculty talk

Internal meeting with Roche

Prior to UEG WEEK, EFCCA chairman Salvo Leone and CEO Luisa Avedano participated in an internal meeting organised by the pharmaceutical company Roche. The meeting gathered over 100 Roche affiliates worldwide and the objective of the session was to provide the patient perspective in particular as concerned unmet needs of patients.

Both EFCCA representatives stressed the importance of involving patient organisations in efforts raised to tackle the issue of unmet needs of the IBD patient community.

Salvo Leone pointed out that despite discussion for many years about the unmet patient needs there still seemed to be a lack of an effective and coherent strategy to overcome some of the identified obstacles.

EFCCA Symposium on data collection

We are pleased to organise the symposium “Digital Health and Data: IBD patients’ view and perspectives” to take place during the ECCO Congress on 14 February 2020 from 14-15h in Vienna, Austria. It will be a unique event bringing together IBD patients, healthcare providers and other stakeholders in order to start discussions on how digital health and big data can contribute in delivering more personalised care and offering a higher quality of life of patients with IBD.

EFCCA believes that the digital “revolution” in health care as well as the data collected from patients, can represent an opportunity to achieve a more harmonic combination between the quality of care and quality of life data.

“Patient at the centre” means giving patients a central role in the whole process that starts from the design of the structure of the data base, goes through the data collection and ends to its analysis. Analysing data from the patient’s perspective can become a powerful and unique way to achieve earlier diagnosis, better care strategies and identify patterns in health outcomes in partnership with medical societies and all relevant stakeholders.

We are looking forward to this symposium as it will promote a high-level discussion on these topics involving key opinion leaders and relevant stakeholders which could be of benefit for the entire IBD community. Our confirmed keynote speaker is Prof. Claudio Fiocchi, Director of IBD and Vice Chairman of Research, Department of Gastroenterology & Hepatology, the Cleveland Clinic Foundation.

ECCO networking event

The European Crohn’s and Colitis Organisation (ECCO) organized the 1st Council of National Representatives Meeting which took place in Barcelona 19 October 2019. The meeting was attended by representatives from the ECCO leadership as well as patient representatives from the EFCCA network including the EFCCA Chairman and CEO.

The meeting was a great occasion to exchange information and for ECCO to present the ECCO strategy and activities. A specific focus was dedicated to the role of patient associations and EFCCA.
ECCO agreed in becoming more involved in World IBD Day, in encouraging physicians to refer to patient associations and EFCCA when talking with their patients, in including patient representatives in some educational activities, and to continue to involve EFCCA representatives in activities such as the guidelines revision.

Impact of perianal fistulae on a Crohn's disease patient's quality of life

The survey on the impact of complex perianal fistulae on a Crohn's disease patient's quality of life, conducted by EFCCA in cooperation with pharmaceutical company Takeda, was closed at the end of December 2019. The survey gathered lots of interest and in the end, there were over 800 respondents who had been diagnosed with Crohn's disease. The responses came from 33 countries, and more than half of the respondents were suffering from one or more perianal fistulas.

An abstract introducing the concept of the survey was submitted and approved for poster presentation to the ECCO congress in Vienna in the beginning of February 2020, which shows the importance of the topic. The EFCCA team, together with Takeda, is currently preparing a poster that presents the concept of the survey as well as preliminary baseline characteristics of the respondents.

A more thorough analysis of the results of the survey follows later this year, giving exciting insights into the life of a Crohn's disease patient suffering from complex perianal fistulas.

ECCO UC Treatment Guidelines

Within the framework of our long-established cooperation with ECCO we are pleased to be participating in a project on the new Ulcerative Colitis (UC) Treatment Guidelines ensuring that the patient perspective is included in these guidelines.

Following a call for interest amongst our EFCCA members we have set up a group of six UC patient representatives who will form an integral part in the discussions and will vote on the most relevant questions to be addressed during guideline development, as well as participate in the discussion and voting around the most important outcomes to be considered in each area. The representatives are from the UK, Finland, Czech Republic, Poland, Iceland and Romania.

An initial kick-off meeting took place in Vienna on November 22-23,2019 which will shape the whole guideline development. We believe that involvement of patients in this project is important in making the guidelines relevant not just for clinicians but also for patients.

The project will run until 2021 when patient representatives will also be invited to attend the final consensus meeting where guideline statements will be discussed and voted on.

World IBD Day 2020

World IBD Day takes place on 19 May each year and unites people worldwide in their fight against Crohn's disease and ulcerative colitis, known as Inflammatory Bowel Disease (IBD). This year EFCCA will concentrate its efforts on theme of "Work and IBD" and will raise awareness around the impact IBD is having on a person's professional life.

Worldwide more than 10 million people live with IBD, the latest figures for Europe (2014) are 3.4 million. With IBD on the rise and mainly affecting young people of working age the impact the disease has on a person's professional life should be of great consideration for society at large and in particular to policy makers and employers.

Many people with IBD want to and are able to successfully work. Studies have shown that good quality work has a positive influence on overall wellbeing. It is therefore alarming that many people with IBD do not feel at ease to talk about their disease with their employers or colleagues and in previous studies carried out by EFCCA about 61% of patients felt stressed or pressured about taking time-off from work due to their IBD; 25% had received complaints or unfair comments and 21% had suffered direct discrimination.

Together with its members and international medical societies EFCCA wants to bring this topic to the European agenda and European policy makers as we believe that with some comprehensive strategies at the workplace, a better understanding of the disease in general and a supportive environment we can make IBD work!

We have created a compendium of available literature including valuable information, examples of good-practices and guidelines of some of our member associations that have already done some important work on this topic. You will also find some other toolkits such as visuals and an infographic. For more information please visit:
www.worldibdday.org

#makeIBDwork #IBDequality #worldibdday2020

Global campaign of highlighting buildings in purple

We will continue to collect and share information about patient association's efforts to raise IBD awareness by highlighting famous buildings and landmarks in purple. The World IBD Day Website will be updated as information is coming in. We will also share on our social media and will use the hashtag #worldibdday2020.

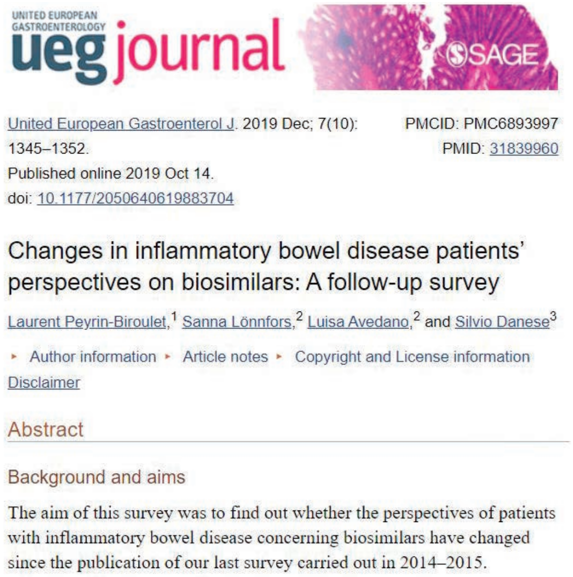
For more information: www.worldibdday.org

BAB2 – Article published!

EFCCA's Biologics and Biosimilars (BAB) survey (conducted in 2014-2015) showed that there were both insufficient awareness and lots of suspicions on biomisilars among IBD patients. A follow-up survey, BAB2, which included the original questionnaire as well as a couple of extra questions, was conducted from July to December 2018 with the purpose to find out whether patients' perceptions on biosimilars have changed since our previous survey. Participation was more active than in the original survey: over 1600 IBD patients completed the survey.

The manuscript, written by the research team and presenting the results of BAB2, has been published in the United European Gastroenterology (UEG) Journal on December 2019.

The article with the results of the BAB2 survey can be read in full text for free at:
www.ncbi.nlm.nih.gov/pmc/articles/PMC6893997



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PMID: 31839960

Changes in inflammatory bowel disease patients' perspectives on biosimilars: A follow-up survey

Laurent Peyrin-Biroulet,[1] Sanna Lönnfors,[2] Luisa Avedano,[2] and Silvio Danese[3]

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Abstract

Background and aims

The aim of this survey was to find out whether the perspectives of patients with inflammatory bowel disease concerning biosimilars have changed since the publication of our last survey carried out in 2014–2015.

The perceived impact of smoking on Inflammatory Bowel Disease

The negative health effects of smoking are well known and proved by research. In Inflammatory Bowel Diseases, however, research has shown an interesting difference: while smoking is associated with more severe disease, increased need for anti-inflammatory medication and early post-operative recurrence in Crohn's disease, studies suggest that in Ulcerative Colitis, smoking might decrease the risk of developing the disease and the progression of the disease.

As there is little patient-centered research assessing patients' perceived impact of smoking or using nicotine-containing products on their IBD, EFCCA is supporting a survey on the topic, sponsored by Philip Morris Products SA.

There are currently over 800 responses and the survey is still open for both Crohn's disease and Ulcerative Colitis patients - participate now at www.efcca.org!

Please note that the survey shall not be, in any circumstance, construed as suggesting cigarettes and/or nicotine-containing products as treatment methods. Please always discuss any questions or worries with your doctor.

Transitioning from child centered care to adult care

For many of us IBD is a part of a story that started when we were sometimes too young to understand the impact it will have on our lives. As we grow older the time will come when we have to leave the specialists and places that have helped us and our families to start this path. We move from child centered care to adult care where a new team of professionals will help us get the best treatments and quality of life we can expect.

This transition is a crucial time in our lives as IBD patients, it could determine our trust in medical specialists and our adherence to treatments. However, this process does not always go smoothly.

This is why we, as the EFCCA Youth Group, have decided to focus on this topic, with the aim of harmonizing the approach one can have of this crucial period.

For that purpose, our final goal will be to elaborate a website that could guide patients, their families and medical team to a smooth transition we all deserve.

> **"Your life is a story of transition. You are always leaving one chapter behind while moving to the next"**

It all started in 2017 when a global survey made by the Youth Group has been launched with our members and partners across Europe to map the needs of young patients with IBD going through the transition process.

During last European Youth Meeting (Brussels 2019), we organized a workshop to allow all the countries' delegates to bring their input and share their ideas about the main areas and key advice that need to be present in this future dedicated website.

We gathered great insight about how the topic was approached in different countries, example of good and bad practices and what was most valuable to their own experience.

After taking notice of all this material, we decided to divide our effort into three main categories based on the targeted population we want to reach: the patients, the medical team, and the relatives.

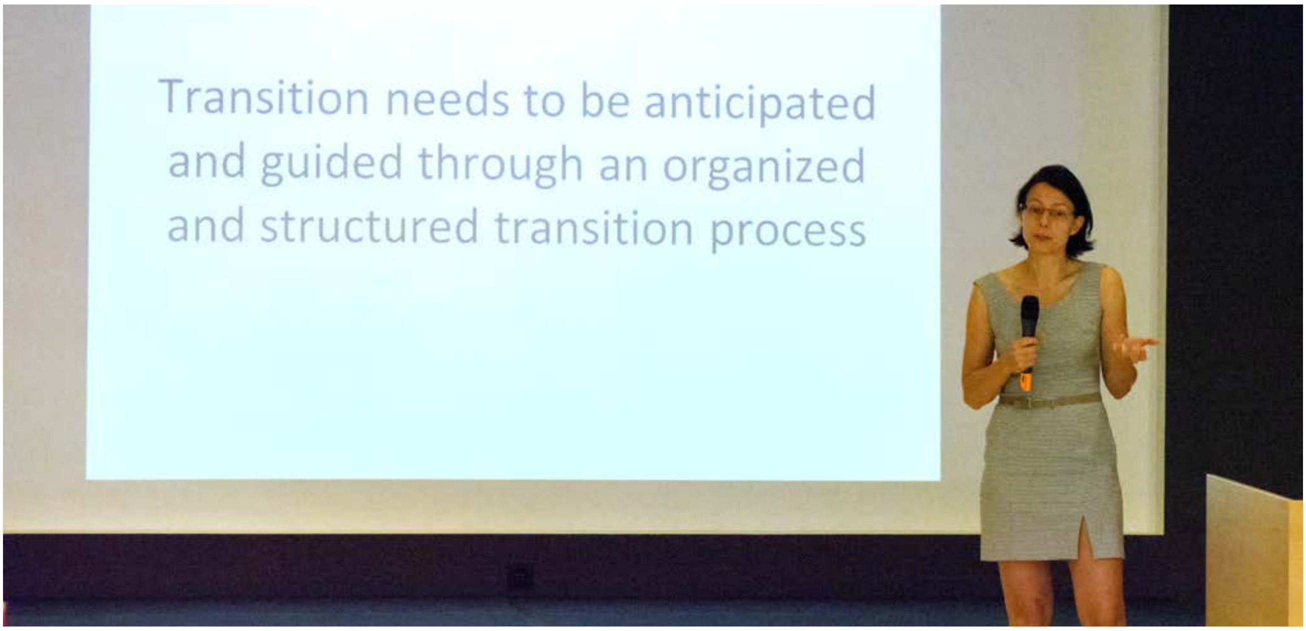
We figured that by compiling all the information about each actor of the transition process we could make a guide as complete as possible, because it is not only about the patient alone but about the whole environment around him.

Our intention for the future is to achieve the creation of the website by this summer so we can launch it publicly for the EYM 2020. Until then, we'll keep on working to help young patients with IBD all over Europe.

> **"We gathered great insight about how the topic was approached in different countries"**

Thank you for reading. If you may have any questions, or wish further information, feel free to contact us directly at: eyg@efcca.org.

The EFCCA Youth Group



Transition needs to be anticipated and guided through an organized and structured transition process

United Kingdom

New children’s book launched

Our new illustrated storybook and video animation will give children the knowledge and confidence to talk about Crohn’s and Colitis.

Meet our Crohn’s and Colitis Cats was designed in collaboration with people affected by Inflammatory Bowel Disease. The storybook is a perfect bedtime read, and the video animation is a useful tool for sharing with friends or raising awareness at schools and events.

The story is aimed at children aged 7-11, whether they have the conditions or know someone who does. It tells the story of Riley and stepdad Owen, who live with Crohn’s and Colitis.

You can personalise the printed book and decide whether Riley and Owen have either Crohn’s, Colitis or IBD Unclassified, depending on your own circumstances.

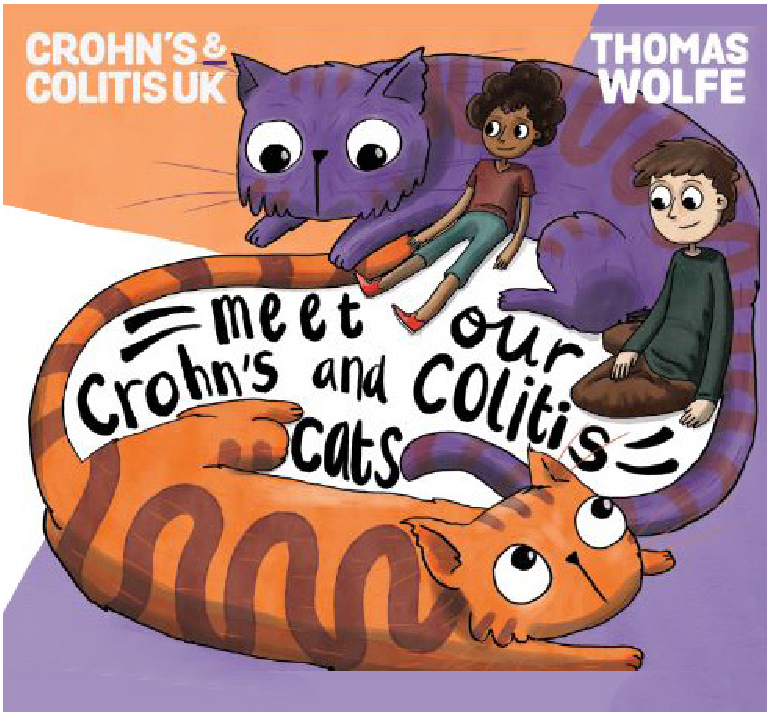
Our story makes the invisible visible by representing Owen and Riley’s conditions in the form of cats - sometimes they follow you around and bother you, and at other times they leave you alone. Riley and Owen always have to take care of their cats, but they’re only a small part of who they are. Challenging situations such as feeling different from friends and taking medicine are explored in a sensitive and friendly way.

Riley and Owen discover that, while it takes guts to live with a Crohn’s or Colitis cat, they can still achieve their dreams. The concepts and pictures were developed by author and illustrator Thomas Wolfe, who lives with Crohn’s.

Thomas says: “Creating the book with Crohn’s & Colitis UK has been an incredibly positive experience. I have enormous faith in their bottomless knowledge of these medical conditions, and in turn they put their faith in me to create a meaningful story. I hope that together we’ve achieved something that can help young people who are living with Crohn’s or Colitis.”

Jaina Engineer, Knowledge and Evidence Manager at Crohn’s & Colitis UK, says: “It takes guts for anyone to talk about Crohn’s and Colitis, but young people face specific challenges which we wanted to address. Meet our Crohn’s and Colitis Cats has the perfect mix of humour, education and compassion to make it the ideal tool to empower children to start their own conversations.

The book will help to break down the stigma surrounding Crohn’s and Colitis.”



UEG Week – World Class Scientific Research

Meet. Exchange. Evolve

ueg week

RAI Amsterdam, The Netherlands I October 10 – 14, 2020

Create your Talking Toolkit

Our Talking Toolkit is a brilliant resource to help you find the words to talk about living with Crohn’s and Colitis.

Part of the It Takes Guts campaign, the online toolkit provides you with all the information, talking tips and resources you need to start conversations with colleagues, friends and family about how the symptoms of Crohn’s and Colitis affect you every day.

Just answer five questions about how your condition affects you day to day, who you want to talk to, what stops you from talking, and what you’d like them to know, and the toolkit will create a printable series of statements and tips you can use to talk to the people in your life.

More than 1,500 people have already used the Toolkit. If you haven’t already created yours, visit the It Takes Guts website to give it a go. And keep an eye out for more It Takes Guts tools in 2020, because no one can see it till we say it.

Create your toolkit:
www.ittakesguts.org.uk/talk/talking-toolkit

New Standards Raise the Bar for IBD Care

The 2019 launch of the IBD (Inflammatory Bowel Disease) Standards, the IBD Patient Survey and the IBD Benchmarking Tool marked a momentous point in the journey of IBDUK since its inception in 2017 and is testimony to the hard work and commitment of 17 professional bodies and patient organisations to reach a consensus on “what good should look like” in IBD services. For more information about the standards and IBDUK, please visit https://ibduk.org/ and to read the IBD Standards in full take a look at the paper published in Frontline Gastroenterology - https://bit.ly/2TdUihr.

Rukshana Kapasi, Director of Crohn’s and Colitis UK is the Chair of IBDUK.

Quality improvement (QI) in IBD is not a new concept, with the IBD QI Programme, led by the Royal College of Physicians, running from the first IBD Audit in 2006 until 2016.

Yet, we know that despite a plethora of quality measures in IBD, there continues to be variation in practice with few realised improvements.

For the first time, services are now able to compare their assessment of their performance with how patients feel their service is performing against the same Standards. An incredible 88% of IBD services across the UK have registered for the IBD Benchmarking tool, which follows the patient journey from referral through to ongoing care and long-term management, and we are working with them to ensure as many as possible complete their self-assessments before the closing date of 31st January 2020. 10,220 patients, covering 99% of services in the UK, also completed the IBD Patient Survey, which ran from July to November 2019 - an incredible response, showing the motivation of the IBD community to improve care.

Patients and carers are the only people who experience the IBD pathway from beginning to end and their perspective on where improvements can be made provide a powerful and unique insight, particularly from a holistic perspective of the impact of IBD on their lives.

What next? Reports on individual service performance will be published in March 2020 and available on the IBD UK website, followed by a national report in May 2020. A programme of QI seminars involving IBD service teams from across the UK is in the pipeline, together with a toolkit of resources to support services develop and implement QI plans. This is only the start, however, of a rolling programme that will include annual IBD Patient Surveys and biennial service self-assessments - QI being a truly continual process. Together, we can drive up the quality of IBD services to improve the experience and outcomes for patients.

For more information have a listen to our podcast https://bit.ly/39Vo7sI.

For further information about this work please contact Amit Parekh at info@ibduk.org

Austria

35th Anniversary of ÖMCCV
1st Anniversary of the CED (IBD) - Compass

In 2019 we celebrated two important anniversaries: 35 years of our Austrian IBD Patient Association ÖMCCV and one year of the CED - Kompass (IBD - Compass) project.

Our association is looking back at 35 years of work for patients with IBD. A small group of persons - knowing each other from hospital stays at the Vienna university hospital - laid the foundation for an Austrian IBD-group. In October 1984 ÖMCCV held its constitution meeting bringing together 60 people. All of them - including myself - were wondering how to raise more awareness about Inflammatory Bowel Diseases which at that time seemed to be something very exotic.

Establishing contacts with other affected persons all over the country, looking for doctors to hold lectures or writing specialist articles for our journal, finding experts on tax law or employment law, raising awareness of our invisible disease were some of the challenges we were facing as probably many of you know yourself quite well!

Starting with our first General Assembly we initiated plans for a magazine, calling it “Crohnicle” - referring to Crohn’s disease. Quite a lot of different initiatives and activities followed through the years, sometimes implemented only with a small group of volunteers, who often struggled themselves with their disease.

But our mission was to provide a valuable life for patients with IBD and to show them how to cope with this difficult disease.

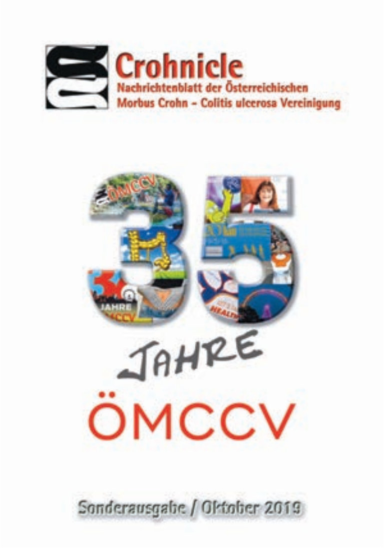
For 25 years I worked hard to realize these aims together with others within our association. Then, for personal reasons, I took a break with my work as secretary of the Austrian association and am happy to have returned for the 35th anniversary of the ÖMCCV with the responsibility of the editorial of our magazine.

Well, just in time I succeeded to issue a special edition for our anniversary together with a bookmark as a gift.

Many physicians whom I knew from former years provided top reports about IBD that were included in the medical information part of our magazine.

Starting with a contribution explaining the beginnings with Burrill Crohn's study in 1932, which described the disease and inflammation of the last part of the small intestine.

Then showing with further abstracts of top Austrian physicians the development in better diagnosis and understanding the mechanism of the diseases, the development of therapy and effective way of medication through more than 30 years, explaining different kinds of operations, the development of analytical devices as well as describing psychosomatic aspects of IBD.



Crohnicle
Nachrichtenblatt der Österreichischen
Morbus Crohn - Colitis ulcerosa Vereinigung

35
JAHRE
ÖMCCV

Sonderausgabe / Oktober 2019

Trying to demonstrate and describe all the different projects and events of our association in this special magazine within the last 35 years, I was astonished how long the list grew, although I had been part of the team through decades.
There were initiatives such as the Crohn's friendly place (in shops for access to toilet), the solidarity card (for quicker toilet access), flywithIBD, medical passport, charity toilet race, the campaign "shit happens", the campaign "compass through the fire", body checks, emergency package, research funding price, attending open days in hospitals and organizing health days, lecture, events and talk, creating brochure and videos/CDs, leading special groups (children and youngsters, pouch, stoma), a lot of press conferences, workshops, national and international meetings, attending congresses, but also organizing rafting tours, beach volleyball-games, hikes, week-end meetings, cooking events and so on.

And not to be forgotten the World-IBD-Day 2019 with the big purple human loop: about 300 persons with purple shirts stood side by side forming a huge purple ribbon!

This event was proceeded by a press-conference together with a football-player and the captain of the football-team of the club "Austria FC", who supported with their publicity the awareness of our invisible diseases.

A videoclip presented invisible problems with IBD - formulated by a physician of the Austrian University, Univ.-Prof. DI Dr. Vogelsang, the captain of Austria FC, two affected IBD-persons and the president of our association, Evelyn Groß.
This campaign ran the mission #youarenotalone.

Well, sometimes it seems to be good to pause and look back on to your work as it motivates yourself again and opens the horizon for further aims. That break and looking back happened with the special-edition magazine!
This brings us to the second anniversary of the past year - the newest initiative of the ÖMCCV: in May 2019 the patient service of the "CED (=IBD) - Compass" celebrated its first year of existence.

This information portal together with CED-Nursing Austria, ÖMCCV and the support of the agency FineFacts offers a unique helpline.

This telephone hotline can be called during 10 hours a week (times can be consulted on our website or on a specific app) and callers will be attended by an IBD nurses answering questions about IBD.

The second service "CED Compass" offers is an information channel - telegram - informing about scientific news, events and activities being retrievable on smartphones or tablets.

Thirdly, questions around nutrition, leisure, work and anything else around IBD will be answered by IBD-nurses by email within 48 hours. And last but not least the CED - Compass Newsletter.

So, we hope to continue our support for people with IBD through national initiatives on all levels and to help them cope with their life as best as possible as well as participating in the international exchange of new ideas and aims for a better quality of life despite chronic disease.

Christine Gmeinder
ÖMCCV - Editorial "Crohnicle"
Austrian Crohn's Colitis Association

Lithuania

Improving the well-being of people with IBD

The Crohn‘s and Colitis Association of Lithuania (CCAL) has organised a number of activities in 2019 with the aim to improve the well-being of people with IBD and help them to better cope with the disease.

One such activity has been promoting Patient Doctor dialogue. We held face to face meetings in our capital Vilnius as well as in Kaunas, the second largest city. During these events we invited patients and medical specialists to present the main clinical challenges to fight IBD. A dietitian provided some general information that IBD patients could follow to feel better and avoid some worsening of their symptoms and more specifically information of how individual foods can affect the intestines and our general well-being.

This was complemented by presentations from gastroenterologists that highlighted the importance of microbiota in gut health and how this is changed in IBD. Other important questions that doctors answered during these meetings and that were previously collected by CCAL dealt with questions such as: traveling with IBD, vaccinations, medicine during pregnancy, sports and disability, complications in IBD. The sheer amount of questions shows us the importance of supporting such events and providing people with correct and valuable information. Our second main activity was the organisation of a summer camp which took place in August of 2019.

It has now become a tradition to travel among different regions of Lithuania. The summer camps are highly popular and include for main elements as follows:

- **Physical activity**: 21 km was cycling race
- **Education**: with the support of psychologist we provided outdoor lessons on the mindfulness technique followed by several social games open to all participants
- **Discussions**: the summer camp provide a great opportunity not only for patients but also their family members to discuss IBD challengers and issues
- **Cognitive activity**: we visited a professional horse tournament, where everybody admired these beautiful animals and their acrobatic jumps.

We look forward to another busy year in 2020 and will keep you posted!

Romania

A lesson of will, power and courage

Our association ASPIIR was very happy to welcome Fanny and Jerome, a French couple and founders of "The Green Journey of IBD" project. In June 2019 they started their journey by bicycle leaving Strasbourg (France) travelling through eleven countries and arriving in Romania by the beginning of August 2019.

The purpose of "The Green Journey of IBD" project includes several goals that reflect the personalities, life experiences and values of this French couple: to explore other parts of the world., to travel in a friendly, environmental way (for example without airplanes) and to raise awareness around IBD.

Why this particular goal about IBDI? In January 2014, Jerome was diagnosed with IBD. After six months with a stoma, Jerome's digestive system was reconnected but without a colon or rectum.

Through their co-partnership with the French IBD associations Afa RCH France Fanny and Jerome would like to promote communication about IBD conditions, the transmission of a positive message to people affected by IBD and to collect useful information about toilets on their cycle route.

We first met Jerome and Fanny in Calarasi, on August 4, before they crossed the Danube, towards Dobrogea and Constanța.

I learned more about their story and found that living with IBD didn't stop Jerome from pursuing his dream. For eight years, after finishing university the two of them put all their savings into one account to make this trip possible.

And then came Jerome's diagnosis. Being diagnosed with IBD and surgery could scare many people or worse, make them withdraw or isolate themselves from social interactions.

But Jerome had the courage not to give up on their dream, on the contrary, he added another goal to his dream: to make this journey also about raising awareness about IBD and life with a stoma.

And you know what? During their cycling tour they slept in a tent, set up in campsites or in the courtyard of any monastery, or in other accommodation offered by people supporting their campaign. Have you ever considered going on such a journey, having IBD or a stoma? For sure many are frightened by this thought. And yet... it completely depends on us.

After 3000 km traveled by bicycles, the two brave young people visited the Danube Delta, preferring the rowing boat over the noise motor boats for exploring the canals. Arriving in Bucharest, Hans and Andreea were their hosts during their stay in the capital where they were acquainted with the Romanian culinary specialties and later we visited together the ASPIIR information point at the Fundeni Clinical Institute.

The visit to the ICFundeni was also organised for a specific reason: sometimes travelling doesn't go according to plan! the efforts of pedaling 3000 km meant that Jerome had a suspected hernia in the peristomal area.

Therefore Jerome's first contact with the Romanian medical assistance came through the appreciable support of the assistant Mrs. Georgeta Păsărin and with the admirable kindness of Dr. Silviu Ciurea, from the Clinic of Liver Surgery and I.C.Fundeni.

And the medical "adventure" of our young man did not end here. Two days later a perianal abscess gave him a headache. He was amazed and grateful to be seen again by Dr. Ciurea who was actually on leave at that time.

We do not know how the journey of the two French youths will continue, if it reaches the planned end in South East Asia, if changes will occur, if IBD will put some obstacles but looking only at the 3000 km covered by bicycles to Romania, we know for sure it is a lesson of will, power and courage.

And some questions arise following the story of Jerome and Fanny: how many of us, patients with Crohn's or ulcerative colitis, would go on a trip around the world, obviously needing the presence of a toilet a little more often than usual?
How many of us, patients with stoma, would go on a year-long trip or even more, camping in tents or campsites or not so sanitary conditions? The answer and the change are in each of us. And maybe something should change in us. You can find more about their trip in the following links:
www.myatlas.com/LevoyagevertdeMICI
www.facebook.com/levoyagevertdemici

Isabella Grosu, ASPIIR

Israel

Physicians & Patients taking action IBD Academy November, 2019

The Israel Foundation for Crohn's Disease and Ulcerative Colitis (CCFI)

Israel Association of Gastroenterology (IGA)

IBD Academy (Started on November 1), created by physicians, dedicated to take doctor-patient communication to the next level by introducing knowledge to patients - inside an academy facility.

Introduction

One of the major challenges in the management of chronic and life-long conditions such and Crohn"s disease and ulcerative colitis is the promotion and enhancement of patient engagement. Patient education and increase of patient"s knowledge of their condition is crucial in establishing a fruitful and effective communication with healthcare providers, leading to improvement of trust and collaboration, improved compliance with treatment and follow-up and ability to take better and more informed treatment decisions. Although there is an abundance of patient-targeted resources online, those are not always objective and bias-free; moreover, direct and immediate feedback form the source is not available for most online resources.

The main purpose of the Israeli IBD patient academy, established by the Israel Association of Gastroenterology (IGA) together with the Israel Foundation for Crohn's Disease and Ulcerative Colitis (CCFI), was to overcome the patient knowledge gaps by creating a series of frontal learning sessions with clear and structured syllabus and learning objectives. The syllabus was compiled and curated by Prof Uri Kopylov, Head of the IBD service of Chaim Sheba Medical Center in Ramat Gan. The sessions are delivered by a group of experienced IBD physicians from different IBD centers in the country, together with other members of multidisciplinary IBD teams including nutritionists, psychologists, integrative medicine specialists and more.

Following the frontal sessions, the entire content is available online for free for all members of the Israeli IBD community.

Objectives

The goals of the IBD Academy are:

- Allow patients access knowledge directly from source
- Creation of a core knowledge set for an IBD patient to enhance engagement and decision-making and improve Health Care Professionals HCP communication
- Patient empowerment and engagement to take action regarding their treatment & quality of life (QOL)
- Breach of patient-HCP barriers

Organization (timeline)

The IBD Academy started on November 1 2019

- Sessions are taking place once a month
- Academic structure (academic environment, semester blocks, commitment to an entire semester, participant certificates)
- Each session includes several lectures.
- Each lecture tackles a different aspect of treatment, such as:
    - About IBD
    - Treatments
    - Surgical options
    - Nutrition
    - Complimentary medicine
    - Managing your disease

Outcome

IBD Academy is an on-going program & still taking place. Patients who took part in IBD Academy sessions describe:

- Getting a lot of information, previously not known to them
- Information helped patients decide better regarding different treatments
- Patients asked questions they never had the chance to ask
- Many stigmas about medical teams turned out to be wrong

Prof. Uri Kopylov, MD, Head of IBD Service;

Department of Gastroenterology, Sheba Medical Center, Ramat Gan, Israel;

IBD Academy, opening session, November 1, 2019 09:00

Adam Elgressy, Patient experience leader, The Israel Crohn's Disease and Ulcerative Colitis Foundation - CCFI;

Eyal Tzur - Chairman, The Israel Crohn's Disease and Ulcerative Colitis Foundation - CCFI.

Greece

Vasilopita

One of the most beautiful and inspirational traditions of the Greek Orthodox Church is the annual family celebration of the Vasilopita. This original event which happened in Cappadocia of Caesarea in the last half of the fourth century a.d., is very much alive in Greece's Orthodox homes each year.

The Greek word Vasilopita is directly translated as "Bread of Basil". When the Vasilopita is prepared, a coin (called flouri) is baked into the ingredients. Sweet flavouring is added to the bread which symbolize the sweetness and joy of life everlasting.

It also symbolizes the hope that the New Year will be filled with the sweetness of life, liberty, health, and happiness for all who participate in the Vasilopita Observance. When the observance begins, usually but not exclusively, on New Year's Day, the bread is traditionally cut by the senior member of the family, and the individual who receives the portion of the Pita which contains the coin is considered Blessed for the New Year.

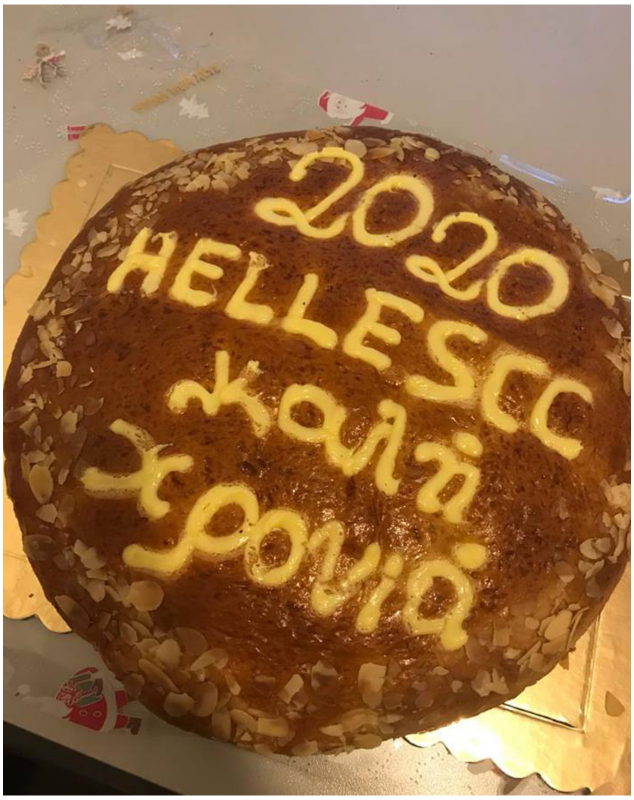
The pieces of the Vasilopita are divided as follows: the first piece (in religious families) is offered to Jesus Christ, one piece is for the "home", one for the "poor" and the other pieces go to the family members.
They are some variations of this in recent years, depending on the interests of those involved in cutting it.
This age-old tradition commenced in the fourth century a.d., when Saint Basil the Great, who was a bishop, wanted to distribute money to the poor in his Diocese.

He wanted to preserve their dignity, so as not to look like charity, he commissioned some women to bake sweetened bread, in which he arranged to place gold coins. Thus the families in cutting the bread to nourish themselves, were pleasantly surprised to find the coins. The Vasilopita is a beautiful tradition and is such a wonderful way to begin each New Year.

In modern days, schools, companies and various organisations keep the tradition of cutting the Vasilopita throughout Greece. Honouring this old custom, HELLESCC members gather and cut this bread each year in many Greek cities wishing each other and all patients with IBD a Happy New Year full of health and happiness.

We hope this story has inspired you all to follow this old tradition, too.

Alexandra Gliati, HELLESC



Spain

All about clinical trials

ACCU Spain encourage patient participation in the different areas of our health system including research. This is the reason why on the weekend of 25 and 26 October 2019, representatives from ACCU Catalunya, ACCU Madrid and ACCU Granada participated in a EUPATI Spain workshop to improve their knowledge in the field of clinical research.

The workshop covered a wide range of information such as the importance of patient participation in the trial design since the early stages of the trials, how to improve the patient recruitment process and many other subjects. In summary, a good training covering the main points necessary in order to achieve a better research that respond to people's real needs.

Portugal

APDI Workshop on IBD and the National Healthcare System

Our IBD patient association APDI organized its 3rd workshop under the name ‘Being a chronically ill patient in Portugal: IBD and the National Healthcare System’ which was attended by 30 people including healthcare professionals and people with IBD.

In the year in which our National Healthcare Service commemorates its 40th anniversary, APDI its 25th and with over 20 thousand people in Portugal living with IBD, our association has launched a debate about what it is like to be a chronically ill patient with IBD in Portugal. We tried to obtain, through dialogue, answers to daily question we get at APDI: regarding the pros and cons of biologic therapy; daily problems in the healthcare service of people with IBD due to the evolving nature and complications of the disease itself and also the financial overload that people with IBD have to deal with despite support from the National Healthcare Service.

The conclusions were very interesting and have already been presented to decision makers.

A family celebration

Our association APDI was born 25 years ago on the initiative of patients, doctors and other partners who wanted to help everyone who had or would eventually have Crohn’s disease or Ulcerative Colitis.

25 years later and a lot of changes, both social, political and economic, APDIs’ spirit stands strong: we were born as a family, we grew as a family, and as a family we hope to remain in the future.

Throughout our lifetime we’ve had a lot of people who supported both our growth and evolution. From PhD Tavarela Veloso to João Galrito and Álvaro Coelho, to other distinguished personalities who still remain with us to this day and those who have only recently joined or are yet to join APDI.

We can surely say that you have all contributed and will keep on contributing so that our path is created consistently with certainty and determination.

We have come a long way since our beginning, when our board members contributed with what they could to help both the day-to-day activities in the association and to make more for the people with IBD.

We were on the first line of every battle that needed waging, be that enlightening peoples’ beliefs about the disease itself or standing our ground to politicians and numerous governments year after year for the subsidization of healthcare costs associated with IBD, such as drugs and medical exams.

We will remain vigilant and present on every front we deem important and determinant so that people with IBD stay properly informed about where, how, why and when to treat for their respective disease.
New battles are ahead of us to continue the fight on IBD illiteracy and make more and better for everyone in APDI.

Transparency and credibility have been present since our birth, and are what we're known for and makes us a family. We wish to continue guiding our work on these principles.
Happy birthday APDI family and here's to the next 25 years.

Cândida Cruz,
Vice-President APDI

Czech Republic

Therapeutic group for patients with IBD

Are you feeling alone? Is your life with chronic disease more than you can handle? Patients support groups are very important because chronic diseases don't go away and people suffering from Crohn disease or ulcerative colitis need to deal with them for the rest of their lives. It is very exhausting and mental state often influence physical state as well.

Our organization Pacienti IBD in the Czech Republic has put together a group of patients of different ages and gender who were keen to help each other and under the surveillance of a professional psychologist deal with their issues.
The Therapeutic group meet every other week for two hours. It is a safe place where patients can talk not only about their disease related issues but also about their daily struggle, relationships, work stuff etc.
Psychologist Mgr. Martina Hazuková leading the sessions shows effective methods of dealing with stress, anxiety and how to accept yourselves and handle all complications. Because it all starts in your brain.

Lucie Lastikova, Pacienti IBD

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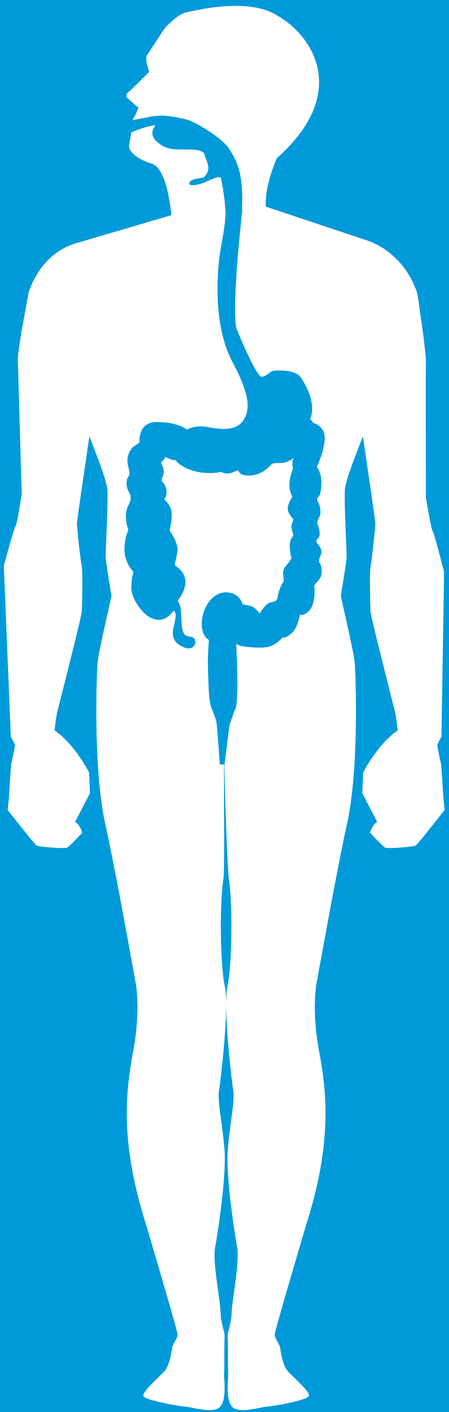

TOMORROW

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I was at a bike race

By Cory Greenberg

“I was at a bike race”, is a sentence which has come to define my journey in a sport for over half my life. An identity wrapped in a sport that started simply as a childhood hobby, and eventually led to a professional racing career which has taken me around the world. So many things in my life have transpired at bike races. A journey full of laughter, hardships, successes, you name it I have experienced it in some way shape or form at a bike race. So in a way, it is somewhat fitting that my first experience with IBD was also at a bike race.

When I tell people I am a professional cyclist, it often times sparks up that same few questions that I have heard for so many years. But, when people hear that I have Ulcerative Colitis, and that I have competed successfully for the last eight years in cycling while managing my IBD, it leads to not only questions but personal stories of IBD. Stories of how IBD affects a loved one or a friend. Stories of personal struggles filled with the many battles that people have faced in their IBD journey. It is in these moments when I share I have IBD that I get the most out of people and hear the hardships that IBD has caused them or someone around them.

My journey with IBD began some eight years ago when I was hospitalized from Ulcerative Colitis. It was a moment in time that put my life and career on hold. In a blink of an eye, I went from fighting to win bike races, to fighting for my health. Before my diagnoses, I had very little knowledge of IBD.

How to treat or care for the condition was never a thought, until I was forced to make it a priority in my life.

After my hospitalization I vowed that I would do everything in my power to overcome IBD and continue against the odds to become a professional cyclist. When I left the hospital some eight years ago, I set out to learn everything I could to educate myself on my disease. I attacked it like I would attack a bike race, preparing myself the best I could to achieve my new finish line of remission.

Now eight years later after laying in that hospital bed unsure of my future, I have been able to achieve remission and my goal of reaching professional cycling. It has not been an easy road trying to compete with IBD around the globe, but with hard work and great support from those around me, I have made my dreams come true. So now, after many years battling the hardships on the racecourse, I have turned my attention to using cycling as a way to support those with IBD by merging professional cycling and IBD awareness together.

A merger of two worlds that brings the hope, education and inspiration that the IBD community desperately needs through the global impact of professional cycling events.

I have found over the years that IBD is a condition that often needs a catalyst to bring awareness to the disease. For me, cycling has become that catalyst. Races have become venues for me to share my story, meet others with IBD, and spread IBD awareness through the many media outlets that cycling offers. But for many people with IBD, it is often a hard conversation that most are not comfortable talking about as the embarrassment can be too much.

It's a condition that unlike other illnesses is often times not outwardly seen, nor is pleasant to talk about due to the nature of what transpires often times behind bathroom doors. It is a condition that has struggled to grab the attention of the general public, leading to the lack of knowledge on what IBD patients are facing.

Most often times though, once the topic of IBD is brought up, it tends to lead to some incredible stories of what people have experienced with their IBD journey and opening a dialog between patient and those that can make a true impact on the disease.

By bringing IBD and cycling together, it is my hope that we can increase the global awareness of IBD and finally create the change needed to make this disease finally a thing of the past.

You can follow Cory on Twitter @corygreenberg
and Instagram @corymike23

New European Commissioner for Health

Stella Kyriakides has been appointed as new European Commissioner for Health and Food Safety starting on 1 December 2019. Previously she served as the first Cypriot national and third woman as President of the Parliamentary Assembly of the Council of Europe.

During her introductory speech at the European Parliament hearing of the Environment, Public Health and Food Safety Committee, Ms Kyriakides said that the environmental and demographic changes faced by European societies can be dealt with only through a “one health” approach, placing good health and healthy food under a single policy umbrella. Her priorities include the new “farm to fork” strategy to improve food safety, action against antimicrobial resistance, and making sure that a steady stream of affordable medicines is made available to citizens.

Her appointment has been welcomed by many patient advocacy groups and we hope that her personal experience as breast cancer patient and knowledge as patient advocate will ensure that the patient perspective will form part of a wider strategy to ensure that health is placed at the center of the Commission’s agenda.

Canada - IBD Impact Report

Crohn’s and Colitis Canada has published the *Impact of IBD in Canada Report* which describes the nationwide burden of IBD and what governments and healthcare institutions must brace for.

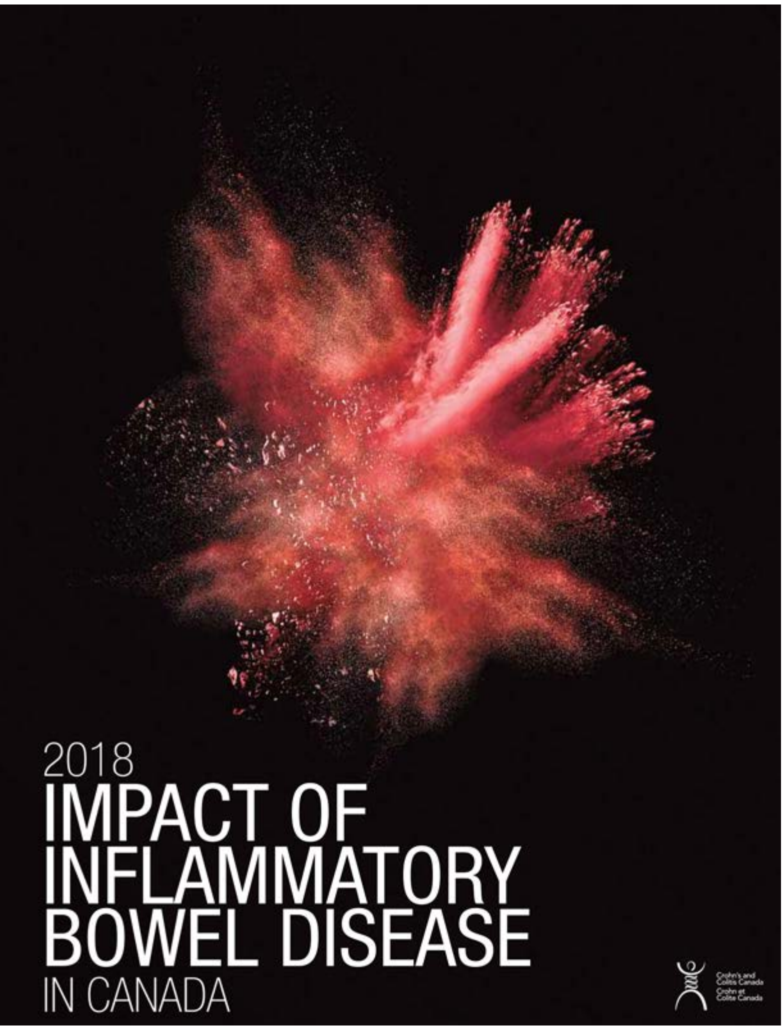
Crohn’s and Colitis Canada has published the Impact of IBD in Canada Report which describes the nationwide burden of IBD and what governments and healthcare institutions must brace for.

IBD affects 270,000 Canadians today and will affect 400,000 by 2030 - a full 1 percent of the population. The cost of caring for them, which currently sits at $2.6 billion a year, will grow in step with that trend. And there are gaps in that care: rural areas face a scarcity of gastroenterologists to expertly manage IBD. Crohn’s disease and ulcerative colitis impact Canadians at opposite ends of the age spectrum: while older adults are the fastest growing group of patients, children are the fastest growing group for new diagnoses.

This report not only explores the impact of IBD on Canadians and key scientific gaps in knowledge, but demands we hold vital conversations about the future. With IBD clinics already stressed by the volume of patients, how will they manage such a surge in demand? How can telemedicine or other new technologies and models of care provide more patients with access to specialists? How can we bring expensive biologic therapies, vastly superior to older drugs, to those who need them?

The number of Canadian children with IBD has climbed 50 percent in just 10 years. Dr. Eric Benchimol, pediatric gastroenterologist and epidemiologist at the Children's Hospital of Eastern Ontario (CHEO) and University of Ottawa, says we are identifying it earlier thanks to newer technology; additionally, the medical community has greater recognition that this is a pediatric disease and doctors are more willing to order endoscopies and MRIs to identify Crohn's and colitis in youngsters. However, the reasons for this rising rate in children remain unknown.

"Everywhere in the Western world, rates of new diagnoses among adults are stable but rates among children are spiking," says Dr. Benchimol, co-author of the Impact of IBD in Canada report. "This alarming trend is a call for us to investigate early-life environmental risk factors and other underlying causes of IBD."



Meanwhile, the cohort of older adults is rising along with the demand for IBD treatment, fueled by Canadians diagnosed in their teens and twenties who have reached retirement age. In less than two decades, boomers will elevate Canada's senior population to 9.5 million (23 percent of the country) from about 6 million seniors in 2016.

"We face the significant challenge of contending with age-related comorbidities such as type 2 diabetes and cancer," says Dr. Gilaad Kaplan, gastroenterologist and epidemiologist at the University of Calgary and co-author of the report.

Managing IBD is difficult on its own, but decisions are far more complex when balancing the medical management of other conditions. The Impact of IBD in Canada report is a crucial instrument as we face the challenges to come posed by these diseases.

To policymakers, it illustrates the science behind Crohn's and colitis specific to Canada. To scientists, it shines light on any gaps in research that might exist.

"Ultimately," says Dr. Benchimol, "this report asks: what are we going to have to do in the future to make a difference?"

To read the full report please go to:
https://crohnsandcolitis.ca

The potential of big data for public health in the EU

The joint Big Data Task Force of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have published a report in which they propose ten priority actions for the European medicines regulatory network to evolve its approach to data use and evidence generation, in order to maximise best use of big data to support innovation and public health.

The joint Big Data Task Force of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have published a report in which they propose ten priority actions for the European medicines regulatory network to evolve its approach to data use and evidence generation, in order to maximise best use of big data to support innovation and public health.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices, electronic health records, clinical trials or spontaneous adverse reaction reports. Coupled to rapidly developing technology, big data can complement the evidence from clinical trials and fill knowledge gaps on a medicine, and help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems. The rapidly changing data landscape forces regulators to evolve and change the way they access, manage and analyse data and to keep pace with the rapid advances in science and technology.

“I look forward to working with the European Commission and national competent authorities to see how these concrete proposals can be implemented to better harness the potential of big data. This will help to further strengthen the robustness and quality of the evidence upon which we take decisions on medicines,” said Guido Rasi, EMA’s Executive Director.

“The changes proposed will require investment to build up capacity and skills at national and EU level. This is needed if we want to establish the EU network as a reference for data-driven decision-making,” said Thomas Senderovitz, Chair of the HMA Management Group.

The report makes several recommendations out of which ten are viewed as priorities. The most ambitious of these top ten recommendations is the establishment of an EU platform to access and analyse healthcare data from across the European Union (Data Analysis and Real World Interrogation Network, or DARWIN). This platform would create a European network of databases of verified quality and content with the highest levels of data security.

The report also emphasises the need to ensure data are managed and analysed within a secure and ethical governance framework, and in active dialogue with key EU stakeholders including patients, healthcare professionals, industry, health technology assessment bodies (HTAs), payers, device regulators and technology companies. All these activities should be done in collaboration with international initiatives on big data.

For more information: https://www.ema.europa.eu/en

the
MELODY
Trial

Modulating **E**arly **L**ife Micr**O**biome through **D**ietary Intervention in Pregnanc**Y**

A Dietary Intervention to Improve the Microbiome Composition of Pregnant Women with Crohn's Disease and Their Offspring

Inga Peter[1,2] • Ana Maldonado[3] • Caroline Eisele[1] • Christine Frisard[4] • Shauna Simpson[4] • Nilendra Nair[1,5] • Alexa Rendon[1] • Kelly Hawkins[1] • Caitlin Cawley[3] • Anketse Debebe[1] • Leonid Tarassishin[1] • Sierra White[1] • Marla Dubinsky[6,7] • Joanne Stone[8] • Jose C. Clemente[1,2,9] • Joao Sabino[1,6,10] • Joana Torres[6,11] • Jianzhong Hu[1] • Jean-Frederic Colombel[6] • Barbara Olendzki[4]

[1]Department of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai, New York City, New York, USA; [2]Institute for Data Science and Genomic Technology, Icahn School of Medicine at Mount Sinai, New York City, New York, USA; [3]Department of Microbiology and Physiology Systems, University of Massachusetts Medical School, Worcester, MA, USA; [4]Department of Population and Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA, USA; [5]Department of Nutrition, Harvard T.H. Chan School of Public Health, Boston, MA, USA; [6]Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York City, New York, US; [7]Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York City, New York, USA; [8]Department of Obstetrics, Gynecology and Reproductive Science, Icahn School of Medicine at Mount Sinai, New York City, New York, USA; [9]The Precision Immunology Institute, Icahn School of Medicine at Mount Sinai, New York City, New York, USA; [10]Department of Gastroenterology, University Hospitals of Leuven, Leuven, Belgium; [11]Division of Gastroenterology, Hospital Beatriz Ângelo, Loures, Portugal

Research teams at the Icahn School of Medicine at Mount Sinai in New York, New York and the University of Massachusetts Medical School in Worcester, MA have recently launched a new clinical trial called the MELODY Trial: Modulating Early Life Microbiome through Dietary Intervention in Pregnancy.

Background

Crohn's disease (CD), a type of inflammatory bowel disease (IBD), is a chronic condition of the gastrointestinal tract. The composition of the gut microbiota is thought to play a role in the development of IBD, and the gut microbiota is impacted by diet. Additionally, diet may be effective in the treatment of IBD.[1-4] Maternal diagnosis of IBD has been identified as the greatest risk factor for IBD in offspring.[5-7]

Our group has shown in a previous study that babies born to mothers with IBD have reduced gut bacterial diversity, which is a known characteristic of IBD patients.[8]
There is accumulating evidence that the colonization of the gut microbiota during early life is affected by the child's mother's diet during her third trimester of pregnancy.[9]

Given this information, we aim to prevent transmission of IBD in a high-risk group of individuals, babies born to mothers with IBD, by altering their mother's diet and therefore gut microbiota during the last trimester of their pregnancy.

Goal

The trial will implement a diet intervention followed during the third trimester of pregnancy by women with Crohn's disease.

We hope to show that the diet can beneficially shift the microbiome in pregnant women with Crohn's disease, thereby decreasing their risk of disease relapse after giving birth.

We also hope to show that the diet can improve their offspring's microbiome during early life, thereby supporting development of a strong, effective immune system during the critical window of immune system development in early life.

The Intervention

The diet intervention we are using is the IBD Anti-Inflammatory Diet, or IBD-AID, which was designed by the study team at the University of Massachusetts Medical School.

The IBD-AID is derived from the Specific Carbohydrate diet and modified with current research on the human microbiome.

This diet helps to restore balance between helpful and harmful bacteria in the gut while promoting good nutrition. The IBD-AID consists of four pillars or guiding principles:

1. **Inclusion of Probiotic foods** (fermented foods that have live bacteria within them, such as yogurt, kefir, kimchi, miso, and fermented vegetables);

2. **Inclusion of Prebiotic foods** (foods that feed and maintain beneficial intestinal bacteria, such as steel-cut oats, bananas, artichokes, leeks, and asparagus);

3. **Avoidance** of certain carbohydrates that are pro-inflammatory and may disturb the healthy gut flora (lactose, wheat, refined sugar, trans fats and corn);

4. **Good overall nutrition** (a variety of fruit and vegetables, lean proteins, healthy fats, and lots of water). For detailed information on the IBD-AID™, including foods, recipes, and phases, please visit: www.umassmed.edu/nutrition/ibd/ibdaid

The diet is adapted to address specific needs of third trimester pregnancy without compromising the IBD-AID™ principles.

Participants following the diet will receive detailed instructions and counseling throughout the intervention period from trained dietitians about how to adapt their lifestyle, shopping, and eating habits to align with the IBD-AID principles.

Study Design

The study is a non-randomized trial including three arms: 1. Pregnant CD patients counseled and following the IBD-AID™, 2. Pregnant CD patients following their habitual diet, and 3. Pregnant healthy women following their habitual diet.

CD patients may choose whether or not they participate in the diet intervention. Biospecimen collection includes maternal stool and saliva at baseline (27-29 weeks gestation), at 35 weeks gestation, and at 37 weeks gestation, as well as at 6 and 12 months postpartum.

Babies' stool samples include the meconium, the first stool discharge following birth, and diapers collected periodically throughout the first year of life.
Breast milk is also collected if mothers are breastfeeding their baby. Umbilical cord blood is collected following delivery by a healthcare provider.

Detailed assessment of diet in all three arms of participants will be conducted through weekly online surveys and through completion of phone calls with trained dietitians. This will also allow us to monitor compliance to the diet intervention.

The primary study outcomes include changes in the maternal microbiome between baseline and the time of completion of the IBD-AID™, and differences in the maternal and infant microbiome between intervention and control groups.

Our goal is to recruit 198 mother-baby pairs; 66 CD patients self-selected to IBD-AIDTM, 66 CD patients self-selected to habitual diet, and 66 unaffected controls on habitual diet with no intervention. Participants must be living in the continental United States to be eligible.

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