Government of South Australia
Health
Central Adelaide Local Health Network

Royal Adelaide Hospital
Queen Elizabeth Hospital

Inflammatory bowel disease newsletter

May 2021

CALHN Inflammatory Bowel Disease Newsletter

2nd Quarter 2021

Introduction

Greetings to you all from the IBD services of Royal Adelaide Hospital and The Queen Elizabeth Hospital.
We are aiming to send you joint newsletters quarterly from our network (CALHN – Central Adelaide Local Health Network), and here is our first for the year.

The aim of the newsletter is to:

- Introduce you to new staff
- Let you know about any changes to clinical service delivery
- Provide some education about different aspects of IBD
- Let you know about research we are undertaking
- Highlight certain hot topics in IBD
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We hope you enjoy this newsletter and welcome any ideas for future topics you would like to have discussed.

Kate Lynch, Rob Bryant, and the RAH and TQEH IBD teams

Royal Adelaide Hospital

TQEH Inflammatory Bowel Disease Service

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Welcomes and farewells to new and departing staff

Ms Kreuch

Royal Adelaide Hospital

At Royal Adelaide Hospital we would like to welcome new and returning staff to the IBD Department.

Ms Denise Kreuch has joined us a clinical trials coordinator

Dr Duong

Dr Tuan Duong has returned after two years in Wollongong doing his gastroenterology registrar training, and is our current IBD fellow.

Dr Abdul Shaikh has completed his IBD fellowship and training in gastroenterology and is now a consultant member of the IBD team.

Dr Shaikh

Dr Kate Lynch has returned from maternity leave in her new role as Head of the IBD Department.

Welcome to all! You can read a little more about them below.

Dr Lynch

Lucy Cronin (IBD nurse) has returned from maternity leave after the birth of her second child. We have been very grateful for the cover of **Stephanie Zorman** during this time and will be sad to see her go. She will continue to work in the endoscopy unit and so you may see her there!

We would like to say farewell to IBD Nurse **Julie Hughes**. Julie has worked in the team since 2010 and is well known to many of you. She recently retired a few weeks ago and will be missed. She has worked so hard to advocate and improve the service and has been a great asset to many of you also.
We wish her many happy years ahead. Julie's replacement has not yet been allocated.

Dr Soo

Dr Raja

Welcome to new staff

The Queen Elizabeth Hospital

At The Queen Elizabeth Hospital we would like to welcome **Dr Wei Ting Soo**, Advanced trainee and IBD fellow who has a special interest in bowel ultrasound and IBD in pregnancy.

We are delighted that **Dr Sibhi Raja** has joined us as a pre-advanced training IBD fellow whilst undertaking a Masters of

Biographies

Dr Kate Lynch

Dr Kate Lynch is a consultant gastroenterologist and hepatologist with special expertise in inflammatory bowel disease and autoimmune liver disease. Her initial training was at University of Adelaide for her undergraduate medical training, and then through Royal Adelaide Hospital for her specialist gastroenterology training. She spent seven years in Oxford, UK, performing a clinical fellowship as well as research, and completed her PhD there in an immunology based project in inflammatory bowel disease and a rare associated liver condition, Primary Sclerosing Cholangitis.

Since returning to Australia in 2019, Kate has become involved in clinical research in IBD and PSC – both new therapies as well as independent research. She also sits on the Statewide Adolescent Transition Care Clinical Network, which aims to improve health transition processes for adolescents in SA. When she is not at work, she enjoys spending time with her husband and 10 month old son.

Dr Abdul Shaikh

Dr Abdul Shaikh is a consultant gastroenterologist with special interest in inflammatory bowel disease (IBD). He's recently joined the unit and IBD services at Royal Adelaide hospital and also practises privately.

He graduated from Baqai Medical University in Pakistan in 2004 and came to Australia in 2007 to further his medical training. He trained in gastroenterology at the Lyell McEwin Hospital, Queen Elizabeth Hospital and Royal Adelaide hospital. He was the IBD Fellow at Royal Adelaide Hospital in 2020 and was admitted to the Royal Australasian College of Physicians in 2021.

Dr Shaikh has an interest in evaluating the role of diet in inflammatory bowel disease and is pursuing research in this area at the Royal Adelaide Hospital. He is also actively involved in the clinical trials unit at the Royal Adelaide hospital offering people with IBD other alternatives.

Dr Tuan Duong

Dr Tuan Duong completed his 2 years of general gastroenterology training at the Wollongong hospital, NSW. Prior to that, he was a pre-advanced trainee IBD fellow at the RAH. He returns as a current IBD fellow to complete his gastroenterology training.

Dr Wei Ting Soo

Dr Wei Ting Soo is a third-year advanced trainee and Clinical IBD Fellow at TQEH. She completed her 2-year core advanced training in Gastroenterology at TQEH, RAH and FMC. She is pursuing her passion in IBD, in particular fertility and pregnancy in IBD, and is currently undergoing training to be an accredited Gastrointestinal Ultrasound (GIUS) provider. TQEH is now offering preconception counselling services in IBD patients of child bearing age group, and utilising GIUS as a mean of disease activity monitoring in pregnant IBD patients.

Dr Sibhi Sreecanth Raja

Dr Sibhi Sreecanth Raja is an IBD Fellow at TQEH. He graduated from the Royal Free and University College London Medical School, UK in 2014. He subsequently completed his internship at King's College London, UK in 2015 prior to embarking on a one-way trip to Adelaide, Australia. Sibhi has since successfully completed his Basic Physician Training (BPT) with the Royal Australian College of Physicians (RACP) and is keen to pursue a career in Gastroenterology. He is passionate about research in IBD and is on the verge of commencing a trial exploring the role of Faecal Microbiota Transplant (FMT) in Ulcerative Proctitis at TQEH (see more about this trial below!).

Denise Kreuch

Denise Kreuch has started part time as Clinical Trial Coordinator with the IBD department in February. She is also completing her PhD in Endocrine Physiology at the University of Adelaide. While her previous research focused on the impact of low-calorie sweeteners on gut function, including gut hormone release, glucose absorption and changes to the gut microbiome, she is excited to immerse herself in the world of inflammatory gut diseases and is eager to acquire new skills and knowledge. She is also looking forward to continuing to work with GIU staff and get to know her new colleagues better.

CALHN IBD Clinic Structure 2021

New RAH Clinic Structure

We have taken feedback from patients that they find it frustrating that often they see a new doctor over and over, and that there is a lack of continuity for many. As such, we have implicated a new structure, whereby patients are allocated to a specific consultant. Patients' appointments will then be alternated between their allocated consultant and a registrar or fellow. The registrar/fellow will report back to the patient's consultant when they see the patient, so that senior supervision is maintained for all clinical decisions.

In this way, we hope patients will have some continuity of care with the same consultant on alternate visits, whilst still maintaining the teaching ethos of the hospital through involvement of registrars and fellows. Occasionally, such as when patients need to be seen urgently due to a flare, or when a doctor is away due to annual leave or illness, this model may not work perfectly, but on the whole we hope it will be more satisfactory for patients.

TQEH Clinic Structure

The TQEH remains a Consultant led service, where each patient is allocated to a specific IBD Consultant, to whom Registrars/Fellows report. We aim to provide continuity of quality care for IBD patients whilst facilitating training opportunities and experience for junior medical staff.

Outpatients bookings/availability

Clinics at the RAH and TQEH are currently at capacity. Given limited resources, our clinics are always full and often need to be overbooked to make sure patients are seen in a timely fashion. For this reason, we ask patients understand that we may run late at times. We also ask that patients make every effort to attend the clinic appointment they have been given as it is very difficult to reschedule appointments and still see patients in time for their prescription renewals etc. We thank all our patients for their understanding and efforts in helping us with this.

COVID-19 vaccination

Due to the large volume of emails being sent to the IBD Service with queries regarding the COVID-19 vaccine, we apologise we do not have the resources to reply to each email individually on this topic.

We recently emailed an information sheet on the COVID-19 vaccine to patients on our IBD email list. This is the advice given from the Gastroenterology Society of Australia (GESA). It has recently been updated and we attach the most recent version at the end of this newsletter. Please read this sheet for more detailed information.

In summary, we encourage all patients with IBD to receive the COVID-19 vaccination. There are a few small instances where you should seek medical advice first (see the attached info sheet). In particular, if you are on a steroid medication. If this is the case, please email us again, with COVID-19 VACCINE AND STEROIDS in the subject line.

Please note, patients on biological therapies (such as Humira [adalimumab], Remicade [infliximab], Stelara [ustekinumab], and Entyvio [vedolizumab]) and immunomodulators (such as azathioprine, mercaptopurine, methotrexate) are safe to receive the vaccine as per the GESA guidance. It is unclear whether these medications will impact on the efficacy of the vaccine. This is being studied currently in an ongoing trial, and we will let you know as more information comes to light. In the meantime, we recommend going ahead to receive the vaccine.

You should follow governmental guidance as to which vaccine you receive, which may be dependent on the facility where it is being provided and your age. As per governmental guidance, this includes the preference for Pfizer vaccination to be given to people who are under 50 years old. There are no data to suggest that patients with IBD are at greater risk of side effects with the AZ vaccine.

Finally, we are not providing the COVID-19 vaccine from our department to our patients. This should be done through your GP, or other vaccine provider if and when they become available.

Dr Kate Lynch and Dr Rob Bryant

Biosimilars

Some of you may have heard about "biosimilars" arriving on the market, but what are they? They are similar to what we call "generic" drugs for non-biologic medications. When biologic drugs (such as infliximab, adalimumab, vedolizumab, ustekinumab) come off patent (typically 6-8 years), then other drug companies are allowed to apply for a licence and approval within Australia (through the TGA – Therapeutic Goods Administration) and manufacture similar products to the originator. For example, the originator for infliximab was the brand "Remicade", but over the last few years, other infliximab brands have been available such as "Renflexis" and "Inflectra". Since April 1, 2021, there have been 4 more brands of adalimumab (originator Humira) which have become available. A subcutaneous form of infliximab (Remsima) has also recently become available.

To become approved in Australia, the biosimilar must demonstrate that they are not inferior to the originator in terms of safety and efficacy. These studies have been done, hence the above drugs mentioned have been approved for use in Australia. The studies do show that the biosimilars are not inferior to the originators, however ongoing evaluation of these drugs continues to ensure they truly are as efficacious and safe.

Having multiple brands of a drug brings the price down of these drugs to the government which is a very important cost saving to allow funding of other important therapies in the future. Hence, it is important for clinicians to support the use of biosimilars when it is possible and appropriate.

If you have any questions about this, feel free to discuss this further with your treating doctor at your next appointment.

Dr Kate Lynch

Crohn's and Colitis Awareness Month

May is Crohn's and Colitis Awareness Month

Wed 19 May World IBD Day!

Click on the link below to find out ways you can become involved!

https://protect-au.mimecast.com/s/gulaCK1qxJhZQpQghMAGby?domain=crohnsandcolitis.com.au/

Ms Rachel Grafton

Smoking in IBD

Our data show that 1 in 5 patients with Crohn's disease are smokers. Patients with Crohn's disease who smoke are more likely to have more severe disease, to require more IBD medications, hospital admission and surgery. Furthermore, patients with IBD who have surgery for CD tend to have more complications and are more likely to have CD recurrence after surgery. It is therefore important for patients with IBD, and in particular CD, to stop smoking. Let's make June a smoke free month for patients with IBD.

If you need any assistance with giving up smoking, there are many resources and supports at your fingertips. *Quitline* (13 78 48) is a confidential telephone advice and information service for people who want to quit smoking. *MyQuitBuddy* is a personalised app to help you quit smoking your way. There are *programmes available through your GP*, including medications can assist you with smoking. And *hypnotherapy* has been shown to be successful in helping you to quit (and can be accessed through a referral to our RAH IBD psychologist, Dr Taryn Lores). Visit *Be Smoke Free* for more helpful tips and advice on how to quit smoking.

Dr Tuan Duong, Dr Kate Lynch, and Professor Jane Andrews

Faecal calprotectin and its use in IBD

What is faecal calprotectin?

Calprotectin is a protein found in a type of white blood cell called neutrophils, which play an important role in acute inflammation. During an inflammatory process, proteins in neutrophils, including calprotectin are released.

In active inflammatory bowel diseases (ulcerative colitis and Crohn's disease), there are inflammatory processes at the lining of the bowels. The more severe the inflammatory process is, the higher the number of neutrophils are involved and the higher the amount of calprotectin is released. This can be measured by collecting a stool or faecal sample. In other words, faecal calprotectin can be used as a surrogate marker for inflammation in inflammatory bowel disease (IBD).

What is faecal calprotectin's use in inflammatory bowel disease?

Subjective and objective markers are used to monitor IBD. Subjective markers including patient reported symptoms are commonly used. However, patients with active inflammation can sometimes report minimal symptoms and conversely, patients may have a lot of symptoms which are not due to active IBD. In other words, often, there can be disconnect between patients symptoms and the degree of inflammation actually present.

Objective markers such as inflammatory markers in blood tests (CRP, ESR, albumin, platelets) and stool test (faecal calprotectin) can be used to assess disease activity in IBD. Other objective tests including gastrointestinal ultrasound, MRI and colonoscopy can be used as well.

A recent international treatment guideline in IBD suggested a "treat to target" approach, which means aiming for the resolution of inflammation of the lining of the bowels and utilising objective markers to monitor inflammation. Colonoscopy is commonly used to directly monitor disease activity in IBD, however, it is invasive and costly. Blood tests including CRP, ESR and albumin and faecal calprotectin are non-invasive and cheaper alternatives.

Faecal calprotectin and its use in IBD *(continued)*

Faecal calprotectin has been shown to be a good surrogate marker to monitor response to treatment and to predict relapse in IBD. When it is used during active IBD, a reduction of faecal calprotectin level overtime is reflective of disease response to treatment. When it is used during remission, it helps to predict relapse of ulcerative colitis a few months prior to disease flare. Faecal calprotectin has also been showed to help predict Crohn's disease recurrence after surgery. Faecal calprotectin is usually measured every 3 or 6 months depending on IBD activities.

It is of note that the faecal calprotectin level can be elevated by other factors such as non-steroidal anti-inflammatory medications, infection and bleeding in the bowels. Your doctors may need to use other tests (colonoscopy/ ultrasound/ MRI) to assess IBD if the results of non-invasive objective markers are not in agreement with clinician's disease assessment.

Practical aspects of handing in your faecal sample for calprotectin level.

Finally, it is worth noting that the faecal calprotectin test is not covered by Medicare. However, it is free of charge through SA Pathology if a request form is used from CALHN (RAH or TQEH). If you hand in your specimen to an alternative pathology company (e.g. Clinpath, Australian Clinical Labs), then you will likely incur a fee which cannot be reimbursed by the hospital. Note that many GP surgeries utilise private pathology companies rather than SA Pathology. Also, only SA Pathology results appear on our CALHN electronic results system. Hence, it is important to have all your lab tests (especially faecal calprotectin) done at a SA Pathology lab.

Dr Tuan Duong

Research Study of the Month - TQEH

Study Title: UP-FMT (Examining the role of faecal microbiota transplantation (FMT) to induce remission in resistant ulcerative proctitis (UP): a pilot study)

What is UP-FMT?

UP-FMT is a study investigating Faecal Microbiota Transplantation (FMT) in patients with troublesome symptoms from distal ulcerative colitis (ulcerative proctitis). The purpose of UP-FMT is to confirm that FMT is a safe and tolerable treatment. We will also be looking to see if FMT improves symptoms as well as bowel inflammation in patients with UP.

What does participating in UP-FMT involve?

Participants will receive 6 FMT enemas at TQEH gastroenterology unit over an 8-week period. All patients enrolling in the trial will receive FMT enemas. Participants will undergo baseline assessments as well as pre- and post-treatment flexible sigmoidoscopies at TQEH.

Who we are looking to recruit?

We are aiming to recruit 25 patients aged 18-80 across South Australia and regional referral centres (e.g. Alice Springs, Broken Hill). Our study is aimed at UC patients with disease limited to the rectum and sigmoid colon (<30cm from anal verge) and with persistent disease activity despite use of oral and/or topical 5-ASAs (e.g. mesalazine).

Who is running the trial?

UP-FMT is being run by The Queen Elizabeth Hospital (TQEH) IBD service in conjunction with the Central Adelaide Local Health Network (CALHN). Please call the TQEH IBD Trials Team (phone: 82228984; 0435 597 597, email: Health: IBDresearchteam@sa.gov.au) for more information. Alternatively, please discuss with your treating Gastroenterologist whether you are suitable for this trial. We accept referrals from Gastroenterologists in both public and private settings across South Australia.

Dr Sibhi Sreecanth Raja

Research Study of the month - RAH

Study Title: Evaluation of a new clinical care pathway: Crohn's Disease Exclusion Diet plus Partial Enteral Nutrition in adult patients with active Crohn's Disease - PRED END Study

Diet in IBD has long been a focus of interest for clinicians and people with IBD. Many people with IBD are already changing their diets. People want to know what they should eat and information on the internet is not consistent and not evidence based. At the Royal Adelaide Hospital, we want to stay ahead of the curve and so we are launching a study that will evaluate a special diet called the 'Crohn's Disease Exclusion Diet' (CDED) plus a specific liquid formula referred to as 'Partial Enteral Nutrition' (PEN) as an alternative way of treating Crohn's disease.

There is evidence that this particular diet works as well as steroids in children and young adults in treating flares of Crohn's disease. We would like assess how well adult people with active Crohn's disease tolerate this dietary approach. As part of the study, we would also like to learn more about how this dietary approach affects people with Crohn's disease and their general health by measuring different markers of inflammation in blood and stool specimens. The results of this study may allow us to use this approach as an alternative to steroids and become the standard of care in all adults with active Crohn's disease.

The study has already been approved by Human Research Ethics Committee and is ready for recruitment. Please contact Ms Charlotte Goess (study coordinator) or Dr Abdul Shaikh for further information.

Email; charlotte.goess@sa.gov.au or Phone; 08 7074 2198

Dr Abdul Shaikh and Ms Charlotte Goess

Pharmaceutical Clinical Trials update

The RAH IBD clinical trials team are always pleased to be able to offer exciting new treatment options. The highlights for this newsletter are two clinical trials for patients with mild to moderate Ulcerative Colitis.

A current topic in the media and healthcare professions, our microbiome and gut health are also an evolving trend in clinical trials. We are currently running a microbiome capsule trial (SERES trial) aimed at recolonising the gut with 'good' bacteria, with the evidence suggesting that patients with ulcerative colitis often have alterations in their gut bacteria. Running over 27 weeks, there are 4 places left in the first phase which has no placebo arm.

The second trial (PROGENITY) is using Humira, a commonly used IBD biologic medication, as an enema instead of a subcutaneous injection. This approach is expected to improve drug efficacy. We have received some early data which has shown a great improvement in disease symptoms and endoscopic response, after only 3 doses of the drug. The data from this study will be used to develop a capsule. Patient's will be reimbursed for their time spent on the study.

Feel free to discuss the clinical trial option with your Gastroenterologist or IBD Nurse, or contact Clinical trials nurses, Lorelle Smith or Julie McMahon on 7074 2201 or 7074 2200 or email: Lorelle.smith@sa.gov.au and/or Julie.mcmahon@sa.gov.au.

Ms Lorelle Smith and Ms Julie McMahon

IBD Psychology Service Updates

Research – Pilot trial of gut-directed hypnotherapy for Crohn's disease

We are currently recruiting for our pilot trial of gut-directed hypnotherapy for people with Crohn's disease. Hypnotherapy is being explored as a complementary treatment – we want to find out whether adding hypnotherapy to medical treatment provides any benefits compared to medical treatment alone. Specifically, we want to find out whether conducting this type of research is feasible, and whether there are any changes to patients' symptoms, disease activity, mental health and/or quality of life.

For this trial we are seeking adult patients with active Crohn's disease and no major psychiatric diagnoses or trauma history. To date we have recruited 16 participants from the RAH IBD Service and from the community. We are seeking a minimum of 30 participants. The intervention will delivered virtually via telehealth, so participants will not need to attend the hospital to participate.

If you are interested in finding out more about this study and what participation involves, please register your interest by emailing:

Health.RAHGASTROENTEROLOGYSTUDY@sa.gov.au

Mental health screening via CCCare

CCCare is our IBD-specific clinical management software, which has improved the way in which we manage patient care and medical records. A recent update to the software's functionality is the addition of mental health and quality of life screening questionnaires.

IBD Psychology Service Updates *(continued)*

Completing these questionnaires helps give us an idea of your current state of psychological wellbeing, including your mood, level of stress, and quality of life. The results are automatically recorded in your medical record and help flag potential issues to your IBD clinician. If your scores suggest an elevated level of anxiety, stress or low mood, you can talk with your IBD clinician about where and how to access support. Completing these screening questionnaires also allows us to monitor your mental health and quality of life over time. Your IBD clinician may ask you to complete these online questionnaires before, during or following your IBD appointment. If you have any questions about how your data will be managed and stored, please speak with your IBD clinician.

The Royal Adelaide Hospital was one of the first sites to start using the embedded screening questionnaires, after the dedicated mental health and quality of life module was co-developed with colleagues from Liverpool Hospital in NSW in mid 2020. During the implementation period, the Depression, Anxiety and Stress Scale (DASS-21) was sent out to 91 patients at our IBD service. About half completed the survey (46%), with the results on average suggesting a mild level of distress.

Remember you can always speak with your treating team about your mental health if you have any concerns. Psychological support and intervention is available on a short-term basis through the IBD Service for patients presenting with IBD and health-related concerns.

If you are in need of mental health support in the meantime, you can contact Lifeline on 13 11 14 or beyondblue on 1300 22 4636. For emergency assistance contact mental health triage on 13 14 65.

Ms *Taryn Lores*