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BIG

BRITISH AND IRISH
GASTROENTEROLOGY

Europa Hotel, Belfast
27 - 28 April, 2017



Irish Society of
Gastroenterology



Ulster Society
of
Gastroenterology



BRITISH SOCIETY OF
GASTROENTEROLOGY



Autoimmune hepatitis

Crohn's disease

Collagenous colitis

Getting on with their lives

By getting on with their steroid



The only budesonide with three indications



Efficacy localised at the site of the disease¹⁻⁴



Limiting the risk of systemic side effects²⁻⁴

Budenofalk®

Budesonide, the Dr Falk way

Prescribing Information (Please refer to full SPC before prescribing)

Presentation: Budenofalk® gastro-resistant granules, each sachet contains 9mg budesonide, Budenofalk® gastro-resistant capsules, each containing 3mg budesonide. **Indications:** Induction of remission of mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon. Induction of remission of active collagenous colitis. Autoimmune hepatitis (capsules only). **Dosage: Adults:** For Crohn's disease and collagenous colitis: one sachet or three capsules daily with liquid half an hour before food, without chewing or crushing, or one capsule three times daily. Limit treatment to 8 weeks, then withdraw gradually. For autoimmune hepatitis: one capsule three times daily. Possibly combine with azathioprine. Maintenance of remission: one capsule twice daily. Revert to 3 capsules daily if transaminases ALAT and/or ASAT elevate again. Treat until remission is achieved or 24 months. **Children:** Not recommended; safety and efficacy not established. **Contra-indications:** hypersensitivity to any constituent. Hepatic cirrhosis. **Warnings/Precautions:** Change from other steroids may result in symptoms due to reduced systemic steroids. Use with caution in patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataracts or family history of glaucoma or diabetes or any condition in which glucocorticosteroids may have undesirable effects. Not appropriate for upper GI Crohn's or extraintestinal symptoms. Long term, high dose use may result in glucocorticosteroid systemic effects. Infection: suppression of the inflammatory response and immune function increases susceptibility to infections and their severity. Clinical presentation of infections may be atypical and presentation of serious infections may be masked. Chickenpox and herpes zoster are of particular concern. Passive immunisation needed within 10 days in exposed non-immune patients taking systemic glucocorticosteroids. Urgent specialist care required on confirmed chickenpox. Give normal immunoglobulin immediately after measles exposure. Do not give live vaccines to those with chronic glucocorticosteroid use. Antibody response to other vaccines may be diminished. With severe liver function disorders: increased systemic bioavailability. Suppression of the HPA axis and reduced stress response: supplementary systemic glucocorticoid treatment may be needed. Avoid concomitant treatment with CYP3A4 inhibitors. Do not use in patients with galactose or fructose intolerance, glucose – galactose malabsorption, sucrose – isomaltase insufficiency or Lapp lactase deficiency or congenital lactase deficiency. In autoimmune hepatitis evaluate transaminase levels every 2 weeks for the first month and then every 3 months. **Interactions:** Beware concomitant administration of cardiac glycosides and saluretics. CYP3A4 inhibitors: avoid concomitant administration. CYP3A4 inducers: may reduce systemic and local exposure, necessitating dose adjustment of budesonide. CYP3A4 substrates: may compete with budesonide increasing plasma concentrations depending on relative affinities. Small, non-significant effect of cimetidine on budesonide kinetic effects. Oestrogens/

oral contraceptives may elevate plasma concentrations and enhance corticosteroid effects. Steroid-binding compounds and antacids may reduce budesonide efficacy; administer at least 2 hours apart. Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values). **Use in pregnancy and lactation:** Avoid use in pregnancy unless essential. Do not breastfeed during Budenofalk treatment. **Undesirable effects:** Cushing's syndrome, growth retardation in children, glaucoma, cataracts, dyspepsia, constipation, gastric or duodenal ulcers, pancreatitis, increase in risk of infections, muscle and joint pain and weakness and twitching, osteoporosis, osteonecrosis, headache, pseudotumor cerebri (including papilloedema) in adolescents, depression, irritability and euphoria, psychomotor hyperactivity, anxiety, aggression, allergic exanthema, petechiae, ecchymosis, contact dermatitis, delayed wound healing, increased risk of thrombosis, vasculitis (after withdrawal from long-term treatment), fatigue, malaise. Side effects characteristic of systemic glucocorticosteroid therapy may occur. Exacerbation or reappearance of extraintestinal manifestations when switching from systemically acting glucocorticosteroids may occur. Frequency is likely to be lower than with equivalent dosage of prednisolone. **Legal category:** POM. **Costs:** UK NHS: 60 sachets £135; 100 capsules £75.05. Ireland (PtW): 60 sachets: €152.15; 100 capsules: €78.96. **Licence holder:** Dr Falk Pharma GmbH, Leinenweberstr.5, D-79108 Freiburg, Germany. **Licence numbers:** (granules) PL08637/0020 (UK) PA573/2/3 (IE) (capsules) PL08637/0002 (UK) PA573/2/1 (IE). **Prepared:** October 2016.

Further information available on request.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (UK residents) or at <https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form> (residents of the Republic of Ireland). Adverse events should also be reported to Dr Falk Pharma UK Ltd.

References:

1. Bar-Meir S *et al.* Gastroenterol 1998; 115(4): 835-40.
2. De Cassan C *et al.* Dig Dis 2012; 30(4): 368-75.
3. Czaja AJ. Dig Dis Sci 2012; 57(8): 1996-2010.
4. Miehlke S *et al.* Gastroenterol 2002; 123(4): 978-84.

Dr F17/052

Date of preparation: March 2017

Welcome Message from Peter Watson



Dear Colleagues and Friends,

It is my great honour and pleasure to welcome all participants: speakers and presenters, delegates, sponsors, industry representatives and guests to BIG in Belfast. This is the second BIG when the USG combines with and hosts our “parent” organisations of BSG and ISG. The first BIG in 2013 was a great success and we aim to build on that to make this one even bigger and better.

The organising committee have put together an exciting programme of really relevant topics in gastroenterology and hepatology with a good balance of state- of- the- art expert contributions and abstracts of new research from young trainees and investigators. There are 25 generous travel bursaries on offer to trainees and investigators , which we feel sure will encourage involvement by the upcoming generation . Look out for the ever popular “hot topic” sessions that are designed to quickly deliver the main take-home messages and promote lively debate.

The venue is the Europa Hotel right in the centre of Belfast . It provides excellent accommodation and conference facilities as well as being a popular social hub. It is always said that the net-working that goes on around a conference is its main benefit. The Europa environment is ideal for this and will give everyone a great opportunity for discussion and discovery.

Belfast is arguably at its most attractive in April and an evening at the gala dinner at the Great Hall at Queen’s University in the beautiful Lanyon building promises to be a highlight.

I feel sure that BIG will prove to be a worthwhile event both professionally and socially for all attendees. Enjoy!

Peter Watson
President USG

USG Executive Committee

President:	Dr. Peter Watson , Consultant Gastroenterologist Royal Victoria Hospital, Belfast.
Hon Sec:	Dr. Patrick Allen , Consultant Gastroenterologist South Eastern Trust.
Hon Treas:	Dr Jenny Addley , Consultant Gastroenterologist Ulster Hospital, Dundonald. Belfast
Member:	Mr. Eamon Mackle , Consultant Surgeon Craigavon Area Hospital.
Member:	Dr. Helen Coleman , Senior Lecturer in Cancer Epidemiology Centre for Public Health, Queens’ University Belfast.



Entyvio: the first and only gut-selective biologic for adult patients with moderately to severely active UC and CD¹

TREAT WITH PRECISION

PRESCRIBE WITH CONFIDENCE:
Gut-selective Entyvio targets only the site of inflammation¹

Entyvio[®] (vedolizumab) PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: 300 mg powder for concentrate for solution for infusion. **Indication:** Adult patients with moderately to severely active ulcerative colitis (UC)/Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor- α (TNF α) antagonist. **Dosage & Administration:** Treatment should be initiated and supervised by a specialist healthcare professional experienced in diagnosis and treatment of ulcerative colitis or Crohn's disease. Patients should be monitored during and after infusion in a setting equipped to manage anaphylaxis. **Ulcerative colitis:** Recommended dose regimen 300mg administered by intravenous infusion over approximately 30 minutes at 0, 2, 6 weeks and 8 weeks thereafter. Reconsider treatment if no evidence of therapeutic benefit at week 10. If patients experience a decrease in response, they may benefit from increased dosage frequency to 300mg every 4 weeks. Corticosteroids may be reduced/discontinued in patients who respond to treatment with Entyvio. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **Crohn's disease:** Recommended dose regimen is 300mg administered by intravenous infusion over approximately 30 minutes at 0, 2, 6 weeks and 8 weeks thereafter. Patients who have not shown evidence of therapeutic benefit may benefit from a dose at week 10. Continue therapy every 8 weeks from week 14 in responding patients. Therapy should be discontinued if no evidence of therapeutic benefit is observed at week 14. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **Paediatric populations:** No data available in children aged 0-17 years. **Not recommended. Elderly patients:** No dosage adjustment required. **Renal or hepatic impairment:** Entyvio has not been studied in these populations. No dose recommendation can be given. **Contraindications:** Hypersensitivity to Entyvio or any of the excipients. Active infections such as tuberculosis (TB), sepsis, cytomegalovirus, listeriosis and opportunistic infections such as Progressive Multifocal Leukoencephalopathy (PML). **Warnings and Precautions:** Patients should be observed continuously during infusions for signs/symptoms of hypersensitivity reactions.

Patients should continue to be observed for two hours following infusion completion for the first two infusions and one hour for subsequent infusions. **Infusion-related reactions (IRR):** Hypersensitivity reactions have been reported, the majority were of mild to moderate severity. Discontinue treatment if anaphylaxis or other serious allergic reactions occur and institute appropriate treatment. In mild to moderate IRR, slow or interrupt infusion. Consideration for pre-treatment with antihistamine, hydrocortisone and/or paracetamol should be given prior to next infusion, for patients with history of mild/moderate IRR to Entyvio. **Infections:** Not recommended in patients with active, severe infections until infections are controlled. Consider withholding in patients who develop severe infection while on treatment with Entyvio. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Entyvio treatment. **Progressive Multifocal Leukoencephalopathy (PML):** No cases were observed in Entyvio clinical trials, but John Cunningham (JC) virus infection resulting in PML and death has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs/symptoms. **Malignancy:** Underlying increased risk of malignancy in UC and CD. Immunomodulatory products may increase risk. **Prior and concurrent use of biological products:** No clinical data available for Entyvio use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should wait at least 12 weeks prior to initiating Entyvio therapy. Entyvio not recommended for concomitant use with biologic immunosuppressants as no clinical data available. **Live and oral vaccines:** Patients may continue to receive non-live vaccines. Patients recommended to be up-to-date with all appropriate immunisations prior to initiating Entyvio. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically

meaningful effect on Entyvio pharmacokinetics. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use adequate contraception and continue for at least 18 weeks after last Entyvio treatment. Since maternal antibodies are excreted in breast milk, decision whether to discontinue breast-feeding or discontinue/abstain from Entyvio should be made according to relative benefit to child of breast-feeding or to mother of Entyvio. **Undesirable Effects: Very Common (>1/10):** nasopharyngitis, headache, arthralgia. **Common (>1/100, <1/10):** bronchitis, gastroenteritis, URTI, influenza, sinusitis, pharyngitis, paraesthesia, hypertension, oropharyngeal pain, nasal congestion, cough, anal abscess, anal fissure, nausea, dyspepsia, constipation, abdominal distension, flatulence, haemorrhoids, rash, pruritus, eczema, erythema, night sweats, acne, muscle spasm, back pain, muscular weakness, fatigue, pain in extremities, pyrexia. **Other serious undesirable effects (>1/1000 to <1/100):** respiratory tract infection, infusion site reaction, infusion-related reaction. **Refer to the SmPC for details on full side effect profile and interactions. Basic NHS Price:** £2,050. **Legal Classification:** POM. **Marketing Authorisation:** EU/1/14/923/001 300mg powder for concentrate for solution for infusion. Takeda UK Ltd is responsible for sale and supply of Entyvio in the UK. Further information is available from Takeda UK Ltd, Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Buckinghamshire, HP10 0DE. Tel: 01628 537900 Fax: 01628 526617. **PI Approval Code:** UK/EV/1511/0240 **Date of revision:** November 2015.

Please refer to the summary of product characteristics for details on the full side-effect profile and drug interactions of Entyvio. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda UK Ltd. Tel- 01628-537900

▽ This medicinal product is subject to additional monitoring.
This will allow quick identification of new safety information.

References:

1. Entyvio Summary of Product Characteristics. www.medicines.org.uk March 2017.

BIG Meeting

Europa Hotel, Belfast, 27th-28th April 2017

Programme

Thursday 27th April

- | | | | |
|-------|--|-------|---|
| 08.30 | Registration | 14.15 | Oral Free Papers (3 & 4) |
| 09.45 | Session 1.
Gastroenterology and Surgical Session | 14.35 | Hot Topics' in Liver Disease |
| 09.45 | Novel findings in risk factors for colorectal adenomas
Dr Martha Shrubsole,
Vanderbilt Epidemiology Center USA | 14.35 | Update on cholestatic liver disease
Dr Gideon Hirschfield,
Queen Elizabeth Hospital, Birmingham |
| 10.05 | Bowel cancer screening update – The five nations experience of Bowel Cancer Screening
Professor Robert Steele,
Dundee UK | 14.47 | Acute on chronic liver failure
Professor Julia Wendon, Kings College London |
| 10.25 | Future directions in Minimally Invasive Rectal surgery for Gastroenterology
Professor Peter Sagar, Leeds. UK | 14.59 | Update on portal hypertension
Dr Johnny Cash, Royal Victoria hospital, Belfast |
| 10.45 | Acute Gastrointestinal trauma- lessons from the front line
Mr Christopher Streets,
Bristol Royal Infirmary, UK | 15.11 | Alcohol and HCV
Dr Stephen Stewart, Mater Hospital, Dublin |
| 11.05 | Coffee break – Poster Viewing – Meet the Industry | 15.23 | Update on Viral Hepatitis
Dr Neil Mc Dougall,
Royal Victoria Hospital, Belfast. |
| 11.30 | Session 2
Hepatology Session | 15.35 | Coffee Break – Poster Viewing – Meet the Industry |
| 11.30 | Oral free papers (1 & 2) | 16.00 | Session 3
Neurogastroenterology Session
State of the Art Management for your patients |
| 11.50 | Liver transplant when to refer and common post-transplant complications
Professor John O'Grady, King College. London | 16.00 | Update on Functional dyspepsia- what should you be doing for your patients?
Professor Jan Tack,
(TARGID), University of Leuven, Belgium |
| 12.10 | How to get a sick liver patient into the ITU
Professor Julia Wendon, Kings College. London | 16.20 | New drugs in IBS for the clinic and future.
Dr Orla Craig, Leeds University Hospital UK |
| 12.30 | The epidemic of liver disease-fatty liver and alcohol
Dr Michael Mc Bride, CMO NI
With panel discussion and debate –
Professor Martin Lombard BSG President
Professor Padraic Mac Mathuna ISG President,
Dr Stephen Stewart Mater Hospital Dublin
and Professor Frank Murray, President RCPI | 16.40 | Testing for functional gut disorders
Professor Eamon Quigley, Houston, Texas |
| 13.10 | Lunch - Poster Viewing - Meet the Industry | 17.20 | Close of meeting |
| | | 19.45 | Conference Dinner in Queens University |

In adult patients with moderate to severe active Ulcerative Colitis who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

EFFICACY THAT LASTS^{1,2,a}

The first and only subcutaneous anti-TNF with 4-week efficacy during maintenance treatment^{1,2,b}

Please consult the Summary of Product Characteristics before prescribing.

^aBased on results of PURSUIT Maintenance study.

^bPatients with body weight less than 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks, thereafter. Patients with body weight greater than or equal to 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks, thereafter.¹

SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN

SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)

Prescribing Information [Refer to full SPC text before prescribing Simponi (golimumab)]

Indications: *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate, the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. *Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Dosage and administration:** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA or UC. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. **RA:** Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. **PsA:** Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. **AS and nr-Axial SpA:** Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. **UC: Patients weighing < 80 kg:** Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. **Patients weighing ≥ 80 kg:** Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). **Missed doses:** If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. **Older patients (≥ 65 years):** no dose adjustment required. **Paediatric patients (< 18 years)** and patients with renal and hepatic impairment: Simponi is not recommended in these populations. **Contraindications:** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. **Malignancies and lymphoproliferative disorders:** Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine

(AZA) or 6-mercaptopurine (6-MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development of HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-blocking agents) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart Failure:** Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. **Neurological events:** Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery:** Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations:** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. **Excipients:** Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **Interactions:** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **Pregnancy and Lactation:** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **Side-effects:** Refer to Smpc for complete information on side effects. **Very Common (≥ 1/10):** upper respiratory tract infection; **Common (≥ 1/100):** bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, anaemia, allergic reactions, autotuboid positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. **Serious, including fatal adverse events** have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma*, hepatosplenic T-cell lymphoma*, leukopenia, thrombocytopenia, pancytopenia, aplastic anaemia, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. *Observed with other TNF-blocking agents, but not observed in clinical studies with golimumab. **Package quantities:** 150 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 150 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection. **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number:** 50 mg Pre-filled Pen EU/1/09/546/001; 50 mg Pre-filled Syringe EU/1/09/546/003; 100 mg Pre-filled Pen EU/1/09/546/005. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Date of Revision of Text:** December 2015. **Further information is available on request from:** MSD, Red Oak North, South County Business Park, Leopardstown, Dublin D18X5K7 or from www.medicines.ie. **Date of preparation:** May 2016.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie
Adverse events should also be reported to MSD (Tel: 01-299 8700)

References: 1. EU Summary of Product Characteristics for SIMPONI 12 Jan 2016; 2. Sandborn WJ, Feagan BG, Marano C, et al. Subcutaneous Golimumab Maintains Clinical Response in Patients with Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2014;146:96-109.



Red Oak North, South County Business Park, Leopardstown, Dublin D18 X5K7, Ireland.

Programme continued...

Friday 28th April

- | | | | |
|-------|---|-------|---|
| 08.30 | Satellite symposium (sponsored by Takeda) | 10.35 | Oral free papers (5 & 6) |
| 09.00 | Parallel nursing session (ISEN & NI Nurses) | 10.55 | <i>Risk of Malignancy in IBD – how to manage your patient.</i>
Professor Larry Egan, NUI Galway |
| | Session 4
Gastroenterology Session | 11.20 | <i>How should we optimally manage Post-operative Crohns disease?</i>
Professor Jack Satsangi, Edinburgh UK |
| 09.45 | Hot Topics in IBD | 11.50 | Lunch - poster viewing - Meet the Industry |
| 09.45 | <i>TB screening in IBD</i>
Dr Sara Hedderwick, Belfast trust. NI | 12.15 | Session 6
Endoscopy Session |
| 09.55 | <i>Challenges on stopping therapies - immunomodulation/anti-TNF</i>
Professor Jack Satsangi, Edinburgh. UK | 12.15 | Oral free papers (7 & 8) |
| 10.05 | <i>Accelerated dosing of infliximab for Acute severe UC</i>
Dr David Kevans, St James Hospital. Dublin | 12.35 | <i>ERCP tips and tricks</i>
Dr George Webster, UCLH London |
| 10.15 | <i>New drugs in IBD for the clinic</i>
Professor Larry Egan, NUI Galway | 12.55 | <i>Management of pre-malignant and malignant Gastric polyps</i>
Professor Pradeep Bhandari, Portsmouth UK |
| 10.25 | <i>Immunosuppression dilemmas in Elderly IBD patients</i>
Dr David Kevans, St James Hospital Dublin | 13.15 | <i>Advanced EMR tips and tricks</i>
Professor Brian Saunders, St Marks Hospital, London |
| 10.35 | Session 5
Inflammatory Bowel Diseases session | 13.40 | Presentation of prizes and close of meeting |



Presentation: Modified Release tablets containing 400mg mesalazine or 800mg mesalazine. **Indications:** *Ulcerative Colitis* - Treatment of mild to moderate acute exacerbations. Maintenance of remission. *Crohn's ileocolitis* - Maintenance of remission. **Dosage and administration:** *400mg tablets* - Adults: Mild acute disease: 6 tablets (2.4g) once daily or in divided doses, with concomitant steroid therapy where indicated. Moderate acute disease: 6 to 12 tablets (2.4g - 4.8g) daily. 2.4g may be taken once daily or in divided doses, higher doses should be taken in divided doses. Maintenance therapy: 3 to 6 tablets (1.2g - 2.4g) once daily or in divided doses. *800mg tablets* - Adults: Mild acute disease: 3 tablets (2.4g) once daily or in divided doses with concomitant steroid therapy where indicated. Moderate acute disease: 3 to 6 tablets (2.4g - 4.8g) daily. 2.4g may be taken once daily, higher doses should be taken in divided doses. Maintenance therapy: 2 to 3 tablets (1.6g - 2.4g) once daily or in divided doses. *400mg and 800mg tablets* - No more than 2.4g should be taken at one time. Tablets must be swallowed whole. **Elderly:** Normal adult dose may be used unless liver or renal function is severely impaired. **Children:** Limited documentation of efficacy in children >6 years old. Dose to be determined individually. Generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg. **Contra-indications:** Hypersensitivity to salicylates, mesalazine or any of the excipients, severe impairment of hepatic or renal function (GFR less than 30 ml/min).

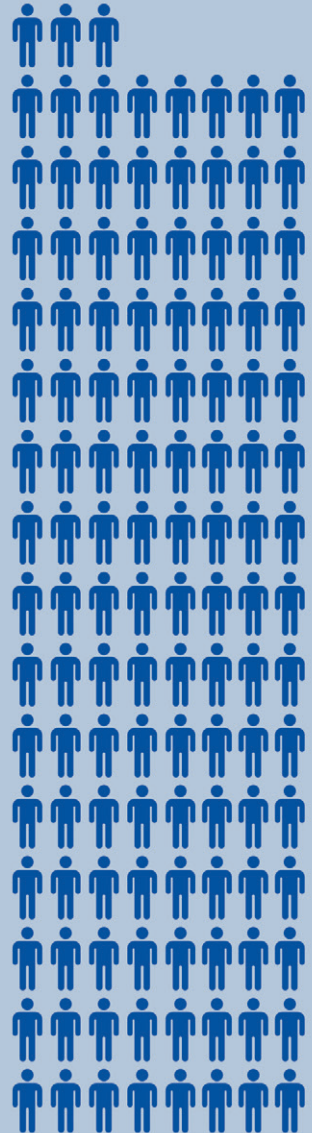
Warnings and Precautions: Urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Caution in patients with raised serum creatinine or proteinuria. Stop treatment immediately if renal impairment is evident. Haematological investigations are recommended prior to and during treatment, at discretion of treating physician. Stop treatment immediately if blood dyscrasias are suspected or evident. Caution in patients with impaired hepatic function. Liver function should be determined prior to and during treatment, at the discretion of the treating physician. Do not use in patients with previous mesalazine-induced cardiac hypersensitivity and use caution in patients with previous myo- or pericarditis of allergic background. Monitor patients with pulmonary disease, in particular asthma, very carefully. In patients with a history of adverse drug reactions to sulphasalazine, discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Use with caution in patients with gastric or duodenal ulcers. Intact tablets in the stool may be largely empty shells. If this occurs repeatedly patients should consult their physician. Use with caution in the elderly subject to patients having normal or non-severely impaired renal and liver function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Interactions:** No interaction studies have been performed. May decrease the anticoagulant activity of warfarin. May increase the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine. Monitoring of blood cell counts is recommended if these are used concomitantly. **Fertility, pregnancy and lactation:** Only to be used during pregnancy and lactation when the potential benefit outweighs the possible risk. No effects on fertility have been observed. **Adverse reactions:** *Common:* dyspepsia, rash. *Uncommon:* eosinophilia (as part of an allergic reaction), urticaria, chest pain. *Rare:* myocarditis, pericarditis. *Very rare:* altered blood counts (aplastic anaemia, granulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia), hypersensitivity reactions (such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis), peripheral neuropathy, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), interstitial pneumonia, eosinophilic pneumonia, lung disorder, acute pancreatitis, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure which may be reversible on withdrawal, nephrotic syndrome, oligospermia (reversible). *Not known:* lupus-like syndrome with pericarditis and pleuropericarditis as prominent symptoms as well as rash and arthralgia. Consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg - PL36633/0002; packs of 90 tablets (£16.58) and 120 tablets (£22.10). 800mg - PL36633/0001; packs of 90 tablets (£40.38) and 180 tablets (£80.75). **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire, LN5 0HX, UK. Octasa is a trademark. ©2010 Tillotts Pharma UK Ltd. Further information is available from the Marketing Authorisation Holder. Date of preparation of API: January 2017

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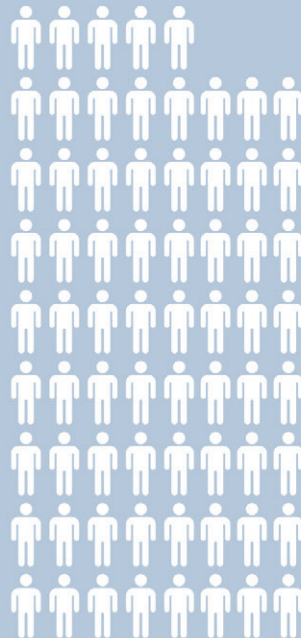
123[†]

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Tillotts Pharma UK Ltd. (address as above) Tel: 01522 813500.

References 1. Data on file, Tillotts Pharma UK Limited. [Price change - withdrawal from PPRS]. 2. MIMS. Accessed online, December 2016. UK/OC/0017/1116a. Date of preparation: December 2016.

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BIG Conference Friday 28th April 2017

Endoscopy Nurses Programme (NIENG & ISEN)

- 08.30 **Registration**
- 09.15 **Welcome and housekeeping**
- 09.30 ***“Early rectal cancers and TEMS”***
Mr Kevin McElvanna, Consultant Colorectal Surgeon,
 South Eastern Trust, Belfast.
- 10.00 ***“Colonic stenting for malignant obstruction”***
Dr Grant Caddy, Consultant Gastroenterologist,
 South Eastern Trust, Belfast.
- 10.30 **Coffee break**
- 11.00 ***“The nurse’s role in managing biologic therapy for patients with IBD”***
Marian O’Connor, Consultant Nurse – Inflammatory Bowel Disease,
 IBD Unit, St Mark’s Hospital, London.
- 11.30 ***“Endoscopy workforce”***
Irene Dunkley, Nurse Consultant - Gastroenterology & Endoscopy,
 Hinchingsbrooke Health Care NHS Trust and BSGNA Chairperson.
- 12.00 **Close**
- 12.15 **Lunch**
- 12.45 **AGM of NIENG**

IBD Nurse Session

Friday 28th April 2017

(Sponsored by Tillotts Pharma UK)

- 12:20 **Demonstrating the Value of Your Service**
Marian O’Connor Consultant Nurse –
 Inflammatory Bowel Disease St Mark’s Hospital
- 13:10 **Wellbeing Programme**
Ruth Hall
 IBD Specialist Nurse
- 13:30 **Questions**
- 13.45 **IBDNAI AGM**
Election of Committee
- 14.30 **Close**

Biographical Sketches

Dr Peter Watson,
President USG



Since 1991 Dr Watson has been consultant gastroenterologist at the Royal Victoria Hospital and senior lecturer in the Centre of Medical Education at Queen's University Belfast, where he is Academic Clinical Lead for Undergraduate Medicine. He was elected President of the Ulster Society of Gastroenterology in October 2016.

His research interests have been in coeliac disease and more latterly Barrett's oesophagus and oesophageal cancer. He is on the Trials Management Group of AspECT (Aspirin and Esomeprazole Chemoprevention Trial of Oesophageal Cancer in Barrett's Oesophagus) and is co-lead of the recently formed Northern Ireland GI Research Network, which aims to promote research in gastroenterology in the clinical community.

He is serving a second term on the Oesophageal Committee of the British Society of Gastroenterology and has been an author on the BSG guidelines for Barrett's oesophagus and the forthcoming guidelines on oesophageal strictures.

He is an enthusiastic advocate of promoting excellence in medicine by means of shared experience and ideas with experts and peers at educational meetings such as BIG

Professor Martin Lombard,
President BSG



Professor Martin Lombard is currently a Consultant Hepatologist and Gastroenterologist at the Royal Liverpool University Hospital, holding an Honorary Chair at the University of Liverpool. He qualified and trained in Medicine and Gastroenterology in Dublin and studied Hepatology at Kings College Hospital & the Institute of Liver Studies in London. He has been Clinical Director at both of the acute Trusts in Liverpool, was Training Program Director for Mersey Region and has Chaired the National Training Board for Gastroenterology previously and was until recently Chair of Cheshire & Merseyside NHSE Clinical Senate. He has presented and lectured on numerous topics from liver disease to organizational management and healthcare reconfiguration. He has an extensive publication record in Liver and HPB disorders, has previously set up the Research Governance Framework at RLUH, and is a clinical strategy advisor to Liverpool Health Partners. He was recently appointed Clinical Director for the North West Coast Clinical Research Network (National Institute of Health Research).

He set up and published the BSG audit which benchmarked standards for ERCP and as the first National Clinical Director for Liver Disease at the Department of Health (2010-13), he co-produced the Atlas of Variation of Liver Disease with NHS Rightcare, the NCEPOD report on alcohol related deaths, the Nurse Competency Framework for Specialist Nurses with RCN, and contributed to numerous annual reports with the Health Protection Agency and the Chief Medical Officer and

was a contributor to the Lancet Commission on Liver Disease and a participant on the clinical reference group for hepatitis C commissioning.

From June 2016 he is President of the British Society of Gastroenterology, a professional organisation with over 3,000 members, drawn from the ranks of physicians, surgeons, pathologists, radiologists, scientists, nurses, dietitians, and others interested in the field. Founded in 1937, the BSG has grown from a club to a major force in British medicine and a renowned influence at European and broader international levels for the promotion of gastroenterology and hepatology for the benefit of all patients with digestive disorders.

Professor Padraic MacMathuna,
President ISG



1981 UCD graduate with training in Ireland, London and Boston in Gastroenterology. Appointed Consultant Gastroenterologist to Mater University Hospital in 1995.

Track record in clinical and laboratory research in areas from Colon Cancer biology, CT Colon Imaging, High Risk colorectal Cancer screening and endoscopic intervention. Appointed Associate Professor of Medicine in recognition of contribution to the postgraduate (Former Postgraduate Dean) and undergraduate academic activity of the Mater and UCD. Currently a member of the NCCS Advisory group on Colorectal Cancer Screening and a participant in the NCCS Expert Group on Hereditary Cancer Risk.

Dr Martha Shrubsole,
Vanderbilt Epidemiology Center USA



Dr. Martha Shrubsole is Research Associate Professor in epidemiology at Vanderbilt University Medical Center where she is also the Director of the Vanderbilt Survey Research Shared Resource and the Associate Director of the International Epidemiology Field Station at VUMC.

A major focus of Dr. Shrubsole's research is to identify modifiable factors for the prevention of colorectal neoplasia and breast cancer particularly nutrients and nutrient-gene interactions in the one-carbon metabolism pathway. In addition to one carbon metabolism, Dr. Shrubsole has studied unique inflammation biomarkers in colorectal carcinogenesis. She has contributed multiple publications towards understanding risk factors for serrated polyps and conventional adenomas. She is funded by the US NIH to evaluate new directions in gut microbiome research in studies of colorectal cancer. Dr. Shrubsole is also lead or key investigator in the Vanderbilt GI SPORE, the Southern Community Cohort Study, multiple US National Cancer Institute-funded clinical trials, and other large epidemiologic studies.

Professor Robert Steele,
Professor of Surgery
University of Dundee, UK



Professor Robert Steele obtained his initial surgical and academic training in Edinburgh, Hong Kong and Aberdeen and

was appointed as Senior Lecturer in Surgery at the University of Nottingham in 1990. He was then appointed Professor of Surgical Oncology at the University of Dundee in 1996 and as Professor of Surgery and Head of Academic Surgery in 2003. His main interests are the treatment of and screening for colorectal cancer. Having led the UK demonstration pilot that was used to inform the decision to introduce national screening programmes throughout the United Kingdom, he is at present the Clinical Director of the Scottish Colorectal Cancer Screening Programme, and has published extensively in this area. He has chaired several NHS QIS and HIS groups related to colorectal cancer and colorectal cancer screening and he chaired the SIGN group that developed the latest set of colorectal cancer guidelines. He is a past member of Council of the Royal College of Surgeons of Edinburgh and Editor of "The Surgeon". He is co-founder and co-director of the Scottish Cancer Prevention Network, Chair of the Health Improvement, Protection and Services (HIPS) Research Committee of the Scottish Government's Chief Scientist's Office, Chair of the Board of Directors of the Scottish Cancer Foundation and is immediate past President of the Association of Coloproctology of Great Britain and Ireland. In 2016, he was appointed as Independent Chair of the UK National Screening Committee.

Professor Peter Sagar,
Leeds, UK



Peter Sagar qualified from Leeds Medical School in 1983 with honours after initially gaining a First Class Honours degree in Pathology in 1980. After basic surgical training at The General Infirmary at Leeds and becoming a Fellow of the Royal College of Surgeons, he went on to complete a Doctorate in Medicine with research into new techniques in the surgery for inflammatory bowel disease. This work was awarded the prestigious Patey prize by the Surgical Research Society in 1990.

His research interests continued as a Lecturer in Surgery at the University of Liverpool, before working as a Chief Resident at the Mayo Clinic, Rochester, Minnesota.

In 1996, he started at Leeds General Infirmary and has gone on to develop a national referral practice for the management of recurrent pelvic malignancy.

Areas of interest

Rectal bleeding, change of bowel habit, abdominal symptoms, endoscopy, colonoscopy, Colorectal (bowel) cancer; Colorectal surgery (lower GI); Bowel disease including inflammatory (IBD)

Mr Christopher Streets,
Consultant Oesophagogastric Surgery
Bristol Royal Infirmary, UK



Christopher was appointed as a Consultant in Oesophagogastric Surgery at the Bristol Royal Infirmary in 2008. He qualified from the University of Bristol in 1992 and undertook training in the South West and Northern deaneries. He obtained his higher degree from the University of Bristol for research into gastro-oesophageal reflux disease performed at the University of

Southern California, Los Angeles.

Having joined the Royal Navy as a Medical cadet in 1991 Christopher has seen active service in a number of operational areas including the Former Yugoslavia, Iraq and Afghanistan. He was appointed as the Surgeon General's Defence Consultant Advisor in Surgery in 2014. As well as managing his cadre in terms of personnel, equipment and policy he has a particular interest in military and civilian small-team trauma training, alongside his NHS practice.

Professor John O'Grady,
King College. London



Professor John O'Grady graduated from the National University of Ireland (Galway) in 1978. After undertaking his general medical training in Ireland, he joined the Liver Unit at King's College Hospital, London, in 1984. His dual interests initially were acute liver failure and liver transplantation. He was appointed Consultant Hepatologist at St.James' Hospital in Leeds in 1992 but in 1996 returned to King's College Hospital where he currently works as Professor of Hepatology.

He has a long-standing interest in outcomes after liver transplantation. This is reflected in involvement in clinical trials directed at defining optimal immunosuppression (notably the TMC trial). The impact of recurrent disease on long-term outcome has also been of considerable interest to him.

He was President of the British Association for the Study of the Liver (BASL) from 2007-9. Currently he is Chairman of UK Transplant Liver Advisory Group. He is also Deputy Editor of the American Journal of Transplantation. He co-edited the textbook Comprehensive Clinical Hepatology (2 editions) and has numerous publications relating to clinical aspects of liver transplantation and acute liver failure.

Professor Julia Wendon,
Kings College. London



Julia Wendon trained in internal medicine before specialising in liver intensive care and hepatology and has been a consultant within the Institute of Liver Studies, King's College Hospital since 1992.

Her focus is in liver intensive care incorporating encephalopathy, hepatorenal failure, haemodynamic failure, sepsis and immune function, liver support systems, liver function assessment and management of acute liver failure.

Dr Gideon Hirschfield,
Queen Elizabeth Hospital, Birmingham



Professor Gideon Hirschfield is Professor of Autoimmune Liver Disease at the University of Birmingham Centre for Liver Research, and Transplant Hepatologist at Queen Elizabeth Hospital, Birmingham.

He graduated from Trinity College Oxford in 1994 and subsequently from Cambridge where he completed his clinical studies. He completed his advanced Gastroenterology

and Hepatology training in Cambridge, and was awarded Specialist status in 2007. Until January 2012 he then worked in Toronto, Canada, where he was a Staff Physician and Assistant Professor of Medicine at the University Health Network and University of Toronto. During this time he managed one of the largest autoimmune liver disease cohorts in North America. He joined the Birmingham Liver Unit in January 2012 and now divides his time between translational research in autoimmune liver disease, and his clinical, Transplant/Hepatology, practice at the University Hospitals Birmingham. In keeping with Birmingham's extensive clinical programme, in particular the cohorts of patients with PBC, PSC and AIH he manages, are some of the largest internationally, resulting in a unique clinical expertise related to their day-to-day management pre- and post-transplant, as well as opportunity to involve patients in translational research projects, and in novel clinical trials of new therapies.

Dr Johnny Cash,
Consultant Hepatologist
Royal Victoria Hospital, Belfast



Dr Johnny Cash is a consultant Gastroenterologist and Hepatologist in the Royal Victoria Hospital, Belfast. His main clinical interests are liver transplantation and the complications of cirrhosis, particularly portal hypertension.

He also has an interest in healthcare modernisation and has recently been appointed assistant medical director for continuous improvement in the Belfast Health and Social Care Trust. He has been the co-lead for medicine and clinical lead of

the programmed treatment unit in the Royal Victoria hospital since 2011. He has been on the board of the Irish society of Gastroenterology since election in 2011 and is chair of the DHSSPS Drug Treatment & support advisory committee. In his spare time he is a keen fell runner.

Dr Stephen Stewart,
Mater Hospital, Dublin



Stephen Stewart is a Consultant Hepatologist and Director of the Centre for Liver Disease in the Mater Misericordiae University Hospital. He trained in Edinburgh University and did his junior doctor training between The Mater and the hospitals in the North East of England. His PhD was in the immunology of alcoholic liver disease and his subsequent clinical research has been in ALD and NASH. In the years prior to moving back to Dublin he was a Consultant Transplant Hepatologist in the Freeman Hospital in Newcastle upon Tyne and an Honorary Clinical Senior Lecturer with Newcastle University.

Professor Frank Murray,
President RCPI, Beaumont Hospital, Dublin



Prof Frank Murray became a Fellow of the Royal College of Physicians of Ireland in 1994, was elected to the Council in

2002, and was made Registrar in 2007. He is now the 141st President of the Royal College of Physicians of Ireland having been elected to office in 2014.

As President, Professor Frank Murray is the most senior College officer and leads RCPI on behalf of the Fellows and Members. Prof Murray is chair of the RCPI Policy Group on Alcohol, and a member of the RCPI EQUALS Initiative, a group which sources decommissioned equipment in Irish hospitals to send to hospitals in less developed countries. Prof Murray is also the former chair of both the Basic Specialist Training Committee and the Irish Committee on Higher Medical Training. He is actively involved in many other areas of College activities both within Ireland and internationally. Prof Frank Murray is a Consultant Physician/Gastroenterologist at Beaumont Hospital, Dublin and Associate Professor of Medicine at the Royal College of Surgeons in Ireland. Professor Murray graduated from University College Dublin in 1980 and trained in Dublin, Boston USA, and Nottingham, England. He was a Consultant Gastroenterologist in Ninewells Hospital and Medical School, Dundee, Scotland.

Professor Jan Tack,
Professor of Medicine
Head, Department of Clinical and Experimental Medicine
Head of Clinic, Department of Gastroenterology
University Hospital KU Leuven
Translational Research Center for Gastrointestinal Disorders (TARGID) Leuven, Belgium



Professor Jan Tack is currently a Head of Clinic in the Department of Gastroenterology, a Professor in Internal Medicine and head of the Department of Clinical and Experimental medicine at the University of Leuven, and a principal researcher in TARGID (the Translational Research Center for Gastrointestinal Disorders) at the University of Leuven. He graduated summa cum laude in 1987 from the University of Leuven and specialized in internal medicine and gastroenterology at the same institution. A research fellow at the Department of Physiology at the Ohio State University, Columbus, Ohio, USA, from 1989 to 1990, he has been conducting research at Leuven University since 1990. Professor Tack's scientific interest focuses on neurogastroenterology and motility, and includes diverse topics such as the pathophysiology and management of gastrointestinal functional and motor disorders (including GERD, globus, dysphagia, FD, gastroparesis, dumping syndrome, chronic constipation, IBS and opioid-induced bowel dysfunction), the physiology and pharmacology of the enteric nervous system, GI hormones and the control of satiation and food intake. He has published more than 600 articles and 40 book chapters on various aspects of scientific and clinical gastroenterology.

Professor Tack won several awards for Basic and Clinical Research in GI Science. Professor Tack is Editor-in-chief of the United European Gastroenterology Journal, Past-President of the European Society of Esophagology, Past-President of the International Society for Diseases of the Esophagus, and has served as co-editor for Neurogastroenterology and Motility, Gastroenterology, Gut and Digestion. He

serves or has served as a member of the editorial board of Gastroenterology, American Journal of Gastroenterology, Alimentary Pharmacology and Therapeutics, Journal of Internal Medicine, Bailliere's Best Practice and Research in Clinical Gastroenterology, Annals of Gastroenterology and Journal of Gastroenterology.

Dr Orla Craig,

Leeds University Hospital UK



Orla Craig is a graduate of University College Dublin. She completed an MD on immune markers in Irritable Bowel Syndrome at the Alimentary Pharmabiotic Centre, University College Cork. Upon completing her gastroenterology specialist training in Cork and Dublin, she took up an appointment as a consultant gastroenterologist at St James University Hospital, Leeds, where she has recently established a dedicated IBS clinic.

Professor Eamon Quigley,

Chief, Division Gastroenterology and Hepatology, Methodist Hospital, Texas Medical Centre, Houston



Prof Eamon Quigley, past president of the American College of Gastroenterology and the World Gastroenterology Organization, joins the faculty at The Methodist Hospital as head of its gastroenterology division. Most recently, Prof Quigley was professor of medicine and human physiology and a principal investigator at the Alimentary Pharmabiotic Centre at the National University of Ireland in Cork. He is internationally known for his research on gastrointestinal motility disorders, primarily irritable bowel syndrome (IBS); gastroesophageal reflux disease (GERD); neurogastroenterology (the relationship between the central nervous system and the gut); and probiotics in health and disease. A highlight of his ongoing research includes how bacteria in the digestive tract play a major role in pulling nutrients from food to nourish the body, as well as participating in protecting the body from disease. He has published more than 600 peer-reviewed articles, reviews, editorials, book chapters and case reports, mostly in the areas of gut motility, functional gastrointestinal disorders, and GERD. Quigley has received numerous international honors and awards. He served as Editor-in-Chief of the American Journal of Gastroenterology from 1997 to 2003.

Professor Quigley received his medical degree from University College Cork in Cork, Ireland; completed internal medicine residency in Glasgow, Scotland; and did GI fellowship training at the Mayo Clinic and the University of Manchester in England. He served as the Chief of Gastroenterology at the University of Nebraska from 1991 to 1998 and as Dean of the Medical School in Cork, Ireland from 2000 to 2007.

Dr Sara Hedderwick,

Belfast trust. NI



Dr Sara Hedderwick has been a consultant in Infectious Disease and General Medicine in the Belfast Health & Social Care Trust since 2001. She qualified in Medicine from Cambridge University and St Bartholomew's Hospital in 1990, completing her junior doctor training in Guy's Hospital before graduating from the Infectious Disease Fellowship programme at the University of Michigan, USA. Her special interests include fungal infections. The infectious disease unit in Belfast treats the majority of extrapulmonary and complicated tuberculosis within the Province.

Professor Jack Satsangi,

Edinburgh UK



Jack Satsangi combines clinical gastroenterology, in which his main focus is the management of inflammatory bowel disease, with an extensive programme of academic activities - including basic, clinical and translational research. His main clinical interests include the efficacy and safety of biological agents, and management of childhood-onset disease in adulthood. Major active research interests include IBD genetics, epigenetics and biomarker discovery, and a series of clinical trials - most notably in post-operative prophylaxis, stem cell transplantation, and drug withdrawal. He is a PI of the UKIBD Genetics Consortium, and founder member of the International IBD Genetics Consortium. He co-chaired the Working Party involved in the Montreal Classification of IBD in 2005. He established the first BSG IBD Research Strategy committee in 2009/2010, and the IBD Clinical Studies Group as the founding chairman, responsible for drafting 2010 research agenda. He served as Secretary to the BSG IBD Section, heavily involved in re-writing the current Clinical Guidelines. He has mentored or trained several of the highly productive group of research-active IBD clinicians in Scotland. He is a Medical Advisor to CCUK in Scotland, and chaired the National NIHR GI Speciality Group.

Dr David Kevans,

St James Hospital. Dublin



Dr Kevans graduated with an Honours Medical Degree in 2001 from University College Dublin. He undertook postgraduate training on the Irish Higher Medical Training Scheme in Gastroenterology achieving Specialist Certification in 2011. He subsequently took up a three year appointment as an Advanced Fellow in Inflammatory Bowel Disease (IBD) at Mount Sinai Hospital / University of Toronto, one of the largest IBD centres in North America. During his fellowship he was also co-appointed to the Hospital for Sick Children Toronto, Adolescent IBD Transition Service and the University Health Network Toronto, Intestinal Failure Unit. He was appointed as a Consultant Gastroenterologist at St James's Hospital and a Senior Clinical Lecturer at Trinity College Dublin in September 2014. He is currently clinical lead of the IBD programme at

St James Hospital which provides both regional and tertiary level care for IBD patients. Dr Kevans has a strong research pedigree having completed 2 years of translational research during his training resulting in the awarding of a Medical Doctorate from the National University of Ireland. He also received a Canadian Institutes of Health Research award to support his research activities at the University of Toronto. His current research interests include the pharmacokinetics of monoclonal antibody therapies, biomarkers in inflammatory bowel disease, intestinal microbiota in health and disease and the impact of nutrition on gastro-intestinal health. He has presented research at numerous national and international meetings and has authored a significant number of publications.

Professor Larry Egan,
NUI Galway



Prof. Egan graduated from UCG in 1990 (M.B., B.Ch., B.A.O.), and completed internship, house officer and registrar training, based at University College Hospital Galway. He received Membership of RCPI in 1992, and Masters in Medical Science from UCG in 1994. From 1994 to 1999, at the Mayo Clinic in Minnesota he completed further training in Internal Medicine, Clinical Pharmacology & Gastroenterology, receiving American Board certification in those 3 disciplines. NUI Galway conferred an MD in 1999. Prof. Egan then undertook post-doctoral training from 2000 to 2002, in the Laboratory of Mucosal Immunology at the University of California, San Diego, before returning to the Mayo Clinic to take up a consultancy in Gastroenterology, with joint appointment in the Department of Molecular Pharmacology and Experimental Therapeutics. His research focuses on molecular characterization of signaling pathways involved in intestinal epithelial cell stress, death and malignant transformation, and optimization of personalized approaches to biological therapy. In 2005, Prof. Egan was recruited by NUI Galway and the Health Service Executive Western Region as Professor of Clinical Pharmacology/Consultant Clinical Pharmacologist and Head of the Department of Pharmacology & Therapeutics, a position he took up in August 2005. Prof. Egan has served as Interim Director of the HRB Clinical Research facility Galway, as Vice-Dean of Research at the College of Medicine Nursing and Health Sciences at NUI Galway, and as Head of the discipline of Pharmacology and Therapeutics. He was associate editor at Gut, and has been editor-in-chief of the Journal of Crohn's and Colitis since 2014.

Dr Neil McDougall,
Royal Victoria Hospital, Belfast.



Dr Neil McDougall is the Clinical Lead of the Regional Liver Unit in Northern Ireland. He graduated from Queens University Belfast and trained in the NI program before finishing with fellowships in Perth, Australia and Kings Liver Transplant Unit, London. His main clinical interests are viral hepatitis and liver transplantation.

Dr George Webster,
UCLH London



George Webster is a consultant gastroenterologist at University College London Hospitals (UCLH), and The Royal Free London. He is clinical lead for the tertiary HPB medicine service at UCLH. He trained in London and Sydney in general gastroenterology, hepatology, and interventional endoscopy.

His main clinical focus is pancreaticobiliary endoscopy, with > 60 research publications related to ERCP, cholangioscopy, IgG4-related disease, and HPB disease. He is actively involved in endoscopy training, co-author of the Oxford Handbook of Gastroenterology and Hepatology, and is director of Emdolive UK 2017 and the annual London Live Endoscopy Course.

Professor Pradeep Bhandari,
Consultant Gastroenterologist &
Professor of Gastrointestinal Endoscopy
Queen Alexandra Hospital,
Portsmouth. UK



Pradeep Bhandari is a Gastroenterologist who leads the early gastrointestinal cancer services at Portsmouth. In 2004, he went to National cancer center in Tokyo on a visiting fellowship and trained in the principles of early cancer diagnosis and endoscopic resection of superficial neoplasia. He was appointed as a Consultant Gastroenterologist in Portsmouth in 2005. He developed an early cancer service providing advanced endoscopic diagnosis and resection for upper and lower gastrointestinal neoplasia. This service provides the basis of various research projects and advanced training program apart from providing a tertiary referral service for UK.

Dr Bhandari was appointed as a Professor of Gastrointestinal Endoscopy in 2012 and heads the Gastroenterology research at Solent centre for digestive diseases in Portsmouth. His research focus has been around the use of acetic acid in diagnosis of Barrett's neoplasia, cost-effectiveness of endoscopic interventions, advanced endoscopic resections and endoscopic outcome predictors. He was awarded the Hopkins Endoscopy prize by the British Society of Gastroenterology in 2013 and has twice received the ASGE crystal award for his endoscopic work. He sits on to the BSG Endoscopy and research Committee and is a specialist advisor to NICE. He is a member of BSG, ESGE and ASGE. Dr Bhandari has authored and Co-authored several peer reviewed publications, Guidelines, Cochrane reviews and Book chapters. He has lectured at various National and International meetings. He enjoys watching football and playing Cricket and racquet sports.

Professor Brian Saunders,
St Marks Hospital, London



Professor Brian Saunders is a Gastroenterologist and specialist Gastrointestinal Endoscopist. His main clinical interests are the diagnosis, treatment and prevention of intestinal diseases through flexible endoscopy. He has performed >25,000 colonoscopies and has a particular interest in therapeutic colonoscopy especially advanced polypectomy; endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD). Much of his work also involves colonoscopic screening and surveillance of those patients at increased risk of developing colorectal cancer.

Professor Saunders was appointed to the consultant staff at St. Mark's Hospital in 1997 and became Chief of Endoscopy in 2003. In the same year he led the successful St. Mark's bid to become a National Endoscopy Training Centre and he chaired a National workgroup looking at quality assurance and performance assessment for screening colonoscopy. As Director of the Kennedy-Leigh Academic Endoscopy Unit at St. Mark's he helps supervise a team of researchers working on new techniques to improve the management of gastrointestinal diseases through the use of flexible endoscopes. World firsts include development of electromagnetic scope imaging, use of mucosal dye to enhance neoplasia detection, use of electronic imaging to characterize colonic polyps in vivo and development of novel endoscopic devices and techniques to enhance safe endoscopic polyp/early cancer resection. From 2005-2009 he was Dean of the Academic Institute at St. Mark's Hospital and since 2006 he has been Director of Bowel Cancer Screening for NW London. Professor Saunders qualified from University College Hospital in 1988 and was trained in general medicine and then gastroenterology and endoscopy in London and Melbourne Australia. He achieved MRCP in 1991 (FRCP 2002) and was awarded an MD from the University of London in 1996 for his work into "making colonoscopy easier" which formed the basis of his award for the Hopkin's Endoscopy prize from the British Society of Gastroenterology in 1996. In 2016 he was awarded an honorary FRCS for his work into minimally-invasive endoscopic surgery. He has authored/co-authored more than 150 scientific papers, written >20 book chapters and has given more than 100 invited lectures or live demonstrations of endoscopy throughout the World. In 2002 and 2015 he gave the Foundation lecture at the British Society of Gastroenterology and was the J Edward Berk lecturer at the American College of Gastroenterology in 2004. He is an International Committee Member of the American Society of Gastrointestinal Endoscopy, Committee member of the British Society of gastroenterology Endoscopy Research Group and faculty member of the European Society of Gastrointestinal Endoscopy. In 2005 he was guest editor of the journal North American Clinics of Gastrointestinal Endoscopy and has co-authored the classic text "Practical Gastrointestinal Endoscopy".

ISG Board Members

Dr Subhasish Sengupta,
Secretary ISG, Consultant
Gastroenterologist
Beaumont Hospital, Dublin / Our Lady
of Lourdes Hospital, Drogheda



Dr Subhasish Sengupta works as a Consultant Gastroenterologist at Our Lady of Lourdes Hospital, Drogheda. Dr Sengupta graduated from Calcutta University, India and subsequently obtained his MRCP (UK) in 2000. He successfully completed his Specialist Registrar training (CCST) in Gastroenterology mainly working in Mater Misericordiae and Beaumont University Hospitals Dublin in 2007. His worked on 'Adrenergic Control of Gallbladder Motility' and obtained his Masters Degree from University College Dublin (UCD) in 2007. He then undertook his Advanced Interventional Hepato-biliary fellowship at Dublin and Beth Israel Deaconess Medical Center, Boston MA, USA 2007-2008. Apart from doing general GI work between Lourdes Hospital Drogheda and Louth Hospital, Dundalk, he does hepatobiliary procedures (ERCP and EUS) at Beaumont University Hospital, Dublin.

Special Interests: Pancreaticobiliary Disease and Inflammatory Bowel Disease.

Dr Barbara Ryan,
Consultant Gastroenterologist,
Tallaght Hospital, Dublin



Barbara Ryan graduated from Trinity College Dublin in 1993. She completed her higher specialist training in Ireland during which time she completed a MSc in Molecular Medicine and also a MD in colorectal cancer biology. She did a fellowship in endoscopic ultrasound at the Klinikum Rechts der Isar, at the Technical University of Munich and then moved to a gastroenterology fellowship the University Hospital of Maastricht in the Netherlands for two years in 2001. In 2003 she took up a consultant post in Manchester Royal Infirmary before returning to Ireland in 2004 to her current post. Her research interests include colorectal cancer, IBD and IBD-related bone disease. Her clinical interests include IBD, interventional endoscopy, pancreatobiliary endoscopy and endoscopic ultrasound.

Dr Glen Doherty,
Treasurer ISG, Consultant
Gastroenterologist
St. Vincent's Hospital, Dublin



Glen grew up in Northern Ireland and graduated in Medicine at Trinity College Dublin in 1998. He was awarded his PhD by NUI in 2006 and completed his gastroenterology training in Ireland followed by an advanced IBD fellowship at Beth Israel Deaconess Medical Center and Harvard Medical School, Boston. Since 2010 he has worked as a consultant



MOVENTIG
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TREATMENT OF OPIOID-INDUCED CONSTIPATION (OIC) SHOULD BE A NO-BRAINER

Indicated for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s)* **MOVENTIG 25mg once-daily** is a PAMORA† that treats OIC at its source in the bowel with minimal impact on opioid-mediated analgesic effects on the central nervous system (CNS).¹



WHEN LAXATIVES FAIL TO RELIEVE OPIOID-INDUCED CONSTIPATION MOVE TO MOVENTIG 25mg

* Definition of laxative inadequate responder (LIR): In the two weeks prior to first study visit patients had to have reported concurrent OIC symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the pre-study period.¹

† PAMORA: Peripherally-Acting Mu-Opioid Receptor Antagonist.

REFERENCES: 1. MOVENTIG Summary of Product Characteristics.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

PRESCRIBING INFORMATION (prepared October 2016.)
Moventig® ▼ 12.5mg and 25mg film-coated tablets (naloxegol oxalate). Consult Summary of Product Characteristics (SmPC) before prescribing.

Indication: Opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s) (concurrent OIC symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the previous 2 weeks). **Dosage and administration:** Recommended 25 mg once daily. Take on empty stomach at

least 30 minutes prior to first meal of day or 2 hours after first meal of day. Crushed tablets can be mixed with water (120ml) and drunk immediately or administered via a nasogastric tube (CH8 or greater). **Renal impairment:** Moderate to severe renal impairment starting dose 12.5mg. Discontinue if side effects impact tolerability. Increase to 25mg if well tolerated. **Hepatic impairment:** Use in severe hepatic impairment not recommended. **Moderate CYP3A4 inhibitors:** Starting dose 12.5mg, can be increased to 25mg if well tolerated. **Paediatric population (<18 years):** Safety and efficacy not yet established. **Adverse effects:** Consult SmPC for full list of side effects. Very Common: Abdominal pain, diarrhoea. Common: Nasopharyngitis, headache, flatulence, nausea, vomiting, hyperhidrosis. Uncommon: Opioid withdrawal syndrome. **Contraindications:** Hypersensitivity to active substance or any of the excipients or any other opioid antagonist. Patients with known or suspected gastrointestinal (GI) obstruction or patients at increased risk of recurrent obstruction. Patients with underlying cancer who are at heightened risk of GI perforation, such as those with underlying malignancies of gastrointestinal tract or peritoneum, recurrent or advanced ovarian cancer or vascular endothelial growth factor (VEGF) inhibitor treatment. Concomitant use with strong CYP3A4 inhibitors. **Warnings and precautions:** Use with caution in patients with any condition which might result in impaired integrity of the gastrointestinal tract wall. Advise patients to discontinue therapy and promptly report if unusually

severe or persistent abdominal pain develops. Use with caution in patients with clinically important disruptions to the blood brain barrier and observe for potential CNS effects. Discontinue if interference with opioid-mediated analgesia or opioid withdrawal syndrome occurs. Use with caution in patients taking methadone. If opioid withdrawal syndrome is suspected the patient should discontinue Moventig and contact their physician. Use with caution in patients with a recent history of myocardial infarction, symptomatic congestive heart failure, overt cardiovascular (CV) disease or with a QT interval of ≥ 500 msec. Use with caution in OIC patients with cancer-related pain. **Use in pregnancy and lactation:** Not recommended. **Legal category:** POM. **Marketing Authorisation numbers:** Moventig 12.5mg x 30 tablets EU/1/14/962/001; Moventig 25mg x 30 tablets EU/1/14/962/005. **Further information available on request from the Marketing Authorisation holder:** Kyowa Kirin Ltd, Galabank Business Park, Galashiels, Scotland TD1 1QH, UK.

ADVERSE EVENT REPORTING: Adverse Events should be reported. Information about adverse event reporting can be found at www.hpra.ie. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com

KYOWA KIRIN

Date of preparation: March 2017

Code: IRE/MOV/0033

gastroenterologist at St Vincent's University Hospital in Dublin and as a senior clinical lecturer in the School of Medicine and Medical Science at University College Dublin. His research interests are in the role of innate and adaptive immunity in inflammatory bowel disease (Ulcerative Colitis and Crohns Disease) and in the importance of the host immune response in gastro-intestinal neoplasia, particularly colorectal cancer and Barrett's oesophagus. With his colleagues at the Centre for Colorectal Disease at SVUH/UCD he has an established track record in clinical research on a range of digestive disorders and is actively involved in clinical trials in IBD.

Dr Gavin Harewood

Consultant Gastroenterologist
Beaumont Hospital, Dublin



Dr Gavin Harewood is a medical graduate of National University of Ireland, Galway. Following completion of his general medical training, he moved to Rochester Minnesota where he completed a Fellowship in Gastroenterology and Hepatology along with a Masters Degree in Clinical Research in the Mayo Clinic.

He was subsequently appointed as a Consultant Gastroenterologist in the Mayo Clinic and developed a subspecialty interest in endoscopic ultrasound, health economics and clinical outcomes research. In 2006, he was appointed to his current Consultant post in Beaumont Hospital where he leads endoscopic ultrasound activities and serves as the lead Clinical Trainer in the Endoscopy Department. He also served as the Secretary for the Irish Society of Gastroenterology until 2014. In 2009, Dr Harewood completed a MBA Degree in Health Economics through the UCD Smurfit School of Business.

He has authored more than 100 publications in the peerreviewed medical literature, many dealing with the importance of resource utilisation and economics in healthcare.

Professor Humphrey O'Connor

Consultant Gastroenterologist
Clane General Hospital



A native of Cahersiveen, Co. Kerry, Prof. Humphrey O'Connor M.D., F.R.C.P.I., A.G.A.F., graduated with honours in 1977 from University College Dublin. The Gastroenterology "bug" was acquired during general medical training working for the late great Prof. Oliver Fitzgerald and the recently arrived Dr. Diarmuid O'Donoghue. Specialist training followed in the UK, firstly, in Leeds with Prof. Tony Axon and then Birmingham with Dr. Roy Cockel and Prof. Elwyn Elias. Prof. O'Connor was awarded the BSG Hopkins Endoscopy Prize in 1982. He returned to Ireland in 1989 as Consultant Physician at Tullamore General Hospital and was appointed in 2002 to Naas General Hospital, Tallaght Hospital and Clinical Professor of Gastroenterology, Trinity College Dublin. He has lectured and published widely on Helicobacter, GORD, ERCP, and pancreaticobiliary disease and retains a special interest in undergraduate clinical teaching. Away from medicine, he is a fanatical Kerry follower and plays very amateur golf.

Dr Tony C.K. Tham

MB BCh BAO, MD, FRCP, FRCPI
Ulster Hospital, Dundonald, Belfast



Dr Tham qualified from the Queen's University of Belfast's medical school. He trained as a gastroenterologist and physician in the Northern Ireland training program. He completed his training as an Advanced Gastroenterology Fellow in the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA. He has been Consultant Physician and Gastroenterologist in the Ulster Hospital, Dundonald, Belfast since 1997. During this time, he has developed gastroenterology services in the Ulster Hospital, especially in therapeutic endoscopy and ERCP. His other interests include inflammatory bowel disease (IBD). He has more than 70 publications in peer reviewed journals. He is the first author of a book entitled "Gastrointestinal Emergencies" and the third edition has just been published. He is the Guidelines Editor for Gut and on the international editorial board of Gastrointestinal Endoscopy. He has contributed to several other book chapters. He was the Head of the School of Medicine, Northern Ireland Medical and Dental Training Agency and is currently Training Program Director in general internal medicine. He sits on the Specialist Advisory Committee for general internal medicine at the Joint Royal College of Physicians Training Board. He is the secretary of British Society of Gastroenterology (BSG) clinical services and standards committee. He is the guidelines lead for the BSG. He is an examiner for the Royal College of Physicians and also Queen's University. He has assisted in obtaining funding for IBD nurses and biological therapy in N. Ireland.

Mr Jürgen Mulsow

Consultant
General and Colorectal Surgery



Jürgen Mulsow is a Consultant Surgeon in the Department of Colorectal Surgery at the Mater Misericordiae University Hospital and Clinical Lecturer in Surgery at University College Dublin. He undertook specialist training in Ireland before completing a Fellowship in Colorectal Oncology at the University Clinic in Erlangen, Germany.

His specialist interests include the treatment of colorectal and peritoneal malignancy, inflammatory bowel disease, pelvic floor disorders, and surgical education and training. He was awarded the Association of Surgeons of Great Britain and Ireland Medal for first place in the Intercollegiate Exit examination (FRCS) in 2010 and was the 2012 Association of Coloproctology of Great Britain and Ireland Travelling Fellow to the United States.

Dr Paul Lynch

Consultant Gastroenterologist
Antrim Area Hospital



Paul Lynch is a consultant gastroenterologist at Antrim, Causeway and Whiteabbey Hospitals with a particular interest in therapeutic endoscopy and ERCP. He is a graduate of Queen's University of Belfast and undertook his specialist training within the Northern Ireland Deanery which included



AFTER 20 YEARS, A NEW APPROACH IN PBC^{1,2}

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OCALIVA offers a new option for patients with inadequately controlled PBC on UDCA or as monotherapy¹

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OCALIVA is a first-in-class selective and potent FXR agonist, is thought to play a crucial role in bile acid homeostasis and pathways controlling inflammation and fibrosis^{1,3}

Proven efficacy

When OCALIVA was given in combination with UDCA,* almost 5 times as many patients achieved reductions in ALP and stabilisation of bilirubin levels at 12 months compared with UDCA alone.¹ The effects of OCALIVA were sustained over an additional 12 months of therapy in the open-label extension study⁴

OCALIVA is indicated for the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.¹ OCALIVA has a conditional licence.

*UDCA was withheld from patients intolerant to UDCA.⁴

¹35 patients receiving OCALIVA 10 mg + UDCA (48%) and 46 patients receiving OCALIVA titration + UDCA (46%) achieved the primary composite endpoint of ALP <1.67 x ULN with a \geq 15% reduction from baseline and total bilirubin \leq ULN compared with 7 patients on placebo + UDCA (10%); UDCA was withheld from patients intolerant to UDCA.⁴

Abbreviated Prescribing Information

OCALIVA[®] ▼ (obeticholic acid)

(Please refer to the Full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: OCALIVA supplied as film-coated tablets containing 5 mg and 10 mg obeticholic acid.

Indication: For the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

Dosage and administration: Oral administration. The starting dose is 5 mg once daily. Based on an assessment of tolerability after 6 months, the dose should be increased to 10 mg once daily to achieve optimal response. No dose adjustment of concomitant UDCA is required in patients receiving obeticholic acid. For cases of severe pruritus, dose management includes dose adjustment such as reduced dosage, temporal interruption or discontinuation for persistent intolerable pruritus; use of bile acid binding agents or antihistamines (see SmPC). No dosage adjustment for elderly.

Renal impairment: No dose adjustments are required. **Hepatic impairment:** No dose adjustment for mild hepatic impairment (Child-Pugh Class A). The recommended starting dosage for moderate/and severe (Child-Pugh Class B/C) hepatic impairment is 5 mg once weekly. Titrate to 5 mg and subsequently to 10 mg twice weekly (at least 3 days between doses) if patient does not achieve adequate reductions in alkaline phosphatase and/ or total bilirubin after 3 months, depending on

response and tolerability. **Paediatric population:** No data. **Contraindications:** Hypersensitivity to the active substance or any excipients. Complete biliary obstruction.

Special warnings and precautions for use: Liver-related adverse events occurring as early as within the first month of treatment; elevations in alanine amino transferase (ALT), aspartate aminotransferase (AST) and hepatic decompensation have been observed and patients should be monitored during treatment with OCALIVA. Severe pruritus; see recommendations for dosage reduction and use of bile acid binding resins or antihistamines.

Interactions: Following co-administration of warfarin and obeticholic acid, international normalised ratio (INR) should be monitored and the dose of warfarin adjusted, if needed, to maintain the target INR range. Therapeutic monitoring of CYP1A2 substrates with narrow therapeutic index (e.g. theophylline and tizanidine) is recommended. Obeticholic acid should be taken at least 4–6 hours before or after taking a bile acid binding resin, or at as great an interval as possible.

Fertility, pregnancy and lactation: Avoid use in pregnancy. Either discontinue breast-feeding or discontinue/abstain from obeticholic acid therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. No clinical data on fertility effects.

Undesirable effects: Very common (\geq 1/10) adverse reactions were pruritus, fatigue, and abdominal pain and discomfort. The most common adverse reaction leading to discontinuation was pruritus. The majority of pruritus occurred within the first month of treatment and tended to resolve over time with continued dosing. Other commonly (\geq 1/100 to < 1/10) reported adverse reactions are, thyroid function abnormality, dizziness, palpitations, oropharyngeal pain, constipation, eczema, rash, arthralgia, peripheral oedema, and pyrexia.

Overdose: Liver-related adverse reactions were reported with higher than recommended doses of obeticholic acid. Patients should be carefully observed and supportive care administered, as appropriate.

Legal category: POM

Marketing authorisation numbers: EU/1/16/1139/001 & 002

Marketing authorisation holder: Intercept Pharma Ltd, 2 Pancras Square, London, NIC 4AG, United Kingdom
Package Quantities and Basic NHS cost: OCALIVA 5 mg and 10 mg £2,384.04 per bottle of 30 tablets.

Date of revision: 20/DEC/2016

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Intercept Pharma Ltd on +44 (0)330 100 3694 or email: drugsafety@interceptpharma.com

Abbreviations. ALP, alkaline phosphatase; FXR, farnesoid X receptor; PBC, primary biliary cholangitis; UDCA, ursodeoxycholic acid.

References. 1. OCALIVA (obeticholic acid). Summary of Product Characteristics, 2016; 2. FDA Drug Approval Package: Urso (ursodiol) NDA# 020675. http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20675a.cfm [Last accessed 4 April 2016]; 3. Ding L, et al. Bile acid nuclear receptor FXR and digestive system diseases. *Acta Pharm Sin B* 2015;135-44; 4. Nevens F, et al. A Placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *N Engl J Med* 2016;375:631-43.

undertaking a PhD into gastric neuropeptides at QUB. He completed his training with an advanced endoscopy fellowship in Westmead Hospital, Sydney, Australia. Dr Lynch presently sits on the ISG board and has served as the Secretary for the USG from 2009 to 2012 as well as being the organizing chair for the joint BSG and ISG (BIG) meeting held in Belfast in 2013. He has been involved in regional service development for Northern Ireland including services for standardizing the testing of calprotectin and H. pylori and has been the clinical lead for a regional endoscopy reporting program.

Professor Deirdre McNamara
Consultant Gastroenterologist
Tallaght Hospital, Dublin



Prof. Deirdre McNamara is an Academic Consultant Gastroenterologist at Trinity College Dublin based in Tallaght Hospital. BA Graduate of Trinity College Dublin 1993 Member Royal College of Physician's 1997 MD Trinity College Dublin 2002 Diploma in Cancer Prevention, National Cancer Institute USA 2002 Fellow Royal College of Physician's of Edinburgh 2005 Fellow Royal College of Physician's of Ireland 2010. Her sub-specialty interests include inflammatory bowel disease, obscure GI bleeding, capsule endoscopy and colorectal cancer prevention. She provides capsule services for the greater Leinster region and a national double balloon enteroscopy service. As Co-Founder and Director of Trinity's TAGG Research Centre she has successfully lead a variety of translational research initiatives in her areas of expertise with funding from the Health Research Board, Irish Cancer Society, European Society of Gastrointestinal Endoscopy and the Meath Foundation. Consultant Gastroenterologist & Honorary Senior Lecturer Aberdeen Royal Infirmary and University of Aberdeen 2004-2009. European Society of Gastrointestinal Endoscopy Small Bowel Quality Improvement Committee 2013 –to date. Director TAGG Research Centre, Trinity College Dublin 2012-to date. Head of Department of Clinical Medicine, Trinity College Dublin 2011-2014

Dr David Gibson
Specialist Registrar
St James' Hospital, Dublin



David is a gastroenterology SpR, currently in St James' Hospital, Dublin. He completed his MD entitled 'Optimising Anti-TNF therapy in IBD' in 2014. His interests include IBD and lower GI endoscopy. Outside of work, he is a diehard Newcastle United fan.

USG Committee Members

Dr Patrick Allen
Consultant Gastroenterologist
Secretary USG



Dr Patrick Allen is a Consultant Gastroenterologist working in the South East Trust. He graduated from Queen's University of Belfast in 2002. He completed his training in NI and completed a fellowship in St Vincent's Hospital, Melbourne in Endoscopy and IBD. He has been

Secretary for the Ulster Society of Gastroenterology since 2012 and was on the organising committee for the BIG Meeting held in the Waterfront Hall in 2013. His main interests are IBD and Endoscopy.

Dr Jenny Addley
Consultant Gastroenterologist
Treasurer USG



Dr Jenny Addley Graduated from Trinity College Dublin in 2002 and completed her Gastroenterology Training in Northern Ireland Deanery. She is currently employed as a Consultant Gastroenterologist in the Ulster Hospital, Dundonald. Within Gastroenterology, Jenny has an interest in Hepatology and Quality Improvement, is a member of the Faculty of Medical Leadership and Management and has recently been appointed Alcohol Care Team Lead for the South Eastern Trust. Jenny is also involved with the BSG SWiG group (Supporting Women in Gastroenterology) and currently participates in their Mentorship Programme for new consultants.

Mr Eamon Mackle
Consultant Surgeon Southern Trust



Eamon Mackle admits to being a Surgeon, albeit with interests in GI Surgery and the pelvic floor. He has been a Consultant in Craigavon Area Hospital since 1992. He is President of the Ulster Society of Gastroenterology and is a Past President of the Ulster Medical Society. He is a past member of council of AUGIS. He is an Undergraduate examiner for QUB, RCSI and the Medical University of Bahrain. He is a member of the Intercollegiate Committee for Basic Surgical Examinations as well as a member of the OSCE Subgroup and ViceChair of the IMRCS Paper Panel.

Dr Helen Coleman
Senior Lecturer Queen's University Belfast



Dr Helen Coleman is a Senior Lecturer in Cancer Epidemiology at the Centre for Public Health at Queen's University Belfast, and previously studied there during her PhD and postdoctoral research projects. She has also spent time conducting research at Vanderbilt University, Nashville, TN, USA, Ulster University, and at the MRC-Human Nutrition Research centre in Cambridge, England. Dr Coleman's general research interests are in cancer epidemiology, particularly modifiable risk factors for progression from pre-cancerous conditions to cancer and factors associated with recurrence or survival after a cancer diagnosis. She is also involved in health services research projects that aim to optimise how individuals are treated and followed-up after a diagnosis of a pre-malignant condition or cancer, including analysis of Northern Ireland Bowel Cancer Screening data. Her strong interests are in cancers of the digestive tract, especially colorectal polyp/cancer, and oesophageal adenocarcinoma/Barrett's oesophagus epidemiology.



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Prescribing Information - UK

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Active ingredient: Ferric carboxymaltose (50mg/mL).
Presentation: Solution for injection/infusion. Available as a 2mL vial (as 100mg of iron), 10mL vial (as 500mg of iron) and 20mL vial (as 1000mg of iron).
Indication: Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.
Dosage and Administration: The posology of Ferinject follows a stepwise approach. Step 1: Determination of the iron need; The individual iron need for repletion using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level. The table in the SmPC should be used to determine the cumulative iron dose. Step 2: Calculation and administration of the maximum individual iron dose(s); Based on the iron need determined, the appropriate dose(s) of Ferinject should be administered: A single Ferinject administration should not exceed: • 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion) The maximum recommended cumulative dose of Ferinject is 1,000 mg of iron (20 mL Ferinject) per week. Administration rates for intravenous injection: For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered 100mg iron/min. For doses >500mg to 1,000mg, the minimum administration time is 15 min. Administration of intravenous drip infusion: For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered in a minimum of 6 mins. For doses >500mg to 1,000mg, the minimum administration time

is 15 mins. Ferinject must be diluted in 0.9% m/v NaCl but not diluted to concentrations less than 2 mg iron/mL. Step 3: Post-iron repletion assessments.
Contraindications: Hypersensitivity to Ferinject or any of its excipients. Known serious hypersensitivity to other parenteral iron products. Anaemia not attributed to iron deficiency. Iron overload or disturbances in utilisation of iron.
Special warnings and precautions: Parenterally administered iron preparations can cause potentially fatal anaphylactic/anaphylactoid reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. Ferinject should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Careful monitoring of iron status is recommended to avoid iron overload. There is no safety data on the use of single doses of more than 200mg iron in haemodialysis-dependant chronic kidney disease patients. Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that treatment with Ferinject is stopped in patients with ongoing bacteraemia. In patients with chronic infection a benefit/risk evaluation has to be performed.

Caution should be exercised to avoid paravenous leakage when administering Ferinject. **Special populations:** The use of Ferinject has not been studied in children. A careful risk/benefit evaluation is required before use during pregnancy. Ferinject should not be used during pregnancy unless clearly necessary and should be confined to the second and third trimester. **Undesirable effects:** Common (>1/100 to <1/10): Headache, dizziness, hypertension, nausea, injection site reaction, alanine aminotransferase increased, hypophosphataemia. Please consult the SmPC in relation to other undesirable effects. **Legal category:** POM **Price:** pack of 5 x 2ml = £81.18; pack of 5 x 10ml = £405.88 pack of 1 x 20ml = £154.23 **MA Number:** 15240/0002 **Date of Authorisation:** 19.07.2007 **MA Holder:** Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France **Further details available from:** Vifor Pharma UK Limited, The Old Stables, Bagshot Park, Bagshot, Surrey GU19 5PJ T: +44 1276 853 600 F: +44 1276 452 341 medicallinfo_UK@viforpharma.com Ferinject® is a registered trademark. Date of revision: 07/16

Adverse events should be reported.
Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard
Adverse events should also be reported
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References:

1. Vifor Pharma UK, Data on File 85
2. Ferinject Summary of Product Characteristics
3. Ponikowski P *et al.* Eur Heart J 2016; 37 (27): 2129-2200
4. Evstatiev R *et al.* Gastroenterology. 2011; 141(3): 846-53
5. Kulnigg S *et al.* Am J Gastroenterol. 2008; 103(5): 1182-92
6. Ponikowski *et al.* Eur Heart J. 2015; 36(11): 657-68

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Code: UK/FER/17/0080
Date of preparation: March 2017

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1999-2002	Dr John Collins
1997-1998	Dr Paud O'Regan
1995-1996	Dr Diarmuid O'Donoghue
1993-1994	Mr Gerry O'Sullivan (R.I.P.)
1991-1992	Dr Tom O'Gorman
1989-1990	Professor Tom PJ Hennessy
1987-1988	Dr Michael J Whelton
1985-1986	Professor TG Parks
1983-1984	Mr Joseph McMullin (R.I.P.)
1981-1982	Dr John Fielding (R.I.P.)
1979-1980	Mr Sean Heffernan (R.I.P.)
1977-1978	Dr Robert Towers (R.I.P.)
1975-1976	Professor Donald Weir
1973-1974	Professor Ciaran McCarthy
1971-1972	Professor Patrick Collins (R.I.P.)
1969-1970	Professor Peter Gatenby
1967-1968	Dr Byran G Alton (R.I.P.)
1964-1966	Professor Patrick Fitzgerald (R.I.P.)
1962-1964	Professor Oliver Fitzgerald (R.I.P.)

Organising Team

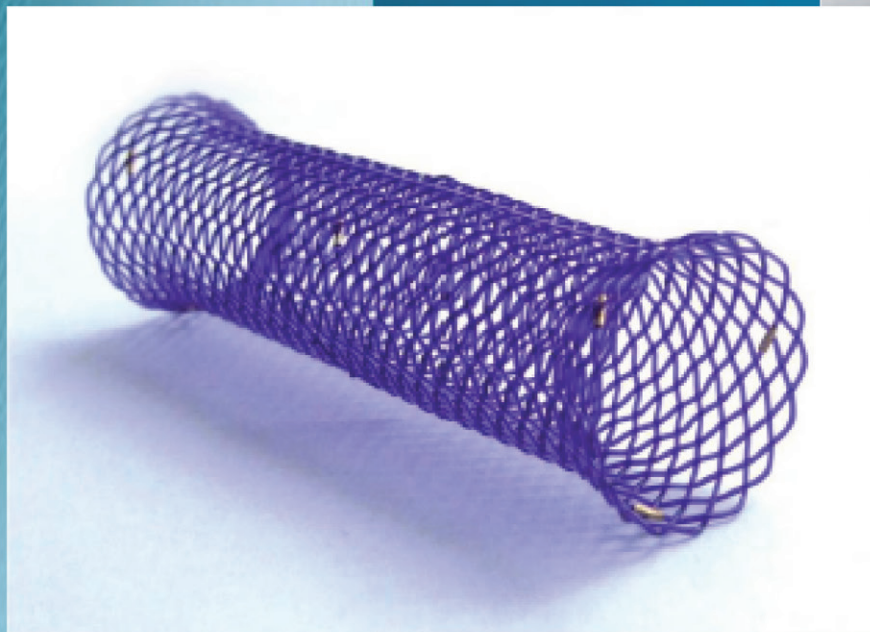


Michael Dineen
Chief Exec ISG
Trading as MCM Ltd

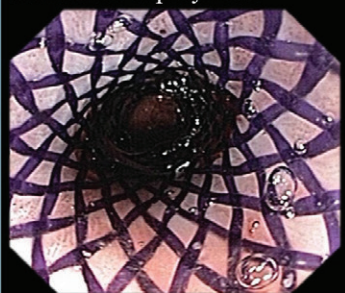


Cora Gannon
Administrator ISG/USG

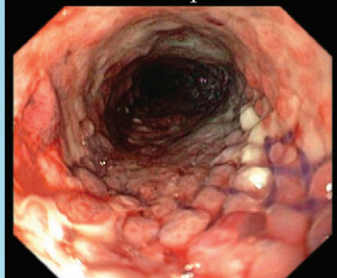
ELLA (BD) Biodegradable Stent



Stent after deployment



4 weeks after implantation



The BD Stent is designed for treatment of benign oesophageal strictures, (peptic, anastomotic, caustic), and achalasia resistant to standard therapy.

(Clinical references available)

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Oral Presentations - BIG Meeting 2017

Abstract No.	Ref. No.	Title of Paper:	Name	Date	Time
1	17BIG115	Real World Experience In Treating Chronic Hepatitis C With Direct Acting Antivirals (DAAs) In Northern Ireland	Hannah McCaughan	Thurs 27th	11.30
2	17BIG116	Use Of "Assessment For Retreatment With TACE (ART)" score to ensure appropriate patient selection: A retrospective review of TACE re-treatment in the Northern Ireland regional TACE service.	Lisa McNeill	Thurs 27th	11.40
3	17BIG218	Mortality On Orthotopic Liver Transplantation Waiting List at National Liver Transplant Unit Ireland	Brian Christopher	Thurs 27th	14.15
4	17BIG242	The hidden burden of hepatitis C related advanced liver disease in the community	Nadeem Iqbal	Thurs 27th	14.25
5	17BIG119	Outcomes following Anti-TNF discontinuation and the risk of relapse in Inflammatory Bowel Disease; A single centre experience.	Lisa Coffey	Fri 28th	10.35
6	17BIG251	The Clinical and Financial Impact of Measuring Infliximab Levels and Antibodies to Infliximab in Inflammatory Bowel Disease Patients	Susanne O'Reilly	Fri 28th	10.45
7	17BIG221	Does the level of a negative 1st round FIT predict subsequent pathology in a colorectal cancer screening programme?	David Gibson	Fri 28th	12.15
8	17BIG239	Lower Gastrointestinal Symptoms In Young Patients: Can Symptoms And Non-invasive Tests Be Used Systematically To Avoid Unnecessary Colonoscopies?	Alaa Alakari	Fri 28th	12.25

Oral Presentation

1 REAL WORLD EXPERIENCE IN TREATING CHRONIC HEPATITIS C WITH DIRECT ACTING ANTIVIRALS (DAAs) IN NORTHERN IRELAND

H McCaughan*, L Stratton, K Patterson, O McCormick, G Wasson, I Cadden, J Cash, R McCorry, N McDougall. *Regional Liver Unit, Royal Victoria Hospital Belfast, UK*

10.1136/gutjnl-2017-314127.1

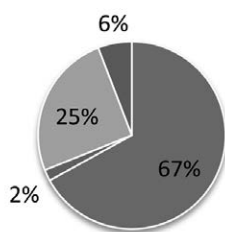
Background Oral direct acting antiviral (DAA) treatments for hepatitis C virus (HCV) have emerged in recent years and show excellent results regarding side effects and clearance of the virus (defined as negative HCV PCR 12 weeks after completion of therapy or SVR12).

Aim To assess response to new DAAs in Northern Ireland according to genotype, presence of cirrhosis, and previous treatment.

Method Treatment outcomes were reviewed for all patients treated with a DAA for chronic HCV in Northern Ireland from March 2015 until July 2016.

Results 105 treatments were given to 104 patients (1 patient treated twice) - 68 males, 41 cirrhotic, and 67 with previous treatment failure. Genotype prevalence is shown in Fig 1. 89 received all oral DAA therapy (44 Abbvie product, 28 Harvoni +/- ribavirin, 15 sofosbuvir/daclatasvir/ribavirin) and 16 received sofosbuvir + Peg interferon + ribavirin. Overall 100 (95%) treatments were successful and achieved SVR 12. Three patients (all cirrhotic genotype 1 with prior treatment failure) stopped treatment (Abbvie) within 3 weeks due to decompensation, one of whom achieved SVR12 with subsequent treatment. 1 patient failed with sof/peg/riba and 1 patient failed to attend for SVR12 check (negative at end of treatment).

■ Genotype 1 ■ Genotype 2 ■ Genotype 3 ■ Genotype 4



Abstract 1 Figure 1

Conclusions In our experience, all-oral DAA therapy is highly efficacious provided patients can complete the course. Caution is required with cirrhotic patients even if well compensated before treatment.

2 USE OF "ASSESSMENT FOR RETREATMENT WITH TACE (ART)" SCORE TO ENSURE APPROPRIATE PATIENT SELECTION: A RETROSPECTIVE REVIEW OF TACE RETREATMENT IN THE NORTHERN IRELAND REGIONAL TACE SERVICE

L McNeill*, L Stratton, PT Kennedy, IS Cadden, WJ Cash, R McCorry, NI McDougall. *Royal Victoria Hospital, Belfast, UK*

10.1136/gutjnl-2017-314127.2

Background The "Assessment for Retreatment with TACE (transarterial chemoembolization)" (ART) score was developed to determine suitability for additional TACE treatment in patients with hepatocellular cancer - it utilises AST, absence of radiological response and Child-Pugh score following initial procedure. Those with a score of <1.5 gain benefit whereas those scoring ≥ 2.5 do not.

Aim To determine whether the ART score successfully predicted those patients who did and did not have repeat TACE for HCC.

Method Retrospective application of ART score to all patients undergoing TACE at the Royal Victoria Hospital, Belfast from March 2011 until July 2016.

Results 99 patients had TACE during the study period of whom 64 had a second TACE. The ART score was ≥ 2.5 in 22 of the 64 and therefore ART score would have excluded one third of retreatments. Of the 35 patients who just had a single TACE treatment, further TACE was not required in 11 (disease was stable in 8 patients, 2 underwent alternative treatments (1 transplant, 1 segmentectomy) and 1 refused). Of the remaining 24 patients not offered repeat TACE, 18 (75%) had an ART score of ≥ 2.5 and 6 were deemed unfit for other reasons (2 demonstrated disease progression not accounted for by ART score, 2 had significant comorbidities and 2 experienced complications following the initial procedure).

Conclusions The ART score successfully identified three quarters of patients deemed unsuitable for repeat TACE treatment. However, if applied ART would have excluded one third of patients who had a successful second TACE.

3 MORTALITY ON ORTHOTOPIC LIVER TRANSPLANTATION WAITING LIST AT NATIONAL LIVER TRANSPLANT UNIT IRELAND

BT Christopher*, MS Ismail, C Kiat, E Tatro, Y McGarry, R MacNicholas, PA McCormick, D Houlihan. *Department of Hepatology, National Liver Transplant Unit, St Vincent's University Hospital, Dublin, Ireland*

10.1136/gutjnl-2017-314127.3

Background Orthotopic liver transplantation is indicated in patients with end-stage liver disease, hepatocellular carcinoma (HCC) within transplant criteria and acute fulminant hepatic failure. Progression to end stage liver failure with high mortality is inevitable without transplantation.

Aim Our aim is to analyse mortality aspects on our OLT waiting list. This retrospective study included patients' cohort over 3 years from January 2014 to December 2016. During this time period, there were 163 patients transplanted.

Method Data was collected from database and patients' medical records.

Results There were 21 deaths (6 females, 15 males) with 8 patients delisted and 4 suspended. The median patients' age was 50. Nine patients (43%) died on waiting list. Of these, three were listed as super-urgent for fulminant hepatic failure (2 acetaminophen overdose 1 autoimmune hepatitis). Median duration on waiting list to death was 3.6 months. There was one patient followed up regularly with 16 months duration on waiting list. The remainder waiting duration was single figured in months. The average MELD score at time of listing was 19(7-53). Causes of death include multi-organ failure (n=5), coroner's case (n=4), end stage liver failure progression (n=4), bleeding oesophageal varices and sepsis (n=1), metastatic cancer recurrence (n=1) and not documented in 6

others. Aetiology of liver disease subgroups are shown in Table 1 (attached). There were 10 patients each in blood group O and A and 1 in blood group B.

Conclusions Limited organ availability and increasing demand for organ transplantation has extended transplant waiting times, thus increased morbidity and mortality for potential recipients.

Abstract 3 Table 1 Aetiology of liver disease in OLT waiting list 2014–2016

Aetiology	Number of Patients
Alcoholic liver disease (ALD)	5
Viral (hepatitis C virus, HCV)	3
ALD/HCV	3
ALD/HCC	2
Autoimmune	2
Acetaminophen overdose	2
Cholestatic liver disease (Primary sclerosing cholangitis, PSC)	1
HCV/HCC	1
metabolic (Non-alcoholic steatohepatitis)	1
PSC/cholangiocarcinoma	1

4 THE HIDDEN BURDEN OF HEPATITIS C RELATED ADVANCED LIVER DISEASE IN THE COMMUNITY

N Iqbal*, C Murphy, T McHugh, A Singleton, S Keating, J Flanagan, G Hawthorne, D Crowley, H Gallagher, F Savage, J Maloney, JS Lambert, S Stewart. *Department of Gastroenterology and Hepatology, Mater Misericordiae University Hospital, Dublin, Ireland*

10.1136/gutjnl-2017-314127.4

Background In Ireland there are large numbers of HCV+ve patients receiving methadone in drug treatment centre (DTCs) who do not attend hepatology services. Most of these patients have never had their liver disease staged. Fibroscan (FS) is a non-invasive tool to assess liver stiffness which correlates closely with hepatic fibrosis. Clinically relevant cut-offs are 8.5 kPa (access to DAAs in Ireland), 25 kPa (significant portal hypertension) and 35 kPa (10%–20% risk of decompensation per year).

Aim To use FS to risk stratify patients receiving methadone in Dublin DTCs.

To determine the impact of active alcohol consumption on FS score.

Method We performed FS on sequential clients receiving methadone in the six larger Dublin DTCs regardless of their HCV status. Clients were also asked regarding alcohol intake and grouped as being –abstinent or not abstinent.

Results A total of 618 consecutive patients (75% male, mean age 38±7.2) were assessed. HCV status was known in 91% (561) of patients with 70% (391) being HCV+ve. The mean FS score was higher in HCV+ve patients than HCV–ve (11.0 kPa ±12.4 vs 5.6 kPa ±4.0; p=0.001). In HCV+ve group, patients that drank alcohol (35%) had a higher score than those that were abstinent (13.2 kPa ±16.4 vs 9.7 kPa ±9.9; p=0.02). There were 128 (33% of total cohort) HCV+ve patients with FS ≥8.5 kPa, 34 (9%) with FS ≥25 kPa and 21 (5%) with FS ≥35 kPa.

Conclusions This study has identified a large number of HCV +ve patients that do not attend hepatology services yet qualify for DAAs. Within this group there are significant numbers of

patients at high risk of decompensation. On-going alcohol use is associated with a significantly higher FS score.

5 OUTCOMES FOLLOWING ANTI-TNF DISCONTINUATION AND THE RISK OF RELAPSE IN INFLAMMATORY BOWEL DISEASE; A SINGLE CENTRE EXPERIENCE

L Coffey*, A Mullen, J Leyden, P MacMathuna. *Mater Misericordiae University Hospital*

10.1136/gutjnl-2017-314127.5

Background Crohn's disease (CD) and Ulcerative Colitis (UC) are chronic inflammatory bowel (IBD) conditions that result in fluctuations of disease activity. Infliximab and Adalimumab are well-established agents associated with inducing and maintaining remission in IBD. Long term use of this agent has an associated risk profile and significant healthcare budget implications.

Aims The aim was to identify patients in remission suitable for discontinuation of anti-TNF therapy and follow their clinical course to identify the patients who maintained a clinical remission

Methods A single centre retrospective of our 1000 IBD patients. We reviewed IBD cohort on Anti TNF therapy. Analysis of colonoscopy findings and patient symptoms at time of discontinuation was performed and subsequent clinical follow following withdrawal of therapy.

Results We identified 65 patients on Infliximab. 37 (57%) have UC and 28 (43%) have CD. Following a mean treatment interval of 41 months Infliximab therapy was discontinued in 19 (29%) patients. Of the discontinuation cohort 11 (58%) patients had UC, 6 (31.5%) had CD 2 (10.5%) were indeterminate colitis. During a follow up of 36 months 18 (95%) remained in clinical remission, while 1 (5%) relapsed. We identified 198 patients on Adalimumab in our cohort for treatment of CD. Of this cohort 3 (1.5%) were discontinued as they were in clinical remission. The follow up for this arm was 50 months. There have been 2 (66%) relapses in this group.

Conclusions Successful remission was achieved in 95% of our Infliximab cohort and 33% of our Adalimumab cohort resulting in fewer hospital admissions, improvement in patient quality of life and decreased healthcare costs that are associated with provision of both maintenance and rescue therapy for flares of disease.

6 THE CLINICAL AND FINANCIAL IMPACT OF MEASURING INFLIXIMAB LEVELS AND ANTIBODIES TO INFLIXIMAB IN INFLAMMATORY BOWEL DISEASE PATIENTS

S O'Reilly*, D Keegan, K Byrne, J Sheridan, HE Mulcahy, GA Doherty, G Cullen. *Centre for Colorectal Disease, St Vincent's University Hospital, Elm Park, Dublin, Ireland*

10.1136/gutjnl-2017-314127.6

Background Approximately 150 IBD patients are currently on infliximab (IFX) at our centre, costing over €2 million in 2016. IFX drug and antibody level measurement was introduced in 2015.

Aim To analyse the clinical and financial impact of measurement of IFX levels and antibodies to IFX (ATI) in 2016.

Method IBD patients with IFX levels and ATI measured between Dec 2015 and Dec 2016 were identified from

laboratory records and an IBD database. The results and clinical reaction to the levels were recorded.

Results 93 (55 Crohn's, 38 UC) patients had levels checked. More than one measurement was made in 25. 37 had subtherapeutic levels (<3 mg/ml), five with ATI. 10 had dose escalation and seven stopped IFX. The remainder were in clinical remission and maintained on current dose. 34 had supertherapeutic levels (>7 mg/ml): 12 had dose reduction and six stopped IFX. The remainder were maintained on current dose. 22 had therapeutic levels (3-7mg/ml): 13 were maintained on current dose, two dose escalated, five dose reduced and two stopped IFX. 76% of IBD patients on IFX had supertherapeutic or subtherapeutic levels. Of these, 41% had a medication/dose change in response to these results. 11% stopped IFX. Projected savings in our centre are €85 000 in 2016.

Conclusions Initial analysis suggests significant cost savings with IFX level measurement, although decisions on IFX dosing are not made on levels in isolation and alternative treatment options may be equally or more expensive. A prospective study would help clarify the true cost savings.

7 DOES THE LEVEL OF A NEGATIVE 1ST ROUND FIT PREDICT SUBSEQUENT PATHOLOGY IN A COLORECTAL CANCER SCREENING PROGRAMME?

DJ Gibson*, T Mooney, J Mooney, D O'Donoghue. *BowelScreen, the National Colorectal Cancer Screening Programme, Ireland*

10.1136/gutjnl-2017-314127.7

Background BowelScreen is based on faecal immunohistochemistry test (FIT); current threshold for positive FIT is 225 ng Hb/mL. During 1st round of screening referral rate for colonoscopy is 5%. Concerns for a higher cut-off compared to some other screening programmes are that significant pathology could be missed but this has to be balanced against overstretched endoscopy departments.

Aim To examine patients who initially have a negative FIT, which subsequently becomes positive in the second round, and correlate quantitative initial FIT to pathology encountered.

Method Retrospective review of all patients with a negative 1st round FIT subsequently becoming positive was performed. In BowelScreen, surveillance interval for adenomas detected is based on ESGE guidelines, categorising patients as high risk intermediate risk or low risk. For this study, 'advanced pathology' (AP) was classified as cancer high risk and intermediate risk adenomas. The initial negative FIT values were divided into 4 groups: 0 (group 1), 1-75 (group 2), 76-150 (group 3) and 151-225 ng Hb/mL (group 4).

Results 488715 individuals were screened in round 1, 95% of whom had a negative FIT. 3.6% were FIT positive in round 2; 295 have proceeded to colonoscopy. 38 patients had an initial FIT in group 1, 208 in group 2, 31 in group 3 and 18 in group 4. 70 patients (24%) were classed as AP (CRC n=16, high risk polyps n=10, medium risk polyps n=44), while 225 (76%) had NAP. We observed a stepwise increase in amount of AP encountered with increasing initial FIT. Group 1: 4/38 (11%); group 2: 50/208 (24%); group 3: 10/31 (32%); group 4: 6/18 (33%). When grouped as a whole, the median initial FIT

for AP was 40 vs 17 ng Hb/mL for NAP ($p < 0.0001$). Initial negative FIT was a better predictor of AP than the 2nd round positive FIT.

Conclusions There is a clear correlation between level of FIT and pathology encountered, even when the FIT is negative.

8 LOWER GASTROINTESTINAL SYMPTOMS IN YOUNG PATIENTS: CAN SYMPTOMS AND NON-INVASIVE TESTS BE USED SYSTEMATICALLY TO AVOID UNNECESSARY COLONOSCOPIES?

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10.1136/gutjnl-2017-314127.8

Background Colonoscopies in young patients presenting with lower GI symptoms are often normal. Avoidance of colonoscopy in such instances reduces patient risk exposure and rationalises limited resource utilisation.

Aim To assess colonoscopy outcome, relevant faecal and blood tests in young symptomatic patients.

Method Colonoscopies performed over 1 year were retrospectively identified from the ERS. Patient charts, faecal calprotectin (FC) and CRP were reviewed. A raised CRP or FC of ≥ 50 ug/g was considered abnormal. Inclusion and exclusion criteria are in table 1.

Abstract 8 Table 1 Study criteria

Inclusion criteria	Exclusion criteria
Age < 45 years	Known Iron deficiency anaemia
Presenting complaint: diarrhoea, constipation and abdominal pain/bloating	Overt or obscure GI bleeding
	Known Inflammatory Bowel Disease

Results 242/2155 medical GI outpatient colonoscopies performed over 12 months met inclusion criteria for the study. Median age 34 years (range 16-45), 141 (58%) female. Indications; (Group A) diarrhoea 132/242 (55%), (Group B) constipation, abdominal pain/bloating 110/242 (45%). Colonoscopy was normal in 104 (79%) of Group A and 102 (93%) of Group B ($p = 0.002$). 28/36 (78%) patients with mucosal inflammation confirmed on histology had diarrhoea ($p = 0.0001$). FC was available in 36 patients, and CRP in 171. In group A the NPV, sensitivity and specificity of CRP/FC were 88%, 42% and 86%. In group B these figures were 95%, 38% and 95%. 21 patients had incidental early adenomatous polyps.

Conclusions Colonoscopy has very low yield in young symptomatic patients, especially those with non-diarrhoeal symptoms. Non-invasive tests should be used systematically to better identify patients requiring colonoscopy. We are conducting a prospective study to explore non-invasive diagnostic paradigms. Implementation of these strategies will help reduce colonoscopy waiting times.

Poster Presentation

9 TRANSFORMING TRANSITION FOR PAEDIATRIC IBD PATIENTS IN NORTHERN IRELAND

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10.1136/gutjnl-2017-314127.9

Background The Paediatric Gastroenterology team in Belfast has been continuously developing their service to facilitate efficient transfer of adolescent care to Adult Gastroenterology. Initially this process was by referral letter only however, in view of the increasing prevalence of Inflammatory Bowel Disease (IBD), establishing a well-structured transition clinic was essential. We sought to elucidate the level of preparedness for, and experience at, transition clinic from our adolescent attendees.

Method We devised a questionnaire which was distributed to all adolescent patients attending transition clinic over a six month period, which they completed anonymously. Data was then collated.

Results Of the twenty two patients surveyed 100% rated the quality of care at transition clinic as excellent or good. 100% agreed they were well supported by the medical and nursing staff present, 82% of which agreed the clinic adequately prepared them for moving to Adult Gastroenterology care. However, only 50% of patients knew their medication names and doses. 32% wanted more advice regarding symptom management and investigations. 75% of patients had ongoing dietetic and psychology input. Concern regarding continuity of these valuable services and the loss of a supportive relationship with the paediatric nurse specialist were the main perceived stressors and anxieties for our patient cohort.

Conclusions Over the last eight years the Paediatric Gastroenterology team has successfully established transition clinics with all five trusts across the province. Collaboration between the Paediatric and Adult Gastroenterology teams in Northern Ireland has transformed the continuity, safety and patient experience for young people with IBD transitioning between our expert services.

10 GRANULOCYTE/MONOCYTE APHERESIS AS MAINTENANCE THERAPY IN CROHN'S DISEASE

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10.1136/gutjnl-2017-314127.10

Background Granulocyte, monocyte apheresis (GMA), extracorporeal absorptive circuit used to treat acute ulcerative colitis (UC) and Crohn's disease. Use in maintenance therapy following remission is uncertain.

Aim To present the outcomes following treatment of 5 patients with maintenance GMA for Crohn's disease.

Method Notes review of patients. Assessed blood results (full blood count, albumin, c-reactive protein) faecal calprotectin (FC), imaging and subjective patient reporting to determine the response

Results 5 patients (P) were included, of whom: 4 were male, mean age 37.4 (24–57) years. All received previous conventional therapies with no or limited effect or had lost response.

All had 8 treatments at weekly intervals as acute therapy followed by maintenance at monthly intervals. P1 (30 year old male, small bowel (SB) Crohn's), 40 columns, consistent normalisation in all markers and FC (from >600 to 248), reversal of temporary colostomy, improvement on MRE, subjective improvement. P 2 (46 year old male, SB Crohn's) 12 columns, consistent improvement in bloods, subjectively in remission. P3 (24 year old male, Crohn's colitis) 9 columns, initial subjective improvement, bloods unchanged from baseline but normal, switched to vedolizumab. P4 (30 year old male, SB Crohn's) 5 columns, no subjective change, stopped. P5 (57 year old female, SB Crohn's) 4 columns, improvement in C-reactive protein, others consistently normal, no change from baseline, subjective improvement but stopped.

Conclusions Five patients received maintenance therapy. Consistent biochemical/subjective symptomatic remission was achieved in two (P1 and 2), subjective remission in a third (P5) but no response in P3 and 4. Remission appeared to continue in those with elevated baseline markers of inflammation. SB Crohn's may respond better than colitis. GMA may have a role as maintenance therapy.

11 HAEMOSTATIC RADIOTHERAPY IN GASTRO-OESOPHAGEAL CANCER: REFERRAL PATTERNS AND TREATMENT EFFICACY

¹G Walls, ^{1,2}R Turkington, ¹C Harrison. ¹Upper GI Clinical Oncology, Belfast City Hospital Cancer Centre, Belfast, Co Antrim, UK; ²Centre for Cancer Research and Cell Biology, Queen's University Belfast, Belfast, Co Antrim, UK

10.1136/gutjnl-2017-314127.11

Background Haemorrhage from unresectable gastric and oesophageal malignancies reduces quality of life, shortens survival, and is associated with considerable burden for blood banks.

Aim The purpose of this study was to evaluate the outcomes of radiotherapy (RT) in achieving haemostasis, and to describe referral patterns to the Clinical Oncology team.

Method Retrospective analysis of all patients with gastro-oesophageal cancer that received RT with haemostatic intention from 2013–2016 in Northern Ireland. Only patients who required packed red cell transfusions were included. Study endpoints included improvement in haemoglobin (Hb) and transfusion requirement.

Results Haemostatic RT was used in 25 cases (13 oesophagus; 12 stomach). Mean age of patients was 77 years (44–89). Mean Hb nadir in the period from first Hb drop to RT was 64 g/L (36–99). Endoscopic intervention was performed in 3 cases (1 Haemospray and clip; 2 Haemospray only). Mean time from diagnosis to first evidence of haemorrhage was 4.5 months (0–12). Mean time from first Hb decrease to radiotherapy referral was 13 weeks (1–45). There was a statistically significant increase in the mean Hb following radiotherapy (87 g/dl to 103 g/dl; $p < 0.0001$). Mean units of packed red cells transfused two months before versus after radiotherapy was 8.5 v 1.2. Mean overall survival after RT was 107 days with a trend to increased survival with increasing RT dose. Treatment failure (death or requirement for transfusion within one month of RT) was 9/24 (37%).

Conclusions Radiotherapy is an effective treatment for haemorrhage associated with gastro-oesophageal malignancy and referrals to Clinical Oncology should be considered early.

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Presentation: A box containing two transparent bags, each containing two separate sachets, A and B. Sachet A contains macrogol 3350 100g; sodium sulphate anhydrous 7.5g; sodium chloride 2.691g and potassium chloride 1.015g as white to yellow powder. Sachet B contains ascorbic acid 4.7g and sodium ascorbate 5.9g as white to light brown powder. MOVIPREP also contains aspartame (E951), acesulfame potassium (E950) and a lemon or orange flavour. **Uses:** Bowel cleansing prior to any clinical procedure requiring a clean bowel. **Dosage and administration:** *Adults and Older People:* A course of treatment consists of two litres of MOVIPREP. A litre of MOVIPREP consists of one Sachet A and one Sachet B dissolved together in water to make one litre. This one litre reconstituted solution should be drunk over a period of one to two hours. This process should be repeated with a second litre of MOVIPREP to complete the course. A further litre of clear fluid is recommended during the course of treatment. The two litres of MOVIPREP may be consumed either as a 'divided dose', one litre the evening before the procedure and one litre in the early morning of the procedure, or as a 'single dose' of two litres the evening before the procedure or two litres in the morning of the procedure. For the 'divided dose' there should be at least one hour between the end of intake of fluid and the start of the procedure. For the 'single dose' in the morning of the procedure, there should be at least two hours between the end of intake of MOVIPREP and at least one hour between the end of the intake of any clear liquid and the start of the procedure. No solid food should be taken from the start of the treatment and until after the procedure. Patients should be advised to allow for the appropriate time to travel to the colonoscopy unit. *Children:* Not recommended in children below 18 years of age. **Contra-indications, warnings etc:** *Contra-indications:* Known or suspected hypersensitivity to any of the ingredients, gastrointestinal obstruction or perforation, disorders of gastric emptying, ileus, phenylketonuria, glucose-6-phosphate dehydrogenase deficiency, toxic megacolon which complicates very severe inflammatory conditions of the intestinal tract. Do not use in unconscious patients. *Warnings:* Diarrhoea is an expected effect. Administer with caution to fragile patients in poor health or patients with serious clinical impairment such as impaired gag reflex, or with a tendency to aspiration or regurgitation, impaired

consciousness, severe renal insufficiency, cardiac impairment (NYHA grade III or IV), those at risk of arrhythmia, dehydration, severe acute inflammatory disease. Dehydration, if present, should be corrected before using MOVIPREP. The reconstituted MOVIPREP does not replace regular fluid intake and adequate fluid intake must be maintained. Semi-conscious patients or patients prone to aspiration should be closely monitored during administration, particularly if this is via a naso-gastric route. If symptoms indicating arrhythmia or shifts of fluid or electrolytes occur, plasma electrolytes should be measured, ECG performed and any abnormality treated appropriately. In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment, arrhythmia and those at risk of electrolyte imbalance, the physician should consider performing baseline and post-treatment electrolyte, renal function test and ECG as appropriate. The possibility of serious arrhythmias, predominantly in those with underlying cardiac risk factors and electrolyte disturbance cannot be ruled out. If patients experience symptoms which make it difficult to continue the preparation, they may slow down or temporarily stop consuming the solution and should consult their doctor. MOVIPREP containing orange flavour is not recommended for patients with glucose and galactose malabsorption. MOVIPREP contains 56.2 mg of absorbable sodium per litre (caution in patients on a controlled sodium diet), 14.2 mg potassium per litre (caution in patients with reduced kidney function or patients on a controlled potassium diet). **Interactions:** Oral medication should not be taken within one hour of administration as it may be flushed from the GI tract and not absorbed. **Pregnancy and lactation:** There is no experience of use in pregnancy/lactation so it should only be used if judged essential by the physician. **Side Effects:** *Very common or common:* abdominal pain, nausea, abdominal distension, anal discomfort, malaise, pyrexia, vomiting, dyspepsia, hunger, thirst, sleep disorder, headache, dizziness, and rigors. *Uncommon or unknown:* Dysphagia, discomfort, abnormal liver function tests, allergic reactions including rash, urticaria, pruritus, erythema, angioedema and anaphylaxis, dyspnoea, electrolyte disturbances, dehydration, convulsions associated with severe hyponatraemia, transient increase in blood pressure, arrhythmia, palpitations, flatulence and retching. Refer to the Summary of

Product Characteristics (SmPC) for full list and frequency of adverse events. **Overdose:** In case of gross accidental overdosage, conservative measures are usually sufficient. In the rare event of severe metabolic derangement, intravenous rehydration may be used. **Pharmaceutical Particulars:** Sachets: Store in the original package below 25°C. *Reconstituted solution:* Keep covered. May be stored for up to 24 hours below 25°C or in a refrigerator. **Legal Category:** UK - Pharmacy only, Ireland - Prescription medicine. **Packs:** One pack of MOVIPREP or MOVIPREP Orange contains a single treatment. **Basic NHS Price:** UK £9.87, Ireland €13.26 **Marketing Authorisation Number:** UK: PL 20142/0005 (MOVIPREP), PL 20011/0006 (MOVIPREP Orange). IE: PA 1336/1/1 (MOVIPREP), PA 1336/1/2 (MOVIPREP Orange). **For further information contact:** Norgine Pharmaceuticals Ltd, Moorhall Road, Harefield, Middlesex, UB9 6NS. Tel: +44 (0) 1895 826606. E-mail: medinfo@norgine.com MOVIPREP[®] is a registered trademark of the NORGINE[®] group of companies. **Date of preparation /revision:** July 2015. **Ref:** UKMPR/0715/0060 **United Kingdom**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals Ltd on 01895 826606.

Ireland

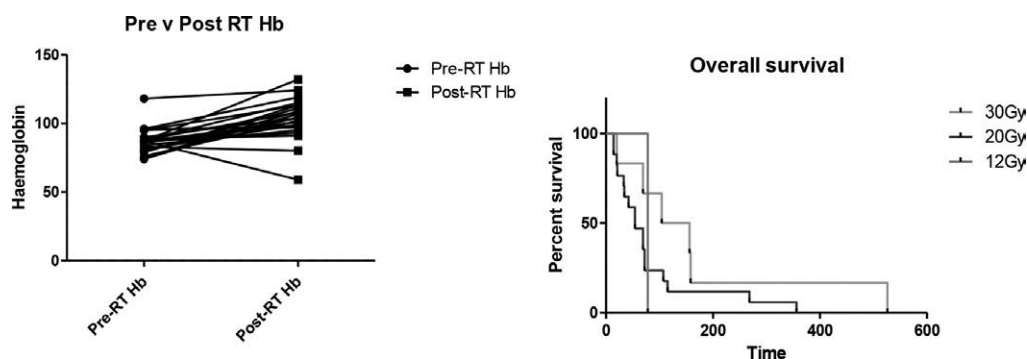
Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals on +44 1895 826606.

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UK/MPR/1016/0131

Date of preparation: October 2016.





Abstract 11 Figure 1

12 **AUDIT TO ASSESS THE LOCAL BLOOD TRANSFUSION PRACTISE IN PATIENTSWHO PRESENT WITH ACUTE UPPER GASTROINTESTINAL BLEEDS IN MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM, TANZANIA**

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10.1136/gutjnl-2017-314127.12

Background Blood transfusion is a major component in the treatment of acute upper gastrointestinal bleeding. Its safety has been questioned in the treatment of less severe cases. A large randomised controlled trial showed significant reductions in re-bleeding and mortality rates in patients who were randomised to a restrictive policy (transfused when haemoglobin was less than 7 g/dL) compared to a liberal policy (transfused when haemoglobin was less than 9 g/dL).

Aim The aim of this study is to identify whether Muhimbili National Hospital in Tanzania follows the evidence-based medicine that a restrictive policy in blood transfusion is advantageous in the treatment of acute upper gastrointestinal bleeding.

Method I performed a prospective audit of patients presenting to Mulhimbili National Hospital (MNH) with AUGIB to assess the current transfusion practice in this patient group. During a 3 week period I identified patients admitted to MNH who presented with meleana and haematemesis. I collected data about haemoglobin levels and blood transfusion from patient's notes.

Results 89.5% of patients who presented with haemoglobin <7 g/dL received a blood transfusion. 50% of the patients with a haemoglobin >9 g/dL did receive a blood transfusion.

Conclusions Muhimbili National Hospital in Dar Es Salaam in Tanzania do not follow the evidence-based medicine that restrictive policy in blood transfusion in acute upper gastrointestinal bleeding is beneficial compared to liberal blood transfusion.

13 **MEDICATIONS THAT AFFECT THE LOWER OESOPHAGEAL SPHINCTER AND RISK OF OESOPHAGEAL CANCER: A NESTED CASE-CONTROL STUDY**

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10.1136/gutjnl-2017-314127.13

Background Excessive relaxation of the lower oesophageal sphincter results in increased gastro-oesophageal acid reflux, a risk factor for oesophageal cancer.

Aim We aimed to investigate the risk of oesophageal cancer in patients prescribed medications known to relax of the lower oesophageal sphincter.

Method Using the Scottish Primary Care Clinical Informatics Unit (PCCIU) database, a nested case-control study of Scottish patients diagnosed with oesophageal cancer between 1999 and 2011 was performed. Medication use was determined from GP prescription records. Conditional logistic regression was used to calculate OR and 95% CI for oesophageal cancer risk in patients prescribed benzodiazepines, calcium channel blockers, nitrates, respiratory sympathomimetics or xanthine medications.

Results A total of 1979 oesophageal cancer patients were matched to 9543 controls. There was a significantly increased risk of oesophageal cancer in patients prescribed respiratory sympathomimetics (adjusted OR 1.27, 95% CI 1.08–1.48) but no dose-response association was observed. No significant increased oesophageal cancer risks were seen for users of other medications that relax the lower oesophageal sphincter (adjusted OR for benzodiazepines 0.94, 95% CI 0.79–1.11; calcium channel blockers 1.05, 95% CI 0.92–1.20; nitrates 1.09, 95% CI 0.92–1.29; or xanthines 1.44, 95% CI 0.91–2.28).

Conclusions Respiratory sympathomimetic medication use was associated with an increased risk of oesophageal cancer. Oesophageal cancer risk was not significantly increased for users of other medications known as relaxants of the lower oesophageal sphincter. Further, the observed association may not be causal because there was no dose response relationship, and possible confounding due to asthma symptoms.

14 MEDICATIONS THAT AFFECT THE LOWER OESOPHAGEAL SPHINCTER AND RISK OF OESOPHAGEAL CANCER: A COHORT STUDY OF 465,768 UK BIOBANK PARTICIPANTS

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10.1136/gutjnl-2017-314127.14

Background Medications that relax the lower oesophageal sphincter may promote acid reflux, a known contributor to oesophageal adenocarcinoma development.

Aim We investigated the association between lower oesophageal sphincter relaxing medications and oesophageal cancer (OC) risk.

Method A retrospective cohort study of participants within the UK Biobank from 2006 and 2014 was performed. Age-dependent Cox-regression analysis was used to calculate adjusted HR and 95% CI for OC risk in individuals prescribed benzodiazepines, calcium channel blockers, nitrates, respiratory sympathomimetics and xanthines.

Results Of 4 75 768 study participants, 409 were diagnosed with OC during 8 years of follow-up. There was a significant direct association with OC in participants using respiratory sympathomimetics (HR 1.71, 95% CI 1.20–2.42), with similar increased risk of oesophageal adenocarcinoma with use of these respiratory medications (HR 1.68, 95% CI 1.10–2.54) and xanthines (HR 4.82, 95% CI 1.16–20.10). Participants taking respiratory sympathomimetics or any lower oesophageal sphincter relaxing medication were also at greater risk of oesophageal squamous cell cancer (HR 2.51, 95% CI 1.29–4.87 and HR 2.03, 95% CI 1.01–4.09, respectively). There was no significant association between OC and the other medications investigated.

Conclusions Respiratory sympathomimetics were associated with greater risk of OC overall, and both adenocarcinoma and squamous cell carcinoma subtypes. Individuals using lower oesophageal sphincter relaxing medications are at increased risk of squamous cell carcinoma, and as this tumour is not associated with excessive acid reflux, an alternative pathway to this cancer with these medications may exist.

15 DOES CHOICE OF BRUSH CYTOLOGY DEVICE INFLUENCE THE DIAGNOSTIC YIELD IN SUSPECTED MALIGNANT BILIARY STRICTURES AT ERCP?

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10.1136/gutjnl-2017-314127.15

Background Suspected malignant biliary strictures lacking a confirmed tissue diagnosis pose a diagnostic dilemma, putting patients at risk of undergoing major surgery for a potentially

benign disease process or repeated diagnostic procedures. Although highly specific, the disappointingly low sensitivity of biliary brush cytology has prompted development of newer equipment and techniques.

Aim We aimed to determine if using a new, larger-bristled "Infinity" brush (US Endoscopy) led to superior detection of malignant biliary strictures at cytology than the "RX" brush (Boston Scientific).

Method We retrospectively reviewed the case notes of 58 patients who had undergone ERCP and brushings within Mater Hospital, Belfast between May 2011–2016. Of these, 33 had been diagnosed with histopathologically-confirmed pancreaticobiliary cancers. The RX brush was used in 13 cases; the Infinity brush in 20 cases.

Results Cytology from the 13 patients with RX brush yielded 5 with cells confirming adenocarcinoma. Of 20 patients whose strictures had been brushed with an Infinity brush, 11 had adenocarcinoma identified. Assuming atypical cells to be classified as non-malignant, the RX brush achieved a sensitivity of 38.5%, in comparison to the 55% sensitivity of the Infinity Brush.

Conclusions The use of the Infinity cytology brush provided a higher yield in detection of malignant cells in our patients than the Boston RX cytology brush, possibly due to its size, design and bristle configuration. We acknowledge however our study numbers were small and we feel that a larger study would be required to determine if the difference in brushings yield is significant.

16 OUTCOMES FOR HOME PARENTERAL NUTRITION PATIENTS IN NORTHERN IRELAND – A TEN YEAR REVIEW (2006–2016)

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10.1136/gutjnl-2017-314127.16

Background Intestinal failure (IF) patients in Northern Ireland requiring home parenteral nutrition (hPN) are managed in the Belfast Trust by the Nutrition team at Belfast City Hospital.

Aim The aims of this review were to analyse the aetiology of IF; admission rates (particularly those due to catheter related blood stream infections (CRBSI)) and patient outcomes.

Method Electronic records including radiology and microbiology results for all patients on hPN in Northern Ireland from 2006–2016 were reviewed.

Results 86 patients used hPN between 2006–2016. One patient was excluded due to incomplete data. The average age at presentation was 51 (range 19–78). The mean number of days hPN was administered was 1072 (range 23–3834). The most common causes of IF were Crohn's disease (29%), surgical complications (22%) and mesenteric ischaemia (18%). There were 414 admissions in the timescale – 137 admissions were due to CRBSI. The CRBSI rate was 1.5 per 1000 catheter days (previously 1.81 (1994–2014)). 43 patients had no infections (51%) and 10 had >5 infections, accounting for 55% of all CRBSI admissions. The most common organisms identified were Gram negative organisms (38%) Coagulase Negative Staphylococci (34%); and Yeasts (11%). 28% of patients remain on home parenteral nutrition; 21 patients have had restoration of intestinal continuity.

Conclusions Parenteral nutrition remains a safe treatment in the management of intestinal failure. Our CRBSI rate has reduced in the past 10 years, likely due to ongoing patient education and training.

17 COMPARISON OF LOW VOLUME POLYETHYLENE GLYCOL-ELECTROLYTE SOLUTION (PEG-ELS) AND PHOSPHATE ENEMA IN FLEXIBLE SIGMOIDOSCOPY: A LARGE RETROSPECTIVE STUDY

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10.1136/gutjnl-2017-314127.17

Background Flexible sigmoidoscopy is a popular method for examining the left side of the colon, but adequate bowel cleansing is critical for detection of mucosal abnormalities, and for minimising the number of repeat procedures. It has, however, long been debated which method, oral preparation or enema, gives the best results.

Aim At our unit both oral and phosphate enema preparations are utilised, and we therefore wanted to find out which type of preparation gives best results.

Methods Patients who underwent flexible sigmoidoscopy from 1st February to 31st July 2016 were retrospectively reviewed using our endoscopy reporting system. Their demographics and the individually achieved quality of bowel preparation (subjectively graded as: Excellent, Adequate or Inadequate) were analysed. A chi-squared test was used calculate p-values.

Results 1054 patients underwent flexible sigmoidoscopy during the study period, of whom 822 were included in this study, after excluding 232 patients (22.01%) due to: no bowel preparation (n=69), no documentation of quality of bowel preparation (n=151) and other reasons (n=12). 494 (46.87%) patients (males 248 (50.20%), mean age 60.48 years, range 15-94 years) had oral preparation with low volume polyethylene glycol-electrolyte solution (PEG-ELS), and 491 (46.58%) (males 245 (49.90%), mean age 65.49 years, range 18-98 years) had phosphate enema. The outcomes are summarised in the table below.

Conclusions Our relatively large retrospective study showed that oral preparation with PEG-ELS resulted in significantly better bowel preparation compared to phosphate enema. PEG-ELS is now the preferred option in our unit where there is no contraindication for this.

Abstract 17 Table 1

Type of bowel Preparation	Excellent	Adequate	Total Adequate and excellent	Inadequate
PEG-ELS (n=425)	223 (52.47%)	161 (37.88%)	384 (90.35%)	40 (9.41%)
Phosphate Enema (n=397)	93 (23.42%)	182 (45.84%)	275 (69.27%)	122 (30.73%)
Total (n=822)			P	
			Value <0.0001	

18 CAN A SHORT TRAINING MODULE IMPROVE NUTRITIONAL KNOWLEDGE OF MALNUTRITION BY JUNIOR DOCTORS?

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10.1136/gutjnl-2017-314127.18

Background Malnutrition is a major cause and consequence of poor health. Hospitalised patients are at increased risk of malnourishment; around 30% of people aged over 65 are at risk of malnutrition on admission. Additionally, malnutrition increases costs hugely to the NHS. Despite the prevalence and cost of this problem, formal teaching to junior doctors about malnutrition is limited.

Aim To assess whether an online training module could improve knowledge of nutritional management of hospitalised patients.

Methods Using SurveyMonkey, a survey was distributed to Foundation Year FY1 and FY2 doctors working at both Newcastle and Northumbria NHS Foundation Trainee (FT). The doctors were asked five questions, then given information relating to malnutrition. Finally they answered the five questions again. The survey took approximately 15 min to complete. Participants could then download a certificate to show involvement with training. Statistical analysis was performed using a paired t-test to assess the doctors' improvement in answering the questions.

Results 87 doctors participated. The results are outlined in the table below.

Abstract 18 Table 1

	1 st round of questions		2 nd round of questions	
	Number of Responses	Percentage of correct answers (%)	Number of Responses	Percentage of correct answers (%)
Q1	84	7.1	76	40.8
Q2	86	48.4	76	85.5
Q3	86	36.1	76	89.4
Q4	86	20.9	75	82.7
Q5	71	22.5	63	31.8

A paired t-test was used to measure the difference in correct answers selected between the 1st and 2nd attempts, p-value of 0.013.

Conclusions Knowledge of malnutrition can be improved by completing a short training module. Future studies should address the technical issues of using SurveyMonkey within FTs and use larger sample sizes to prove the generalisability of the results. Improved knowledge should lead to earlier recognition and treatment of malnutrition with improved health outcomes and reduced costs.

19 BARRETT'S OESOPHAGUS IN CHILDHOOD: A POPULATION-BASED CASE SERIES ANALYSIS

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10.1136/gutjnl-2017-314127.19

Background Adults detected with Barrett's oesophagus (BO) are often entered into surveillance for oesophageal adenocarcinoma (OAC), although cancer risk is relatively low. More rarely, BO can be detected in children. Little is known about the epidemiology of paediatric BO, and it is unclear what the optimal surveillance regimes are in these children.

Aim To evaluate the demographic and clinical characteristics, and future neoplastic progression risk in all paediatric BO patients diagnosed in Northern Ireland between 1993 and 2010.

Method Data was collected using the Northern Ireland BO register and matched to the Northern Ireland Cancer Registry for OAC outcomes until end 2013. Age-adjusted incidence of paediatric BO was calculated, and chi-squared tests performed to compare characteristics between paediatric and adult BO patients.

Results Over 18 years, 42 paediatric BO patients were identified, equivalent to an age-adjusted incidence of <2 per 1 000 000 children. No clear age distribution was evident, with cases ranging from newborns to 15 years old. 85.7% of patients were male, which was a significantly higher male:female ratio than adult BO patients ($p < 0.001$). No patients progressed to HGD/OAC, although the eldest patient would be aged 34 years by the end of follow-up.

Conclusions This is the largest series of paediatric BO ever to be reported. It demonstrates that paediatric BO is a rare disease. The male preponderance of this condition is even more apparent in childhood compared with adult cases. No children developed HGD/OAC during follow-up, suggesting that regular surveillance is not required, at least until early adulthood.

20 EFFICACY AND SAFETY OF GOLIMUMAB INDUCTION FOR MODERATE TO SEVERE ULCERATIVE COLITIS IN THE UNITED KINGDOM: RESULTS FROM THE GO-COLITIS

C Probert*, D Gaya, PJ Hamlin, P Irving, S Sebastian, G Gillespie, H Tate, C Wheeler. *University of Liverpool, UK*

10.1136/gutjnl-2017-314127.20

Background GO-COLITIS (NCT02092285; 2013-004583-56) is a phase 4, multicentre, open-label, single-arm trial in the UK assessing efficacy of golimumab (GLM) in induction and maintenance of clinical response in patients with moderate to severe UC. We report the results of a 6 week interim analysis.

Aim Gather real-world experience of the efficacy and safety of golimumab in an anti-TNF naïve cohort.

Method Anti-TNF naïve patients (≥ 18 year) with UC ≥ 3 months and with moderate to severe disease were included. Patients received SC GLM on day 0 (200 mg) and day 14

(100 mg) during the 6 week induction phase, followed by GLM 50 or 100 mg 4 weekly in the 48 week maintenance phase. Clinical response and remission were summarised descriptively at the end of week 6. Clinical response was defined as decrease in partial Mayo score of ≥ 2 points and $\geq 30\%$ from baseline, plus a decrease in rectal bleeding subscore of ≥ 1 point or absolute rectal bleeding score ≤ 1 .

Results Overall, 205 patients were enrolled (mean age, 39.3 years). The mean baseline (SD) partial Mayo score was 6.4 (1.4). Clinical responses occurred in 141/205 patients (response rate, 68.8%; 95% CI, 62.0% to 75.1%). Clinical remission occurred in 79/205 patients (remission rate, 38.5%, 95% CI, 31.8% to 45.6%). The mean (SD) change from baseline in partial Mayo score ($n=198$) was -3.2 (2.4). Serious adverse events (AEs) occurred in 17 (8%) patients: UC flare/worsening was most common ($n=11$).

Conclusions During the induction phase of GO-COLITIS, 68.8% of patients had a partial Mayo response. AEs were consistent with previous observations.

21 PATIENT-REPORTED QUALITY OF LIFE DURING GOLIMUMAB INDUCTION FOR MODERATE TO SEVERE ULCERATIVE COLITIS IN THE UNITED KINGDOM: RESULTS FROM THE GO-COLITIS STUDY

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10.1136/gutjnl-2017-314127.21

Background GO-COLITIS (NCT02092285; 2013-004583-56) is a phase 4, multicentre, open-label, single-arm trial in the UK assessing efficacy of golimumab (GLM) in induction and maintenance of clinical response in patients with moderate to severe UC. We report the results of an analysis of patient-reported QoL after a 6 week induction phase.

Aim Gather real-world experience of the efficacy and safety of GLM in an anti-TNF naïve cohort.

Method Anti-TNF naïve patients (≥ 18 year) with UC ≥ 3 months and with moderate to severe disease were included. Patients received SC GLM on day 0 (200 mg) and day 14 (100 mg) during the 6 week induction phase, followed by GLM 50 or 100 mg 4 weekly in the 48 week maintenance phase. Clinical response and remission were summarised descriptively at the end of week 6. Patients completed the IBDQ and EQ-5D at baseline and at week 6.

Results Overall, 205 patients were enrolled (mean age, 39.3 years). Statistically significant improvements from baseline to week 6 were observed for the IBDQ total score, and the domains of bowel symptoms, emotional function, systemic symptoms, and social function. Significant improvements in the EQ-5D were observed.

Conclusions During the GLM induction phase of the GO-COLITIS study, patients with moderate to severe UC experienced significant improvements from baseline in disease-specific QoL, including bowel symptoms, emotional function, systemic symptoms, and social function. The degree of improvement in IBDQ total score exceeded the IBDQ increase cutoff (>20 points) previously identified as representative of a patient-defined improvement in an assessment of UC clinical endpoints.

22 A NATIONAL STUDY OF CANCER DIAGNOSES IN IRISH LIVER TRANSPLANT RECIPIENTS WITH PRIMARY SCLEROSING CHOLANGITIS

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10.1136/gutjnl-2017-314127.22

Background Primary sclerosing cholangitis (PSC) is associated with an increased risk of cholangiocarcinoma, colorectal and gallbladder cancers. Orthotopic liver transplantation (OLT) patients are at risk of developing *de novo* malignancies, however limited/conflicting data exists regarding cancer risk post OLT for PSC.

Aim To examine all recorded malignancies over 2 decades in OLT-PSC patients; to compare these to non-transplanted PSC cohort; to analyse for any associated factors.

Method We studied PSC patients attending SVUH (1/1/1994–30/9/2016). We integrated this database with National Cancer Registry Ireland, to enable accurate determination of number of malignancies.

Results 173 PSC pts (75.7% male) have attended SVUH since 1994. 107 (61.8%) have undergone 124 OLT. 27/107 were transplanted for cholangiocarcinoma. 12 *de novo* cancers (excluding non-melanomatous skin) were found during 737.8 person years of follow-up. Median time to cancer diagnosis post OLT was 5 years. As expected, cholangiocarcinoma as OLT indication ($p=0.005$) and older age at transplant ($p=0.05$) were associated with higher mortality. Post-transplant lymphoproliferative disease (PTLD) remains a major complication. 5 pts developed lymphoma post OLT (4.7% of cohort). Two patients developed CRC post OLT; 4 developed colonic dysplasia. 3/4 underwent colectomy. All who developed colonic dysplasia/CRC post OLT had IBD. All 5 colectomies for dysplasia/CRC showed significant co-existing inflammation.

Conclusions This represents national cancer figures for PSC-OLT. The rates of PTLD are slightly higher than previously reported. We could not find any association between the development of PTLD and immunosuppressive regimes for IBD post OLT. This study highlights that IBD/PSC patients remain at significant risk of colonic neoplasia after OLT and require intensive surveillance.

23 SMALL INTESTINAL BACTERIAL OVERGROWTH IN CHRONIC PANCREATITIS PATIENTS WITH PANCREATIC EXOCRINE INSUFFICIENCY; A PROSPECTIVE COHORT STUDY

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10.1136/gutjnl-2017-314127.23

Background Pancreatic exocrine insufficiency (PEI) causes malabsorption and is a major complication of chronic pancreatitis (CP). Small intestinal bacterial overgrowth (SIBO) worsens symptoms and nutritional status in CP, its prevalence is unclear

Aim We examined SIBO prevalence in CP patients with PEI (defined as faecal elastase-1 < 200 ug/g) versus matched healthy controls.

Method 34 patients and 25 controls (matched for age/gender/smoking status) underwent hydrogen breath-testing using a glucose substrate. Exclusion criteria included gastric/pancreatic/intestinal surgery, or antibiotic treatment < 4 weeks prior to study. Persistent rise in breath hydrogen 12 ppm above basal was diagnostic of SIBO.

Results Patients and controls were well-matched, with 67% and 64% males respectively ($p=0.775$), a mean (standard deviation) age of 52.4 (10.4) and 53.3 (10.5) year respectively ($p=0.919$), and 47.1% and 28% smokers respectively ($p=0.143$). Among patients, there was no association found between the presence of SIBO and gender ($p=0.156$), or PPI use ($p=0.328$). There was a significantly positive association found between the presence of SIBO and diabetes ($p=0.033$), while the positive association between the presence of SIBO and pancreatic enzyme replacement therapy (PERT) use just reached significance ($p=0.052$)

Conclusions SIBO prevalence was 15% and not associated with gender, age, or PPI use, but was positively associated with PERT use, and concurrent diabetes. Patients with diabetes may be more likely to suffer from SIBO due to small bowel dysmotility, whilst SIBO and PEI may co-exist, with similar symptoms. We recommend that SIBO should be considered in non-surgical CP patients, if they have gastro-intestinal symptoms that are unresponsive to high-dose PERT, particularly if there is co-existent diabetes. Treatment should be aggressive, and there may be a requirement for repeat therapy.

24 MEASURING THE VALUE OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP) ACTIVITY: AN OPPORTUNITY TO STRATIFY ENDOSCOPISTS BASED ON THEIR VALUE

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10.1136/gutjnl-2017-314127.24

Background The value in healthcare can be defined as patient health outcomes achieved per monetary unit spent.

Aim To characterise the value of ERCP performance of four gastroenterologists.

Method Medical records of patients undergoing ERCP between September 2014 and September 2016 in an academic medical centre were reviewed; all procedures were performed by one of four experienced gastroenterologists, all of whom have performed at least 1000 ERCPs. Procedure value was defined as the quality of procedure (Q) divided by the duration of procedure (T) adjusted for complexity level (C), that is, Q/(T/C). In those patients undergoing multiple ERCPs during the study period, only the index procedure was considered for analysis. ERCP quality and complexity were both graded on a 1 to 4 Likert scale based on American Society for Gastrointestinal Endoscopy (ASGE) criteria; time was recorded (in minutes) from intubation to extubation. Although individual components of procedure cost (eg, ERCP accessories, patient sedation, etc.) were not itemised, the procedure

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*Conor Byrne**

Prescribing Information Humira (adalimumab) 40mg solution for injection in pre-filled pen or pre-filled syringe or Humira 40mg/0.8ml solution for injection for paediatric use. Refer to Summary of Product Characteristics (SmPC) for full information. Presentation: Each 0.4 ml single dose pre-filled pen or pre-filled syringe contains 40mg of adalimumab. Each 0.8 ml single dose vial contains 40mg of adalimumab. **Indications:** Rheumatoid arthritis (RA), adults: In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above: In combination with MTX, for active pJIA, with inadequate response to one or more DMARDs; or monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Entesitis-related arthritis (ERA), paediatrics 6 years and above: For active ERA with inadequate response or intolerance to, conventional therapy. Psoriatic arthritis (PsA), adults: For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. Ankylosing spondylitis (AS), adults: For severe active AS with inadequate response to conventional therapy. Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults: For severe nr-axSpA with objective signs of inflammation (elevated CRP and / or MRI), and an inadequate response to, or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs). Crohn's disease (CD), adults: For moderately to severely, active CD with inadequate response, contraindication or intolerance to corticosteroid and/or an immunosuppressant therapy. Crohn's disease (CD), Paediatrics 6 years and above: For moderately to severely active CD with inadequate response, contraindication or intolerance to conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator. Psoriasis (Ps), adults: For moderate to severe chronic plaque psoriasis who are candidates for systemic therapy. Psoriasis, paediatrics 4 years and above: For severe chronic plaque psoriasis with inadequate response, or if topical therapy and phototherapies are inappropriate. Hidradenitis suppurativa (HS), adults and adolescents from 12 years of age: For active moderate to severe hidradenitis suppurativa (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. Ulcerative colitis (UC), adults: For moderately to severely active UC with inadequate response, contraindication or intolerance to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). Iritis, adults: For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **Dosage and administration:** Specialist physicians experienced in the diagnosis and treatment of the condition, to initiate and supervise treatment. Ophthalmologists to consult with an appropriate specialist before initiation of treatment. Provide patients with special alert card. Patients may self-inject after proper injection training, with physician approval and appropriate medical follow-up. Optimise other concomitant therapies. RA, adults: 40mg dose every other week. Concomitant MTX should be continued. During monotherapy patients may require 40mg each week if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose

interruption, e.g. before surgery or if serious infection occurs. Re-introduction after 70 days dose interruption gave same magnitudes of clinical response and similar safety profile as before dose interruption. pJIA, paediatrics 2 years and above: Treatment beyond 12 weeks reconsidered if no clinical response in that time. pJIA, paediatrics 2-4 years: 24mg/m² body surface area up to 20mg maximum single dose every other week (see vial SmPC for height/weight dosing chart). pJIA, paediatrics 4-12 years: 24mg/m² body surface area up to 40mg maximum single dose every other week (see vial SmPC for height/weight dosing chart). pJIA, paediatrics 13 years and above: 40mg every other week regardless of body surface area. ERA, paediatrics 6 years and above: 24mg/m² body surface area up to a maximum single dose of 40mg every other week. (see vial SmPC for height/weight dosing chart). PsA, AS and nr-axSpA, adults: 40 mg every other week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, Adults: Induction: 80mg at Week 0 followed by 40mg at Week 2. For a more rapid response, 160mg at Week 0 (either as 4 injections in 1 day or 2 injections/day for 2 consecutive days), 80mg at Week 2; risk of adverse events higher during induction. Maintenance: 40mg every other week. If decrease in clinical response, can increase dose to 40 mg weekly. Corticosteroids may be tapered in maintenance phase in accordance with clinical guidelines. Patients with no response by Week 4 may benefit from continued therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, paediatrics 6 years and above <40kg: Induction: 40mg at Week 0, 20mg at Week 2. For a more rapid response: 80mg at Week 0 (2 injections in 1 day), 40mg at Week 2; risk of adverse events higher during induction. Maintenance: 20mg every other week. If insufficient response, consider 20mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, paediatrics 6 years and above >40kg: Induction: 80 mg Week 0, 40 mg at Week 2. For a more rapid response: 160 mg at Week 0 (4 injections in 1 day or 2 injections/day for 2 consecutive days), 80 mg at Week 2; risk of adverse events higher during induction. Maintenance: 40 mg every other week. If insufficient response, consider 40 mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Psoriasis, adults: 80mg induction dose at week 0, 40mg every other week from week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Beyond 16 weeks, patients with inadequate response can increase dosing frequency to 40 mg every week. If adequate response is achieved with an increased dosing frequency, dose may subsequently be reduced to 40 mg every other week. If there is inadequate response to the increased frequency, carefully reconsider treatment. Psoriasis, Paediatrics 4 years and above: 0.8 mg per kg body weight (maximum of 40 mg/dose) weekly for the first 2 doses and then every other week (see vial SmPC for weight dosing chart). Treatment beyond 16 weeks should be reconsidered if no response in that time. HS, Adults: 160mg initially at Day 1 (four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80 mg two weeks later at Day 15 (two 40mg injections in one day). Two weeks later (Day 29) continue with a dose of 40 mg every week. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions should be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Reintroduction after interruption: 40 mg every week. Evaluate periodically the benefit and risk of continued long-term treatment. HS, adolescents from 12 years of age weighing at least 30 kg: 80 mg initially at week 0 (given as two 40 mg injections on day one), 40 mg injection in week 1 followed by 40mg every other week. In adolescent patients with inadequate response to Humira 40 mg every other week an increase in

*Not a real patient.

Reference: 1. Colombel J F, Sandborn WJ, Rutgeerts P, et al Adalimumab for maintenance of clinical response and remission in patients with Crohn's disease: the CHARM trial. *Gastroenterology* 2007; 132 (1): 52-65.

Date of Preparation: March 2017

IREHUG160187d(1)



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dosing frequency to 40 mg every week may be considered. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions should be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **UC; Adults:** Induction: 160mg at week 0 (4 injections in 1 day or 2 injections / day for 2 consecutive days) and 80mg at week 2. Maintenance: 40mg every other week. During maintenance, corticosteroids may be tapered in accordance with clinical practice guidelines. If insufficient response, consider 40mg every week. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time. **Uveitis; Adults:** 80 mg induction dose at week 0, 40 mg every other week from week 1. Experience of initiating treatment with Humira alone is limited. Treatment can be initiated in combination with corticosteroids and/or other non-biologic immunomodulatory agents. Two weeks after initiating treatment, concomitant corticosteroids may be tapered in accordance with clinical guidelines. Evaluate on a yearly basis, the benefit and risk of continued long term treatment. **Contraindications:** Active tuberculosis (TB), severe infections (e.g. sepsis), and opportunistic infections; moderate to severe heart failure (NYHA class III/IV); hypersensitivity to adalimumab or any of the excipients. **Precautions and Warnings:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal product. **Infections:** Patients are more susceptible to serious infections especially if impaired lung function. Monitor for infections, including TB, before, during and for 4 months after treatment. Do not initiate treatment with an active infection, until it is controlled. Consider risk/benefit prior to treatment in patients exposed to high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections. **Serious Infections:** Serious infections, including those with hospitalisation or death reported in patients receiving treatment. **TB:** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated) reported. Screen all patients before therapy initiation for active or latent TB. If active TB is diagnosed Humira therapy must not be initiated. If latent TB is suspected, consult a physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Humira. Despite prophylaxis TB reactivation has occurred on Humira. **Other opportunistic infections:** Opportunistic infections observed in patients receiving Humira. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. **Hepatitis B Reactivation:** Reactivation has occurred in chronic carriers (i.e. surface antigen positive) tested for HBV infection before initiating treatment. HBV carriers should consult with a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs stop treatment and initiate appropriate anti-viral and supportive treatment. **Neurological events:** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders and consider stopping treatment if these disorders develop. Rare association with new onset or exacerbation of symptoms and/or radiographic evidence of central and peripheral demyelinating disease. Known association between intermediate uveitis and central demyelinating disorders. Evaluate patients with non-infectious intermediate uveitis before therapy initiation and regularly during treatment to assess for pre-existing or developing central demyelinating disorders. **Allergic reactions:** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or

anaphylactic reaction stop Humira immediately and initiate appropriate therapy. **Malignancies and lymphoproliferative disorders:** A possible risk of malignancy, including lymphoma and leukaemia, in all patients including paediatric patients, treated with TNF antagonists. Monitor all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non-melanoma skin cancer prior to and during Humira therapy, caution in COPD patients, and in patients with increased risk of malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Humira (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk for developing dysplasia or colon cancer is unknown. Patients with UC, prior history of dysplasia or colon carcinoma to be screened for dysplasia before therapy and during treatment. **Haematologic reactions:** Adverse events of the haematologic system reported with Humira. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to Humira treatment. **Congestive heart failure:** See contraindications. Caution is advised in mild heart failure (NYHA class I/II). Discontinue treatment for new or worsening symptoms of congestive heart failure. **Autoimmune processes:** Autoimmune antibodies may form. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. **Surgery:** Consider the long half-life of Humira for planned surgical procedures. Closely monitor for infections. **Small bowel obstruction:** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture requiring surgical treatment. **Elderly:** Serious infections were higher in patients over 65 years of age, some of whom had fatal outcomes. Consider risk of infection. **Interactions:** Combination of adalimumab with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Not recommended during pregnancy. Women of childbearing potential should use adequate contraception and continue its use for at least five months after the last Humira treatment. Women must not breast-feed for at least five months after the last treatment. **Side Effects:** Very common $\geq 1/10$: Infections, leukopenia, anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction. **Serious, including fatal, side effects have been reported** including infections/sepsis, intestinal perforation, opportunistic infections, TB, endemic mycoses, demyelinating disease, malignancies including lymphoma (including hepatosplenic T-cell lymphoma), leukaemia and skin cancer (including melanoma and merkel cell carcinoma), cytopenias, worsening heart failure, myocardial infarction, pulmonary embolism, pleural effusion, pulmonary fibrosis, cerebrovascular accident, interstitial lung disease, lupus, Stevens-Johnson syndrome, angioedema, anaphylaxis, sarcoidosis, hepatitis, liver failure and worsening of symptoms of dermatomyositis. **Prescribers should consult the SmPC for the complete list of reported side effects. Legal Category:** POM. **Marketing Authorisation Numbers/Presentations:** Vial: EU/1/03/256/001; Pre-filled Syringe: EU/1/03/256/013; Pre-filled Pen: EU/1/03/256/017. Further information is available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24. **HCPs are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Date of revision of PI:** January 2017, PI/256/018

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duration (ie, the cost of endoscopist's time) was considered to be a reliable surrogate estimate of overall procedure cost.

Results In total, index procedures on 465 patients were performed over 24 months; mean of 116 index ERCs per endoscopist. Mean quality varied from 2.25 to 2.53 while adjusted mean duration (T/C) varied from 22.13 to 28.66 min per procedure. Value measurements varied from 8.1 to 10.7.

Conclusions There was a 32% variation in the value of endoscopist activity. As healthcare costs are scrutinised more closely, such value measurements are likely to become more relevant.

25 PRE-EMPTIVE THERAPY FOR CMV VIREMIA IN LIVING DONOR LIVER TRANSPLANT RECIPIENTS: A SINGLE CENTRE EXPERIENCE

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10.1136/gutjnl-2017-314127.25

Background CMV infection is among the most common complication after liver transplantation which may result in graft loss, survival and increased cost. There are two major strategies for CMV disease prevention after transplantation: preemptive therapy and universal prophylaxis. We present our cohort of recipients of Living Donor Liver Transplant (LDLT) with non-detectable CMV DNA pre-transplant, with moderate risk of CMV viremia (D+/R+, d-/R+), who were preemptively treated.

Aim To determine whether preemptive strategy may be feasible approach in patients with moderate risk for CMV viremia in LDLT and its appropriateness for Acute Cellular Rejection (ACR), length of hospital stay and risk of developing other infection and all-cause mortality.

Method In this retrospective cohort, 225 adults with moderate risk for CMV viremia who underwent LDLT at Shifa International Hospital from 29/4/2011 to 26/4/2016 were included. All recipients were checked for CMV viremia at day 7, patients with significant viremia (DNA >137 IU/ml) were treated for CMV preemptively. Non-viremic patients on day 7 were only re-checked if had deranged LFT on follow up.

Results Out of 225 patients, 83 (36.8%) patients had detectable CMV DNA at day 7. Patients with higher pre-transplant MELD >18 had more chances of developing CMV viremia n=42 (50.6) than those with MELD <18 n=41 (49.4) (p=0.018). There was no significant difference in patients with/without CMV viremia for ACR (p=0.48), length of hospital stay, incidence of sepsis and all cause mortality.

Conclusions Pre-emptive CMV strategy may be an acceptable approach in patients with moderate risk of CMV viremia in resource constraint setting; however, this needs prospective randomised trials for validation.

26 OPPORTUNISTIC INFECTIONS IN INFLAMMATORY BOWEL DISEASE: ARE WE ADHERING TO THE ECCO GUIDELINES?

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10.1136/gutjnl-2017-314127.26

Background The use of immunomodulators for inflammatory bowel disease (IBD) has significantly improved disease management. However, these treatments increase the risk of infection. Screening for immunity to serious infection is recommended but compliance with these recommendations is unknown.

Aim To assess adherence to the European Crohns and Colitis Organisation (ECCO) screening guidelines and the rates of developing opportunistic infections in a cohort of IBD patients.

Method All patients currently on biological therapy were identified from a database of IBD patients within the Southern Health Trust. Case records were retrospectively reviewed to identify compliance with screening guidelines, and subsequent development of opportunistic infection.

Results 78 patients were receiving biologics +/- immunomodulators. 62 (79.5%) of patients had Crohn's disease. The majority were pre-screened appropriately for infection (77.9%) with 99% of patients being pre-screened for TB. 72.8% of patients had the recommended viral serology checked.

Six patients (7.69%) developed infections. The majority did not require hospital admission (66.7%). Two patients (33.3%) developed sepsis requiring hospital admission. There was no mortality related to infection.

Infection was more frequent in patients that were on both an immunomodulator and biological therapy (11.9% vs 2.8%, p=0.13) than biological therapy alone.

No patient developed, was treated for or reactivated latent tuberculosis.

Conclusions In this IBD cohort screening for infection was appropriate but could be further optimised. Risk of infection in this cohort was lower than in previous studies. Better adherence to screening recommendations and vigilance for infection may reduce the morbidity associated with immunosuppression in IBD.

27 PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBES; A RETROSPECTIVE ANALYSIS IN PATIENTS WITH HEAD AND NECK CANCER OVER 5 YEARS

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10.1136/gutjnl-2017-314127.27

Background Weight loss and malnutrition are common side effects of disease process and treatment of head and neck cancer. The use of PEG tubes to aid nutrition has been shown to be effective in previous studies and suggest patients benefit from PEGs.

Aim 1) To determine the rate of insertion and use of PEGs

2) To determine complication rates

Method This study assessed 175 patients who had PEG tubes inserted from 2012 to 2016. Data was collected and extracted from patient dietitian record and analysed using SPSS.

Results 175 patients had PEGs placed from January 2012 to December 2016. 39% of PEGs were inserted prophylactically. 67% of patients in the cohort had a diagnosis of oropharyngeal cancer. 27% of patients had laryngeal cancer. 3% had salivary gland cancer. Of all patients who received PEGs from 2012-2016, 25% gained weight and 6% of patients' weight remained stable. 68% did not experience any complication (n=119). 5% experienced a major complication of PEG

infection (n=9), while the remaining 11.5% had minor complications of PEG leakage 7.5% and granuloma formation (4%).

Conclusions Weight loss is almost ubiquitous in head and neck cancers. This study demonstrated that PEGs are a useful aid for patients undergoing treatment for cancer allowing 31% of patients to gain and/or maintain weight. PEGs had relatively low rates of complications with only 5% of patients experiencing a serious complication. This study highlights that patients may benefit from PEG placement during treatment and benefits may outweigh risks.

28 SENSITIVITY OF CLO TESTING IN THE NORTHERN TRUST

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10.1136/gutjnl-2017-314127.28

Background *Helicobacter pylori* is a gram negative organism commonly found in the stomach. The majority of patients infected don't experience any symptoms or complications however it can be associated with PUD, Gastric MALT Lymphoma, Gastric Cancer and chronic gastritis. We usually diagnose *H. Pylori* with the use of CLO testing at endoscopy.

Aim We wanted to assess the sensitivity of these kits after a number of "negative" CLO tests had *H. pylori* confirmed at histology. This is important given the carcinogenic properties of *H. Pylori*.

Method This was a retrospective analysis of every CLO test that was performed between 01/08/16 and 31/10/16. For each patient that had a CLO test we checked the lab system for histology samples to check for any disparity. We also recorded the diagnosis at oesophagogastroduodenoscopy (OGD) and whether or not the patient was taking PPI medications.

Results 179 OGDs with CLO tests were performed in the specified time period. 11/179 were CLO positive (6.1%). 25/179 samples were sent for histology. 5/25 were CLO negative, histology positive. 2 of these patients were on a PPI. 19/25 were CLO negative, histology negative. 1 patient was CLO positive, histology positive.

Conclusions In a 3 month period, 5 cases of *H. pylori* would have been missed if histology wasn't sent. The diagnostic yield for *H. pylori* at histology was 24% compared to 6.1% with CLO testing. Given the carcinogenic properties of *H. pylori* we are now recommending that samples should be sent to histology in addition to CLO testing, if *H. pylori* is suspected.

29 ACUTE GASTROINTESTINAL BLEED (GI) MANAGEMENT SERVICES IN IRELAND: A HOSPITAL BASED SURVEY

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10.1136/gutjnl-2017-314127.29

Background Upper GI bleed (UGIB) is very common medical emergency and despite significant progress in its management it still carries a mortality of up to 10%. In order to assess the current management of UGIB in Ireland we performed a hospital based survey.

Aim In order to assess the current management of UGIB in Ireland we performed a hospital based survey.

Method We developed a 10 question based Monkey Survey and contacted all the Gastroenterology registrars and specialist registrars in Ireland.

Results Out of 26 hospitals contacted, 22 replied. From some hospitals we received more than one reply. Of those who replied 56% had no hospital guidelines and 96% had no formal rota for the management of UGIB and only 20% had access to their endoscopy unit out of hours. Endoscopy was performed within 24 hours of admission in 83% of cases. A formal Severity Assessment Score was used by 60%, with 36% using the Glasgow Blatchford Score. Pre-endoscopy 56% gave PPI infusions, while 6% said they never used them pre-procedure. Only 13% used IV erythromycin as a prokinetic agent. Where we received more than 1 reply from some hospitals there were discrepancies in those replies suggesting a lack of uniform approach internally.

Conclusions From the above results it can be concluded that there is a significant lack of guidelines for the management of UGIB, despite the high mortality it carries and even within the same hospital its management varies significantly. This survey highlights the need for formal guidelines for UGIB to be introduced.

30 ASSESSMENT AND MANAGEMENT OF ACUTE ALCOHOL WITHDRAWAL – AN AUDIT

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10.1136/gutjnl-2017-314127.30

Background 40% of individuals will develop an acute withdrawal syndrome upon stopping or significantly curtailing alcohol intake. A detailed alcohol history can be a useful aid in indentifying those at risk and avoiding adverse consequences of withdrawal.

Aim The aims of this audit were to quantify the proportion of acute admissions where an alcohol history is taken, assess the proportion of patients who were prescribed chlordiazepoxide and the doses used, assess the proportion of patients who were prescribed parenteral multivitamins, and the dose and duration of same.

Method Consecutive case series of 49 patients admitted to STGH from January-December 2016 with HIPE coding of "alcohol dependence with acute withdrawal". The Guys and St. Thomas' NHS Foundation Trust Clinical Guidelines on the detection of alcohol misusers attending hospital were used as reference standard.

Results In 82% (40/49 patients) a clear alcohol history was documented. For 62% of patients (30/49), the number of units of alcohol/week consumed was clearly documented. Median units/week was 50, with a range of 0-250. In 47% (23/49) of cases, a relevant neurological exam was documented in the admission note. Chlordiazepoxide was prescribed in 47% (23/49) of patients, with a median dose of 30 mg tds. Parenteral multivitamins were prescribed in 61% (30/49), for a median duration of 3 days.

Conclusions There exists a significant discrepancy between those identified at risk of acute alcohol withdrawal, and those for whom appropriate treatment is prescribed. Reasons include embedded prescribing practices, time constraints in ED, and uncertainty around appropriate dosing of chlordiazepoxide and parenteral multivitamins.

31 THE PROGNOSTIC VALUE OF TRANSIENT ELASTOGRAPHY: A SINGLE CENTRE IRISH STUDY

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10.1136/gutjnl-2017-314127.31

Background Transient elastography (TE) has facilitated the rapid and non-invasive assessment of hepatic fibrosis. Recent studies have signified its utility in identifying patients with early clinically significant portal hypertension (CSPH), providing valuable prognostic information and has been incorporated in the Baveno VI recommendations.

Aim The aim of this study was to assess for features of CSPH and evaluate the clinical outcomes in patients with TE scores of ≥ 10 kPa.

Method A retrospective review was performed on all patients attending the Hepatology Department in St. James' Hospital with valid TE measurements ≥ 10 kPa using an ECHO-sens Fibro-scanner with a M2 probe.

Results A total of 384 (18%) patients had transient elastography scores ≥ 10 kPa. The most common aetiologies were HCV $n=237$ (61.7%) and NAFLD $n=45$ (11.7%). A TE score of ≥ 30 kPa was highly predictive of numerous composite endpoints: liver-related hospital admissions OR8.6 (95% CI 4.1 to 18.0), decompensation OR12.7 (95% CI 5.47 to 29.3) and death OR8.61 (95% CI 2.8 to 26.5). The Baveno VI criteria demonstrated a good predictive value for the presence of oesophageal varices OR2.7 (95% CI 1.39 to 5.26), however, the negative predictive value was poor 79.1% in our mixed patient population.

Conclusions A TE score threshold of ≥ 30 kPa demonstrated good predictive value for identifying at risk patients. Although the Baveno VI criteria was useful for the discrimination of patients at risk of developing varices, other factors may also need to be considered in order to improve the negative predictive value.

32 DOES FAECAL CALPROTECTIN MEASUREMENT HAVE AN IMPACT ON PATIENT MANAGEMENT?

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10.1136/gutjnl-2017-314127.32

Background Faecal calprotectin (FC) is recommended to support the differential diagnosis of IBD or IBS in adults with recent onset lower gastrointestinal symptoms. FC can assess IBD activity in those with known disease, as a rising level is an early marker of potential relapse. There is presently no formal funding for FC within Northern Ireland.

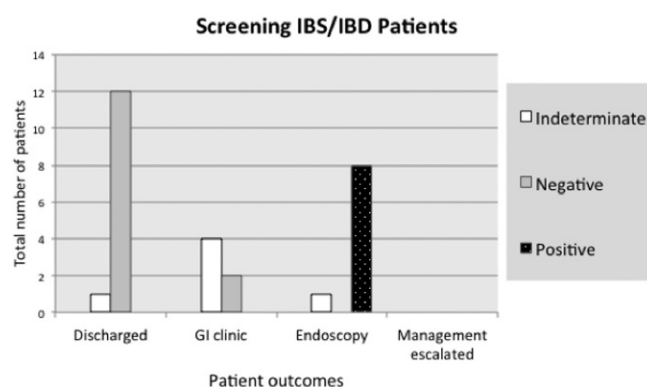
Aim To assess if FC measurement directs an immediate modification in patient management within two out-patient groups: 1) new patients with differential diagnosis of IBS or IBD; 2) review patients with known IBD.

Method A random selection of FC results from secondary care patients over 12 months were analysed. Patient outcomes following the FC result stratified patients into one of four groups: Discharged, colonoscopy performed, clinic review or escalation of medical therapy.

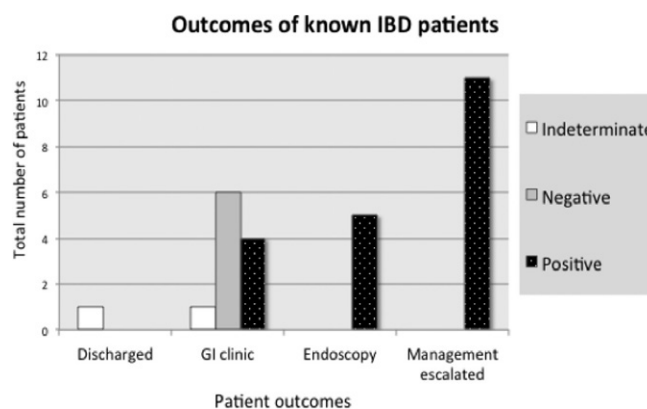
Results Group 1 ($n=28$): 8 positive FC, all proceeding to endoscopy. In the 14 negative FC, 12 patients were

discharged, 2 had clinic review. For indeterminate result: one patient with 2 indeterminate results underwent colonoscopy; 4 had clinic review; 1 was discharged. Group 2 ($n=28$): of the 20 positive results, 11/20 (55%) had medical management escalated, 5/20 (25%) underwent colonoscopy and 20% had clinic review. In the negative and indeterminate results: 7/8 had clinic review.

Conclusions For patients with suspected IBS, a negative FC avoided unnecessary colonoscopy. In patients with known IBD, a raised FC led to an escalation in therapy in the majority of patients to minimise the risk of relapse and potential hospital admission. This study supports the need for a Northern Ireland FC service.



Abstract 32 Figure 1



Abstract 32 Figure 2

33 A CASE-CONTROL STUDY COMPARING PRIMARY NON-RESPONDERS AND RESPONDERS TO INFLIXIMAB THERAPY IN INFLAMMATORY BOWEL DISEASE PATIENTS

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10.1136/gutjnl-2017-314127.33

Background Infliximab has been successfully used for the treatment of IBD for many years. However, treatment failures are common. Primary non-response was reported to occur in 13%–14% of patients in clinical trials. Therefore the early identification of non-response and timely switch to another agent, dose adjustment is of paramount importance.

Aim In literature, there is very little known about primary non-response to infliximab. Most of the studies done in the

past are based on loss of response or emergence of anti-infliximab antibodies. No such single study exists in the literature.

Method Total 218 patients records were searched. Out of 218, only 20 were included as cases. The inclusion criteria was either Crohns or Ulcerative colitis patient who were primary non-responders. Primary non-response was defined as all those patients who fail to respond to the standard induction doses of infliximab. Another 20 subjects were selected from the same pool as controls and were matched with cases in terms of age, sex and disease type.

This study was analysed using EPI-INFO STATCALC software from the CDC.gov.

Results Odds ratios were calculated using the 2by2 tables for matched-pair case control study. Smoking was associated with primary non-response and the OR was 2.33 with 95% CI. Similarly, in this study, there was a trend of primary non-response with low levels of CRP at the time of start of therapy with the odds ratio of 0.25 (95% CI) and p-value 0.054. The odds for albumin, weight and Haemoglobin were 0.8, 0.42 and 0.33 respectively and their p-values did not reach significance due to small sample size.

Conclusions From this study, there is a trend towards primary non-response to infliximab if a patient is a smoker with low levels of CRP at the time of initiation of therapy. Further studies with large sample size are needed to study the clinical significant association between haemoglobin, Albumin, and weight of the patients at the time of initiation of therapy.

34 AN INVESTIGATION OF GASTROINTESTINAL SYMPTOMS, PSYCHOLOGICAL WELL-BEING AND COGNITIVE PERFORMANCE IN INFORMAL DEMENTIA CAREGIVERS

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10.1136/gutjnl-2017-314127.34

Background Caring for a relative with dementia is considered particularly stressful and is associated with numerous adverse health effects at multiple levels of the brain-gut axis. There is also evidence that long-term family caregivers are more likely to develop irritable bowel syndrome.

Aim The current study aimed to compare family dementia caregivers to a non-caregiver control group, and to examine the impact of interventions, designed to help dementia caregivers manage stress and the caregiving role, on gastrointestinal symptoms, cognitive performance and psychological well-being.

Method Caregiver participants were recruited via clinics at St. Finbarr's Hospital, Cork and control participants via the university community. Participants completed the irritable bowel syndrome symptom severity scale, as well as validated tests of stress, anxiety, and depression. Participants also completed cognitive tasks from the CANTAB battery. A subset of caregivers completed both a carer training program and mindfulness-based stress reduction program. Each program was delivered in a group setting by an experienced instructor and lasted 6-8 weeks.

Results Although caregivers had higher levels of stress and poorer cognitive performance, gastrointestinal symptoms were

not altered compared to controls. Following both interventions, caregivers had improved cognitive performance. However, reported stress, anxiety and depression were not significantly altered following the interventions. Stress-reduction interventions also had no significant impact on gastrointestinal function.

Conclusions The stress associated with informal dementia caregivers does not manifest across gastrointestinal symptoms and stress-reduction techniques do not improve gastrointestinal well-being. This is in contrast to the impact of caregiving at higher levels of the brain-gut axis.

35 LEARNING TO TAKE CONTROL

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10.1136/gutjnl-2017-314127.35

Background Bowel care is a complex process, often a taboo subject. It is difficult to source a visual explanation tool for the teaching of the practical aspects of neurogenic bowel dysfunction for spinal cord individuals.

Aim To develop in a scientific manner an animation training video showing the following procedures: Insertion of a rectal suppository, Digital Rectal Stimulation and Digital Removal of Faeces.

This animation is a visual step by step approach, structuralising the education required for individuals with a neurogenic bowel dysfunction. It also supports their carers, families and health care professionals. Visual media will help to organise, process and retain information for the learner.

Method Kick off and research included compiling an interdisciplinary steering group. Relevant information was collected for the animation video including reviewing guidelines/articles/relevant bowel videos, etc. The driver diagram was used to plan the project along with the PDSA cycle (plan, do, study, act). Funding was obtained and animators were briefed on the project.

Results This animation DVD will augment the learning experience, by integrating technology and modernising our training for an enriched learning experience.

Overall results showed that 90% found the animation video excellent and suitable for both individuals with a spinal cord injury and health care professionals.

Conclusions The animation training video is not a standalone teaching tool, but will assist in providing relevant information. It will support training effectiveness for both skills and knowledge, using evidence based practice.

36 COMPARISON OF EFFECTIVENESS OF TWO ONE WEEK TREATMENT REGIMENS FOR H.PYLORI IN SOUTH OF IRELAND PATIENT COHORT

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10.1136/gutjnl-2017-314127.36

Background H. pylori eradication rates for 7 day triple therapy regimens have decreased in many countries in recent years. Recent European guidelines recommend that standard

triple therapy should not be used where local *H. pylori* resistance rates are greater than 15%.

Aim Aim of study was to compare *H. pylori* eradication rates of one week, metronidazole vs Clarithromycin based, triple therapy regimens in a south of Ireland patient cohort.

Method From January 2015 to September 2016 undergoing upper GI endoscopy by two gastroenterologists at the Bon Secours Hospital Cork had *H. pylori* status determined by CLO test (BioHIT). All Clo positive patients received one of two seven day *H. pylori* treatment regimens; PPI, Amoxicillin, Clarithromycin (PAC) or PPI, Amoxicillin, Metronidazole (PAM). All treated patients were offered urea breath test (Diabact UBT) 3- 4 months following treatment.

Results Of 2595 patients having upper endoscopy 188 (7.2%) had positive CLO tests. 45% (106/188) were females and mean age 56 (17 to 84 years). Of the 188 Clo positive patients, 118 (63%) received PAC treatment and 70 (37%) received PAM treatment. Of the 118 PAC patients 83 (69%) attended for UBT and 24 (29%) were positive. Of the 70 patients treated with PAM 50 (71%) returned for UBT and 14 (28%) were positive.

Conclusions In a patient cohort with relatively low *H. pylori* infection rates, one week based Clarithromycin and Metronidazole based triple therapy regimens achieved equivalent eradication of *H. pylori* (71% PAC, 72% PAM). *H. pylori* eradication rates are somewhat higher than recently reported in Ireland, they are well short of current European guidelines and add further weight to the recommendation that one week triple therapy regimen should not be used in this country for first line *H. pylori* eradication.

37 A WEIGHTY ISSUE: NUTRITIONAL SCREENING IN THE AMAU

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10.1136/gutjnl-2017-314127.37

Background IrSPEN states that malnutrition affects ~145 000 adults at any time in Ireland, especially in chronic illness with >95% of malnourished being community based. HIQA's Report "Review of Nutrition and Hydration Care in Public Acute Hospitals" suggests nutritional assessment within 24 hours of hospitalisation to identify high risk or malnourished patients. In 2011, The Acute Medical Assessment Unit (AMAU), CUH reviewed 5560 patients. Nutritional screening is routinely completed on admitted patients however it was unclear what nutrition details were being recorded on day patients.

Aim To assess if nutritional screening is currently being performed in AMAU day patients.

Method A chart review of 52 consecutive day patient discharges was undertaken examining recording of nutritional screening and weight loss history.

Results 52 consecutive patient charts (19 males, 33 females) were examined with an average age of 53.4 years with an average of 1.46 co-morbidities. Weight was recorded on 36.5% of patients with 26.9% having a hydration status measured. A weight loss history was taken in 19.2% of patients, 40% of which listed weight loss as their presenting complaint. One patient had a BMI completed. A nursing pro-forma in relation to diet consumed was completed in 55.8% of patients.

Conclusions Currently full nutritional screening is not being performed on AMAU day patients. An AMAU patient visit could represent a unique opportunity to nutritionally screen and intervene in high risk multimorbid ill community dwelling day patients. Current barriers to implementation of full nutritional screening include staff shortages, staff training and access to dietetics input if found to be at high risk.

38 SINGLE CENTRE EXPERIENCE WITH H.PYLORI ERADICATION THERAPY

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10.1136/gutjnl-2017-314127.38

Background *Helicobacter pylori*, is a gram-negative, microaerophilic bacterium usually found in the stomach and has been linked with chronic gastritis, gastric and duodenal ulcers, gastric cancer and MALT.

An increasing resistance to antibiotics has resulted in changes in the recommended eradication therapy.

The *H. Pylori* study group has recently updated the recommended eradication therapy.

Aim To study the compliance with the updated therapy for *H. Pylori* infection.

Method The prescriptions for triple therapy were collected and reviewed in compliance with the guidelines.

The results of the follow-up Urea Breath Test following completion of eradication therapy were recorded and the rate of successful eradication was compared in the group of patients who were treated according to the new recommendations versus old recommendations.

Results The initial compliance with the new guidelines was 82%. Staff and junior doctor education have resulted in improvement in compliance rate.

Conclusions 1. Longer duration of therapy and more compliance with new guidelines has been associated with improved eradication therapy.

2. Confirming eradication of *H. Pylori* is an essential step in reducing and eliminating long term complications.

39 IS IT TIME TO REVISIT THE RED FLAG REFERRAL SYSTEM?

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10.1136/gutjnl-2017-314127.39

Background The 'red flag referral' system is currently under stress due to the number of suspected cancer referrals. There are guidelines from the Northern Ireland Cancer Network regarding specific criteria for what constitutes a red flag referral.

Aim To assess the efficacy of the 31- and 62 day referral pathways over a 1 year period for both upper and lower gastrointestinal cancers in a district general hospital.

Method All upper and lower GI suspected cancer referrals were assessed over a 1 year period (October 2015 – September 2016). Both 31 day and 62 day referral pathways were analysed following investigation. Data were obtained from cancer trackers.

Results For suspected Upper GI cancers, there were 2629 (1109 31 day in-hospital referrals; 1520 62 day general practice referrals) referrals over the 1 year period. There were 164 confirmed cancers (overall 6.24%, 31 day: 9.64%, 62 day: 3.75%). For lower GI cancers, there were 3951 (1299 31 day in-hospital referrals; 2652 62 day general practice referrals) referrals over the 1 year period. There were 188 confirmed cancers (overall 4.76%, 31 day: 9.62%, 62 day: 2.38%).

Conclusions There was a very low diagnosis of cancer from red flag referrals for both upper and lower GI symptoms. In the current environment of increasing demands on the NHS—is it time for current red flag referral criteria to be revisited?

40 CORRELATION OF RELATIONSHIP BETWEEN INFLIXIMAB AND ADALIMUMAB TROUGH AND ANTIBODY LEVELS WITH CLINICAL RESPONSE RATES AT COMPLETION OF INDUCTION THERAPY

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10.1136/gutjnl-2017-314127.40

Background Anti-TNF α therapies have improved response rates in inflammatory bowel disease. However primary loss of response is problematic.

Aim Aim of this study was to explore relationship between infliximab (IFX) and adalimumab (ADA) trough and antibody levels with clinical response.

Method This was a prospective, single centre study. Patients were recruited from July 2015-August 2016. Inclusion criteria were patients older than 17 years with IBD who started treatment with anti-TNF α drugs (infliximab/adalimumab) Patient demographics, clinical history were collected from electronic records. Clinical disease activity indexes were performed (Harvey-Bradshaw Index for Crohn's disease (CD), and partial Mayo scores for Ulcerative colitis (UC)). Clinical response defined as reduction in HBI \leq 3 or reduction in partial Mayo score \leq 4 and $<$ 30% from baseline. Anti-TNF α trough and antibody levels were measured using ELISA.

Results 35 patients were recruited; 23 CD, 12 UC. 18 patients treated with ADA, 17 IFX. Mean age 40.3 years, 62.9% female, 34.3% thiopurines, 25.7% prior anti-TNF α exposure. Response rate 51.4%, 33.3% for ADA, 70.6% for IFX. Overall trough levels were 12.5 ug/ml for IFX, 4.4 ug/ml for ADA. There was clear link between higher anti-TNF α trough levels at induction with clinical response. For infliximab, mean trough levels in responders were 16.4 ug/ml (IQR 8.4-22.7) versus 5.3 ug/ml (IQR 0.5-8.8) for non-responders (p value 0.02 95% CI: 1.5 to 20.7). Similarly there was a link between higher ADA levels with clinical response, though not statistically significant. Responders mean trough 6.6 ug/ml versus non-responders 3.0 ug/ml (p value 0.14). Antibody formation occurred in 28.5%.

Conclusions Higher anti-TNF α trough levels at induction are associated with improved clinical response.

41 RECTAL NSAIDS AND SELECTIVE PANCREATIC STENTING SIGNIFICANTLY REDUCES ACUTE PANCREATITIS IN NORMAL RISK ERCP

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10.1136/gutjnl-2017-314127.41

Background In high-risk cases a combination of non-steroidal anti-inflammatory drugs (NSAIDs) and selective pancreatic stenting may reduce the risk of post ERCP pancreatitis (PEP). However, studies on whether this practice reduces PEP in normal risk ERCPs have shown conflicting results.

Aim To compare the rate of PEP for normal risk ERCP, where patients are administered rectal NSAIDs immediately following the procedure with selective pancreatic stenting (N/S), against the previous practice, which did not incorporate N/S.

Method Consecutive ERCPs from 2009–2016 were analysed pre and post N/S. In the post N/S group rectal NSAIDs were administered immediately following the procedure. Pancreatic stents were used if the pancreatic duct was cannulated more than three times during the procedure. PEP was defined as post ERCP abdominal pain and a rise in amylase to at least twice the upper limit of normal. Statistical analysis was by paired t and McNemars tests.

Results 574 ERCP procedures were performed, of which 509 were successful (89%). 335 (58%) were female, with an average age of 67.7 (range 16–94 years). 488 were therapeutic (96%). There were no statistically significant differences in the demographics of each group. 23 of 375 (6.1%) in the Pre N/S group developed PEP compared with 4 of 199 (2%) in the Post N/S group, p=0.02.

Conclusions This study shows a further significant reduction of PEP in normal risk ERCP in a cohort of patients with a historically low PEP rate following the introduction of rectal NSAIDs and selective pancreatic stenting.

42 DEPRESSION-ASSOCIATED ALTERATIONS IN THE MATERNAL MICROBIOME DURING PREGNANCY: PRIMING FOR ADVERSE INFANT OUTCOMES?

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10.1136/gutjnl-2017-314127.42

Background Women at high risk of prenatal depressive symptomatology have higher rates of adverse obstetric outcomes (1) and altered infant development (2). The mechanisms

underpinning this may be linked to inappropriate remodelling of the microbiome during pregnancy and subsequent vertical transmission of a suboptimal microbiome at birth.

Aim This cross-sectional study aimed to assess the association between the maternal microbiome and depressive symptoms.

Method Women enrolled in the IMPROVED study at Cork University Maternity Hospital (3) completed the Edinburgh Postnatal Depression Scale (EPDS) and provided faecal samples during the second (n=46) and third trimester (n=33) of pregnancy. Vaginal swabs were collected prior to delivery (n=60). EPDS ≤ 8 and EPDS ≥ 9 were used to indicate low and high depressive symptoms respectively. Microbial community structure analysed by 16S rRNA gene sequencing.

Results Women reporting higher depressive symptoms in second trimester had reduced phylogenetic diversity ($p=0.024$) and species richness (chao1; $p=0.040$) of the gut microbiota. There were significant alterations observed at Phyla, Family and Genus level including an increase in the dominant Faecalibacterium ($p=0.029$) among the higher depressive group. The magnitude of the depression-associated gut alterations was greatly reduced in the third trimester. The vaginal microbiome remained largely unchanged by prenatal depressive symptoms.

Conclusions The experience of depressive symptoms in mid pregnancy is associated with marked alterations in the maternal gut microbiome that do not persist into late pregnancy. Further studies are planned to clarify the implications of these depression-associated maternal microbiome alterations during pregnancy for obstetric outcomes and infant development.

43 SERIAL TRANSIENT ELASTOGRAPHY READINGS INDICATE PROGRESSION OF UNTREATED FIBROSIS AMONG PATIENTS ATTENDING OPIOID SUBSTITUTION TREATMENT CLINIC IN SOUTH COUNTY DUBLIN

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10.1136/gutjnl-2017-314127.43

Background Injecting drug use (IDU) is a major driver of the hepatitis c virus (HCV) epidemic. Opioid substitution treatment clinics (OST) are the main provider of care for these individuals.

Aim To assess the prevalence of significant liver disease and progression in patients attending an OST clinic and evaluate the effectiveness of opportunistic Transient Elastography (TE) service in this setting.

Method Unselected serial TE readings were carried out on patients in the OST clinic in 2008 and 2016. Mortality in the 2008 group was related to TE readings and progression of TE readings from 2008 to 2016 was recorded.

Results In 2008, 84 patients were scanned. Of these 77% were HCV Ab positive and 58% of this group were HCV viraemic. By 2016, all of the 2008 patients with TE scores >13 Kilopascal (Kpa) had died (a total of 13 patients) and 11 of these patients died as a result of liver failure associated with hepatitis c viraemia and alcohol. In 2016 105 scans were carried out on surviving patients from 2008 who still attended the clinic and on new patients attending the clinic. 16 patients (15%) of the 2016 population had TE scores >13 Kpa, the previous threshold for death at eight years.

Conclusions This longitudinal data demonstrates universal mortality at 8 years among OST patients with a TE reading of 13 Kpa or greater. Among surviving patients it demonstrated widespread progression of TE readings to levels indicating a requirement for early DAA treatment, and to levels previously associated with high mortality.

44 CONSCIOUS SEDATION IN ERCP : THE UNCOMFORTABLE TRUTH

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10.1136/gutjnl-2017-314127.44

Background Compared with standard endoscopy, Endoscopic Retrograde Cholangio-Pancreatography(ERCP) is an uncomfortable, complex procedure that typically requires higher doses of sedative and analgesic medication. Our unit, like many throughout Ireland and the UK, performs the vast majority of ERCPs under conscious sedation. Challenges with appropriate sedation levels and patient compliance during ERCP are common.

Aim To evaluate patient comfort (1-4) and sedation score (1-5) with conscious sedation using a scoring system based on the modified Gloucester score.

Method We prospectively evaluated consecutive ERCPs performed under conscious sedation over a three-month period in a single, tertiary referral centre.

Results 121 patients were evaluated. The median age was 73, and 60/121 (49.6%) were female. 46 patients (38%) were ≥ 75 years. 62 patients (51%) had a comfort score of ≤ 2 , and 59 (49%) had a comfort score of ≥ 3 . One patient required reversal of sedation due to respiratory compromise. Median doses of medication were: midazolam (4.27 mg), diazepam (7.5 mg), fentanyl (84 mcg), and pethidine (35.7 mg). 7 patients received more than one benzodiazepines, 7 with more than one opiates and 6 with all four medications.

Conclusions There are limited data to define what is acceptable sedation practice for ERCP. The RCPI have recently recommended that $>80\%$ of colonoscopies should have a comfort score of 1 or 2. Though there are no validated comfort scores for ERCP, our data demonstrate that many patients undergoing ERCP with conscious sedation are subjected to an experience that would be considered unacceptable in general endoscopy.

45 NEW-ONSET DIABETES AFTER TRANSPLANT (NODAT): INCIDENCE, RISK ANALYSIS AND IMPACT ON SURVIVAL

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10.1136/gutjnl-2017-314127.45

Background Orthotopic liver transplant has become the standard of care for end-stage liver disease and hepatocellular cancer. Better immunosuppressant paved way for improved survival rates post-transplant. But with this longevity comes a higher prevalence of chronic diseases such as New Onset Diabetes After Transplant (NODAT), Hypertension, metabolic syndrome etc. which have a negative impact on graft function and patient survival.

Aim To study the incidence of NODAT, factors predictive of NODAT and impact of NODAT on mortality and post-transplant survival.

Method It was a retrospective cohort study of 283 living donor liver transplant recipients from 29/4/2011 till 26/4/2016. Data was collected from records. Simple means and standard deviation was calculated for continuous variables while frequency statistics were calculated for categorical ones. Risk factors were assessed using binary logistic regression analysis.

Results A total of 130 post liver transplant patients were analysed after exclusion. NODAT was present in 41/130 (31.5%) patients, while 19/130 (14.6%) patients had impaired fasting glycaemia.

Acute cellular rejection and Post-transplant Hyperglycemia showed increased odds of acquiring NODAT post-transplant.

NODAT had significant association with mortality and decreased survival ($p=0.05$).

Conclusions This cohort showed that NODAT is an important post-transplant entity with significant impact on mortality and survival. Early identification of at-risk patients is suggested.

46 INPATIENT ADMISSIONS FOR LOWER GASTROINTESTINAL BLEEDING IN THE BELFAST TRUST

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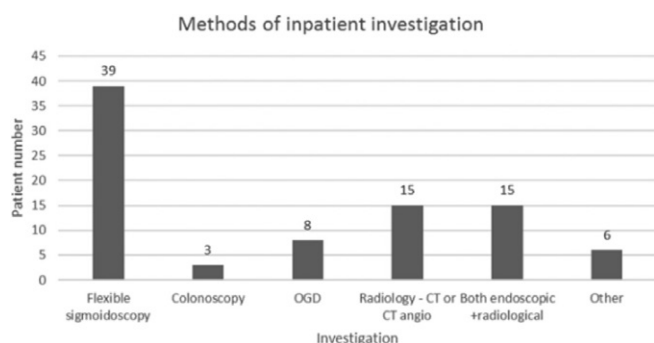
10.1136/gutjnl-2017-314127.46

Background Traditionally, lower GI bleeding (LGIB) is admitted surgically but the recent NCEPOD report has recommended an integrated pathway for all gastrointestinal bleeds.

Aim To retrospectively assess how LGIB is managed within the Trust.

Method Inpatient discharge data were gathered over a 12 month period (March 2015-March 2016). Cases included were those with LGIB as the primary reason for admission. Factors including length of stay, inpatient and/or outpatient endoscopic and radiological investigations. 30 day mortality rate was assessed.

Results 350 patients were identified, 174 were excluded (UGIB or not primary reason for admission). 176 patients were included, age range 17–100 (median 66). Median length of stay=3.19 days (range 0–27). Total bed days 562. 30 day mortality=3.9% ($n=7$, 2 secondary to PR bleeding and 5 due to co-morbidities). $n=86$ (48.9%) patients had inpatient investigations. See Figure 1.



Abstract 46 Figure 1

50 patients had only inpatient endoscopic procedures, 15 had both endoscopic and radiological investigations and 15 had only radiological investigations. Others included EUA and haemorrhoidectomy. $n=46$ (26.1%) had only outpatient investigations. Total bed days=83. $n=44$ (25%) had no investigations. Reasons included known pathology, recent endoscopy or CT imaging, recent intervention (surgical or endoscopic) or not fit for investigation. Most common diagnoses were diverticular bleed $n=59$, haemorrhoids $n=12$, malignancy $n=10$.

Conclusions Less than half had inpatient investigations suggesting that many admissions could have been avoided. The current results show a low mortality rate consistent with other published data. A pathway for the management of stable LGIB bleeding could be developed to minimise unnecessary admissions and streamline access to intervention where needed.

47 A CASE OF PRIMARY GASTRIC MELANOMA: NO LIGHT AT THE END OF THE TUNNEL

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10.1136/gutjnl-2017-314127.47

Background Malignant melanoma of the gastrointestinal tract is usually a metastasis from a cutaneous source. Primary gastric melanoma is an extremely rare clinical entity, with only 14 reported cases worldwide. It is often advanced at time of diagnosis and is associated with a poor outcome.

Aim To describe a case of primary gastric melanoma.

Method A 76 year old gentleman, presented with a one month history of fatigue and exertional dyspnoea. Laboratory investigations indicated an anaemia, with a haemoglobin level of 11.0 g/dL. Subsequent gastroscopy visualised a large, atypical, crater-like ulcerated lesion distal to the cardia in the proximal stomach.

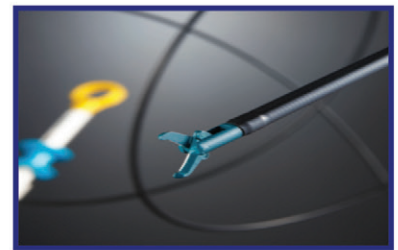
Results Provisional histology was suggestive of a poorly differentiated adenocarcinoma but subsequent cyto-morphology and immunophenotyping were consistent with melanoma, with positive S100 protein, HMB45 and Melan A. Further molecular genetic testing revealed a V600R mutation in the BRAF gene, which is the first primary gastric melanoma with this mutation to be reported in the literature. Given the rarity of the findings, an extensive secondary work-up was undertaken, which concluded the diagnosis primary gastric melanoma.

Conclusions Primary gastric melanoma is a rare disease that can present similarly to other upper gastrointestinal lesions, with weight loss, abdominal pain, melena, and anaemia. Given its rarity, the pathogenesis is poorly understood. Lesions are often endoscopically atypical. Important points to note would include the absence of a primary lesion, as supported by a full skin examination and PET-CT findings, which can help to delineate the limitation to the stomach, thus helping to inform subsequent management.

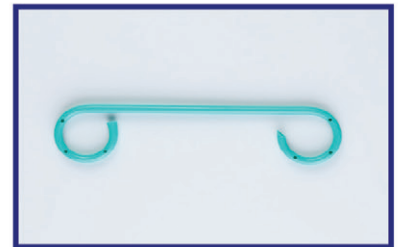
BVM

24 hours a day

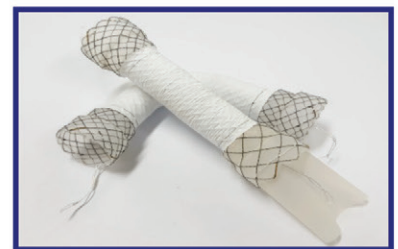
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TIME TO TAP? AN AUDIT OF DIAGNOSTIC PARACENTESIS IN INPATIENTS WITH CIRRHOSIS AT A UNIVERSITY TEACHING HOSPITAL

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10.1136/gutjnl-2017-314127.48

Background Spontaneous bacterial peritonitis (SBP) is a diagnosis associated with significant mortality. It has previously been shown that delayed paracentesis is associated with increased inpatient mortality in patients with SBP.

Aim The aim of this audit was to identify time elapsed between patient presentation and the performance of diagnostic paracentesis at a University teaching hospital.

Method We included all patients who presented to the emergency department with ascites in the setting of cirrhosis and who had a diagnostic paracentesis. In all, 122 patients over 12 months were included in our study. Data was collected retrospectively from electronic patient records. Samples were categorised according to 3 time ranges: <12 hours, 12-24 hours, >24 hours.

Results Time to paracentesis is outlined in Table 1. 29.5% of patients didn't have a white cell count sent as part of their ascites tap. 13 of the 86 patients (15.1%) with WCC sent were diagnosed with SBP, 5 of these were diagnosed >24 hours after presentation. Mortality was higher in patients whose diagnostic paracentesis were delayed until >24 hours after presentation (3/5) compared to those with paracentesis performed at <24 hours (1/9). $p=0.052$.

Abstract 48 Table 1

Time between presentation and diagnostic paracentesis	No. patients	% patients
<12 hours	46	37.7%
12-24hrs	25	20.5%
>24 hours	51	41.8%

Conclusions A significant number of patients experienced delayed paracentesis. Recommendation: Education of NCHDs in the importance of diagnostic paracentesis to guide management and reduce mortality. Further training in the skill of performing paracentesis. Re-audit following these proposals.

49

SUPRA GASTRIC BELCHING SYMPTOMS, PREVALENCE AND ASSOCIATED DISEASE

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10.1136/gutjnl-2017-314127.49

Background Supragastric belching (SGB) is considered a behavioural disorder where air is ingested in to oesophagus and immediately expelled again; it can result in symptoms of excessive belching and has a significant impact on quality of life.

With the advent of the intraluminal impedance recording technique, it has become possible to monitor the passage of air through the oesophagus, either in ab-oral or ad-oral directions.

Aim Determine the prevalence of excessive SGB within our tertiary referral gastrointestinal physiology unit and evaluate

the predominant presenting symptoms and examine its association with gastro-oesophageal reflux disease and motility disorders.

Method Data was collected retrospectively from our data base system, we reviewed 442 reports of 24 hours PH-Impedance and high resolution oesophageal manometry from January 2015 to December 2016.

Symptoms were reviewed from patients' charts. These included the predominant presenting symptom, symptoms of acid reflux and heartburn, regurgitation and dysphagia.

Results A total of 98 (22%) patients were found to have excessive SGB. predominant presenting symptom was heartburn (55%), only 18% had pathological acid exposure. Dysphagia was reported in 23% and regurgitation in 7%. only 7% presented with isolated symptom of belching, Esophageal hypomotility was seen in 48%.

Conclusions Excessive SGB was common finding in 24 hours PH-impedance manometry studies, the main predominant symptom was heartburn, and there appears to be an association with oesophageal hypomotility and to a lesser extent with gastrooesophageal reflux disease.

50

PORTOMESENTERIC VENOUS THROMBOSIS AS AN INDICATION FOR INTESTINAL OR MULTIVISCERAL TRANSPLANTATION

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10.1136/gutjnl-2017-314127.50

Introduction The established indications for Intestinal and Multivisceral (MVT) transplant include IFALD, loss of vascular access and recurrent line sepsis.

Aim Over the last four years there have been an increasing number of patients with portomesenteric venous thrombosis (PMVT) referred some of whom are not cirrhotic.

Method Data was collected on all patients who underwent Intestinal or MVT between 2006 and 2013 in Addenbrooke's hospital, Cambridge and was then divided into pre 2013 and post 2013.

Results Over the last 8 years there were 73 transplants in 67 patients. Between 2006 and 2013 there were 30 transplants compared to 43 transplants since 2013. Short gut syndrome remains the largest indication for transplant with 16 (53%) transplants between 2006 and 2013 and 22 (51%) transplants from 2013. Prior to 2013 only 3 patients had undergone multivisceral transplant for cirrhosis complicated by PMVT. Since 2013 there have been 8 transplants for cirrhosis complicated by PMVT. Five of these were multivisceral transplants while three underwent a liver-small bowel transplant. In 2016 two patients with PMVT not complicated by cirrhosis underwent isolated Intestinal transplants. One patient required a Whipple procedure but was unable to have this due to PMVT. The other patient had recurrent bleeding with PMVT not amenable to conventional therapy.

Conclusions While the established indications for Intestinal or MVT remain, there has been an increase in the number of transplants performed for cirrhotic patients with PMVT in which an isolated liver transplant is precluded.

51 VITAMIN D DEFICIENCY SHOWS NO RELATIONSHIP TO DISEASE ACTIVITY IN AN IRISH INFLAMMATORY BOWEL DISEASE (IBD) POPULATION

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10.1136/gutjnl-2017-314127.51

Background Low levels of vitamin D have been widely reported in IBD with evidence suggesting a role in disease severity and treatment.

Aim Ireland has high rates of vitamin D deficiency both in IBD and general populations. Studies investigating correlation of vitamin D deficiency and disease parameters have been mixed.

Method We conducted a single centre retrospective study in our hospital from Jan 2015- June 2016. The aim was to assess the prevalence of vitamin D deficiency in IBD and non-IBD cohorts and to assess the impact of vitamin D deficiency on disease activity in IBD. Patients were separated into 4 groups: Crohns Disease (CD), Ulcerative Colitis (UC), general gastroenterology (GI) and general medical (non-GI). Basic demographic data disease specific information was recorded. Vitamin D deficiency was defined as <30 nmol/L.

Results 395 patients were studied: 157 CD, 70 UC, 75 GI and 93 non-GI. IBD patients were found to have high rates of Vitamin D deficiency (33% levels <30 nmol/L). Serum Vitamin D did not differ significantly between groups with mean values of 44.9 nmol/L (CD), 50.7 nmol/L(UC), 45.4 nmol/L(GI) and 45.6 nmol/L(non-GI). Symptomatic IBD patients had significantly higher mean CRP levels (8.6 mg/L) versus those who were asymptomatic (3.5 mg/L), ($p < 0.001$). 35% of IBD patients who were symptomatic had vitamin D deficiency compared with 27% of those who were asymptomatic.

Conclusions We found very high rates of vitamin D deficiency in both IBD and non-IBD patients. Absolute levels did not differ significantly between groups. This may be accounted for by high overall prevalence of Vitamin D deficiency in this population or by confounders in the control population.

52 THE EFFECT OF PARACETAMOL LEGISLATION ON ADMISSIONS FROM PARACETAMOL OVERDOSE IN IRELAND

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10.1136/gutjnl-2017-314127.52

Background Paracetamol overdose (POD) is a prevalent issue worldwide and ease of access has been described as a principal factor for the drug so commonly used. In 2001, Ireland introduced a pack size legislation limiting access to 24-tablets in a pharmacy and 12-tablets in a non-pharmacy setting within a single transaction. To date no study has been published to assess the impact of the legislation at a national level.

Aim The aim of this study is to assess whether the 2001-legislation has reduced hospital admissions from POD in Ireland.

Method Data for POD from 1997 to 2011 was obtained from Healthcare Pricing Office, HSE, which collects data for inpatient admissions to hospitals in Ireland. The data from the

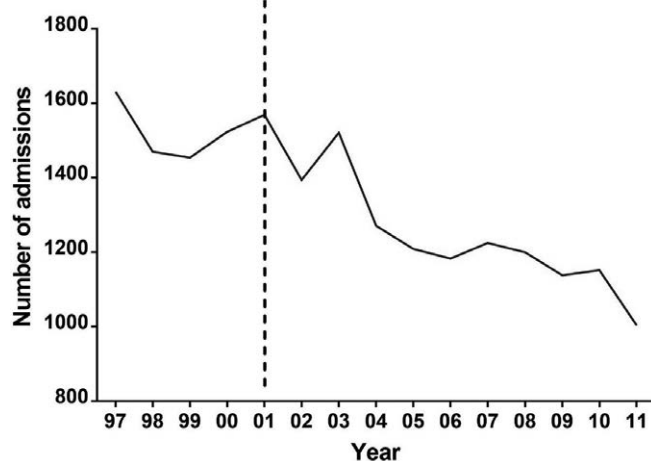
five years before and after the legislation was compared (1997-2001 vs. 2002-2006). Data from 2002-2006 was then compared to a further five years (2007-2011) to assess whether the changes were maintained.

Results There were a total of 14 225 patients admitted from 1997-2006. 7647 patients were admitted from 1997-2001 and 6414 from 2002-2006. There was a statistically significant difference between the mean number of admission during these periods (1529 ± 72.7 vs 1315.6 ± 140.78 ; p -value 0.0166).

From the year 2007-2011, 5719 patients were admitted. When comparing 2002-2006 with 2007-2011, a statistically significant difference was again noted (1315.6 ± 140.78 vs 1143.80 ± 85.73 ; p -value 0.0481).

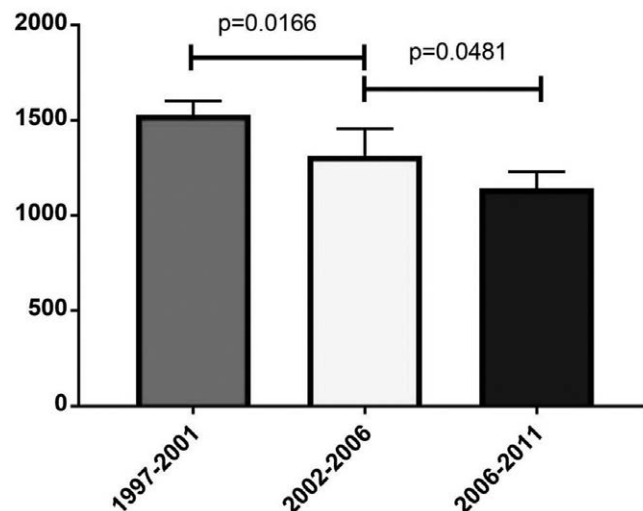
Conclusions This study has demonstrated that the 2001-legislation has significantly reduced POD admissions in Ireland. Results of this study can potentially be used as a basis for legislation on other potential harmful substances for example minimum pricing for alcohol which the Irish government is currently reviewing.

Number of admissions per year



Abstract 52 Figure 1

Mean number of admissions



Abstract 52 Figure 2

53 LONG TERM FOLLOW UP OF MICROSCOPIC COLITIS

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10.1136/gutjnl-2017-314127.53

Background Microscopic colitis (MC) has been increasingly diagnosed in recent years. The two main variants are lymphocytic colitis (LC) and collagenous colitis (CC).

Aim To evaluate the long term natural history and follow-up of patients diagnosed with MC.

Method Patients diagnosed with MC were identified from the histopathology department database in our institution. Clinical details were obtained through a combination of chart review and follow up telephone interview.

Results
Abstract 53 Table 1

	MC (%total)	LC	CC
Number	94	63 (67%)	31 (33%)
Sex: female	69 (73%)	44 (70%)	25 (80%)
Male	25 (27%)	19 (30%)	6 (20%)
Median age at diagnosis	56.5 yrs	55 yrs	58yrs
Smoking	43 (46%)	25 (40%)	18 (58%)
Presentation			
Diarrhea	89 (94.7%)	58 (92%)	31(100%)
Other	5 (5.3%)	5 (8 %)	
Thyroid disease	44 (47%)	37(58.7%)	7(22.6%)
Coeliac disease	11 (12%)	9(14.3%)	2(6.5%)
Medications			
NSAID	26 (28%)	19(30.2%)	7(22.6%)
Statin	28 (30%)	18(28.5%)	10(32.3%)
PPI	40 (43%)	29(46%)	11(35.5%)

Abstract 53 Table 2

	LC	CC	LC+CC
Patients under follow up (F/U)	34(54%)	25 (80.6%)	59(62.8%)
Patients have no follow up(F/U)	29(46%)	6(19.4%)	35(37.2)
F/U colonoscopy 1			
Median duration	2.6 yrs	2.2 yrs	2.4 yrs
Result			
Normal	8(40%)	6(42.8%)	14(41.2%)
MC (LC /CC)	12(60%)	8 (57.2%)	20(58.8%)
F/U colonoscopy 2			
Median duration	6.6 yrs	6.2 yrs	6.4 yrs
Result			
Normal	8(80%)	4(66.7%)	12(75%)
MC (LC/CC)	2(20%)	2(33.3%)	4(25%)
Median follow up duration	5.9 yrs	4.7 yrs	5.3 yrs
Treatment given	Budesonide Colectyramine Mesalazine Salazopyrin Prednisolone	Budesonide Colectyramine Mesalazine Salazopyrin Azathioprine (1 case)	

Conclusions MC is commonly associated with other autoimmune conditions. A significant proportion of patients had no follow-up/did not seek follow-up which raises the possibility that their symptoms were not problematic. Further follow-up

of patients with MC is necessary to gain better insight into the natural history of this condition.

54 THE GEOGRAPHICAL DISTRIBUTION OF COLORECTAL POLYPS IN THE WEST OF IRELAND POPULATION

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10.1136/gutjnl-2017-314127.54

Background BowelScreen, the faecal immunochemical test based national colorectal cancer screening programme, commenced in May 2013. There is a large variation in the global distribution of colorectal cancer, but there is limited data on local geographic variations.

Aim The primary aim was to investigate for local variations in geographic distribution of colorectal polyps in the UHG BowelScreen catchment area.

Method All screening colonoscopies completed were analysed for the presence of advanced pathology (i.e. polyp ≥ 10 mm and/or ≥ 5 polyps detected and/or tumour detected). Only towns with a population ≥ 1000 as per 2011 census figures were included.

Results Between 2013 and 2016; 1191 colonoscopies were included, with 790 patients having a polyp detected (67% of the total cohort) of whom 295 (25%) found to have advanced pathology. 153/1191 (13%) had polyps > 10 mm in size, 153/1191 (13%) had ≥ 5 polyps and 32/1191 (3%) had tumours diagnosed based on endoscopic appearance.

The prevalence of large polyps ranged from 3.2-32/10,000 per settlement. Similar trends were seen with respect to multiple polyps (from 0-23/10,000) and cancer (0-5/10,000). Hot-spots of advanced findings were particularly notable in east Galway (Ballinasloe, Tuam, Loughrea) and mid Mayo (Swinford, Ballyhaunis, Belmullet).

Conclusions There appears to be a wide local variation in the local geographic distribution of advanced colorectal polyps. This variation may be due to a combination of demographic, lifestyle, environmental or genetic differences in each area. Further study is needed, and could identify areas where bowel screen advertising could be intensified to improve participation rates and yields of endoscopy.

55 PATIENT SURVEY TO ASSESS STOOL TESTING COMPLIANCE

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10.1136/gutjnl-2017-314127.55

Background Stool testing is increasingly used as a GI investigational tool. We are currently conducting a prospective study using non-invasive tests including stool testing in the initial assessment of patients referred to our gastroenterology unit. Faecal sample return rate in our study is 60% for patients < 50 years, and 75% for > 50 years.

Aim A patient survey was conducted to identify (1) reasons for reduced faecal testing compliance, and (2) ways to improve it.

Method The anonymous survey was randomly distributed to patients in gastroenterology clinics over 4 weeks.

Results Of 282 surveys distributed, 226 (80%) were returned. 3 were excluded. 223 surveys were stratified into group A: age <50 years (n=120), and group B: age >50 years (n=103). 87 (39%) patients were previously asked to provide a stool sample by a medical professional; 48 in group A and 39 in group B. 55% were female. 81 (93%) patients returned the faecal sample, with no statistically significant difference between the two groups. 82% and 84% felt adequately informed regarding the indication and method for stool collection. Reasons for not completing stool testing in 6 patients were, uncomfortable with test or technical difficulty. The good compliance with stool testing which does not correlate with our previous clinical experience, suggests those not completing stool testing were less likely to participate in the survey.

Conclusions Compliance may be improved by patient education, user friendly stool collection kits, and a public based strategy addressing attitudes, fears, and awareness of stool testing.

56 PERFORMANCE OF A NOVEL MOLECULAR STOOL SCREENING TEST, THE FAECAL COLOGUARD® IN A COHORT OF IRISH SYMPTOMATIC AND SURVEILLANCE PATIENTS

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10.1136/gutjnl-2017-314127.56

Background Screening tests for precancerous polyps and early CRC reduce mortality. Cologuard is a stool-based, commercially available, molecular screening tool that detects occult blood in combination with multiple DNA abnormalities released from neoplastic colonic cells (from small polyps to cancers). Previous population-based studies reported a sensitivity and specificity of 69%–92% and 87% respectively for detection of polyps.

Aim To evaluate the Cologuard in asymptomatic low risk surveillance and symptomatic patients.

Method Ethics approval was obtained and patients were recruited from endoscopy referrals and the colonoscopy surveillance waiting list. Inclusion and exclusion criteria in Table 1. Participants provided stool for Cologuard prior to colonoscopy. Cologuard and Colonoscopy results were correlated to calculate NPV, PPV, sensitivity and specificity.

Abstract 56 Table 1 Study criteria

Inclusion criteria	Exclusion criteria
Age over 40 years	High risk CRC genetic e.g Lynch syndrome
Capacity to understand the study and give informed consent	Iron deficiency anaemia
Symptoms of altered bowel habit, diarrhoea, or constipation	Recent GI bleed
Asymptomatic patients with previous colonic adenomatous polyps	Known Inflammatory Bowel Disease
Asymptomatic patients with family history of adenomatous polyps or CRC	Recent weight loss
	pregnancy

Results 60 patients were recruited. To date 40 have completed the study. 22 (55%) female. Median age 60 years (range 42–80). 18 (45%) patients were symptomatic. Colonoscopy adenoma detection rate was 28% (n=11). Cologuard was positive in 10 (25%) patients, 4 of whom had adenomatous polyps, 1>10 mm size and 3<5 mm. Of 7 negative Cologuard patients with adenomatous polyps 1>1 cm in size, 1=7 mm and 5<5 mm. Cologuard was negative in 23/29 (79%) with normal Colonoscopy. The NPV and PPV of Cologuard were 77%–40%, with 36% sensitivity, and 79% specificity. NPV is 90% for polyps>5 mm. No CRC was diagnosed.

Conclusions Cologuard seems reliable for excluding CRC and adenomatous polyps>5 mm in size, and maybe useful in triaging surveillance patients for Colonoscopy.

57 COLONOSCOPY FOR WEIGHT LOSS – A WASTE OF RESOURCES OR AN IMPORTANT INDICATION?

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10.1136/gutjnl-2017-314127.57

Background Unintentional weight-loss is a common clinical encounter. Frequently, these patients are referred for colonoscopy to rule out lower gastrointestinal pathology.

Aim Determine the diagnostic yield in colonoscopies performed for unintentional weight-loss (WL-O) versus weight-loss and associated GI symptoms (WL-GIs).

Method Retrospective analysis of colonoscopies performed in our centre (May 2013–July 2016). Data was obtained from the Endoscopic Reporting System. Baseline characteristics were established. For sub-analysis, we stratified our cohort into four age groups (<30 years, 30–54years, 55–74years and >75 years).

Results Of 5290 colonoscopies performed, 240 met our inclusion criteria (WL-O n=83, WL-GIs n=157). Baseline demographics were similar in both groups (WL-O Male 54%, mean age 56 years (SD ±16.6) compared with WL-GIs Male 52%, mean age 58 years (SD ±17.2)). Caecal intubation rates were similar in both groups (88% WL-O, 86% WL-GIs). Overall, colonoscopy was normal in 37.9% (64/169). Diverticulosis was detected in 24.9% (42/169), Colitis in 3% (5/169) and adenoma/polyp in 35.4% (85/240). For diagnostic yield between WL-O and WL-GIs, advanced adenoma detection rate was 7.2% (n=6) versus 8.3% (n=13) and CRC detection rate was 2.4% (n=2) versus 2.5% (n=4). CRC plus advanced adenomas was 9.6% (n=8) versus 10.8% (n=17)(p=0.774). Notably, in the WL-O group no high risk pathology was detected in colonoscopies in patients>75 years compared with n=3 in the WL-GIs group.

Conclusions For both groups diagnostic yield was low, comparable to the asymptomatic generapopulation. Diagnostic yield is extremely low in colonoscopies for weight-loss only in patients>75 years. Weight-loss may not be a valid indication for colonoscopy, particularly in >75 years.

58 MEASURING PYLORIC FUNCTION USING THE FUNCTIONAL LUMEN IMAGING PROBE

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10.1136/gutjnl-2017-314127.58

Background Manometric studies are known to be inadequate in evaluating tone and opening patterns of digestive sphincters. The functional lumen imaging probe (FLIP) evolved as an important tool in evaluating sphincteric regions in the gastrointestinal tract.

Aim To evaluate the potential for this technique in a pilot study on a human volunteer to

1. Evaluate the efficiency and efficacy of placing and measuring with the probe endoscopically. 2. Demonstrate if the shape and function of the pylorus could be measured using this device. 3. Evaluate the effect of the administration of a pro-kinetic drug on the function of the pylorus.

Method One subject volunteered for the procedure as the probe is already approved for diagnostic use in the gastrointestinal tract. The EndoFLIP system (Crospon, Galway, Ireland) was set up as previously described using probe model EF-353. An Olympus therapeutic endoscope was inserted as per normal upper gastrointestinal investigation. The probe was inserted into the endoscope biopsy channel and positioned straddling the pylorus. Distension measurements were made with probe volumes of 20 ml, 30 ml and 40 ml before and after the administration of 10 mg of metoclopramide (Primperan).

Results Activity dramatically changed in the pylorus after Primperan. The narrowest region the sphincter measured using the minimum cross sectional (CSA_{min}) area was relatively inactive and stable before the drug but after the CSA_{min} varied significantly during the 20 s measurement window, indicating changes in activity.

Conclusions The FLIP system can successfully measure distensibility in the pylorus and these measurements may be useful in determining proper function in the region.

59 THE ASSOCIATION BETWEEN PHYSICAL ACTIVITY AND OESOPHAGO-GASTRIC CANCER: A PROSPECTIVE COHORT STUDY WITHIN THE UK BIOBANK

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10.1136/gutjnl-2017-314127.59

Background Physical activity has been proposed as a modifiable risk factor for a number of cancers but few observational studies have investigated its effect on oesophageal and gastric carcinoma according to anatomical and histological subsite.

Aim This prospective cohort study aims to analyse the association between physical activity and risk of oesophageal or gastric adenocarcinoma.

Method A cohort of 3 59 425 adults aged 40-69 years (2006-2010) were identified from the UK biobank who completed a self-report International Physical Activity Questionnaire (IPAQ). Of this cohort, 295 incident oesophageal and 218 gastric

cancer cases were identified. Adjusted HRs and 95% CIs for the associations between hours per week from physical activity and categories of physical activity based on IPAQ guidelines (Low, medium and high) and risk of oesophageal cancer and gastric cancer were calculated.

Results When compared with low physical activity, high activity was not associated with oesophago-gastric cancer risk. However moderate level physical activity was associated with a reduction in risk of oesophageal adenocarcinoma by 35% after adjustment for confounders (adjusted HR=0.65, 95% CI 0.45 to 0.95). This held for moderate vs low physical activity and any oesophago-gastric adenocarcinoma (adjusted HR=0.70, 95% CI 0.53 to 0.92). This protective effect was not observed for oesophageal squamous cell carcinoma or total gastric cancer risk across physical activity categories.

Conclusions In this large prospective cohort, high physical activity levels were not associated with overall risk of oesophago-gastric cancer. However, moderate physical activity was associated with a reduced risk of oesophageal adenocarcinoma tumours.

60 TAILORED THERAPY FOR RESCUE TREATMENT OF HELICOBACTER PYLORI INFECTION

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10.1136/gutjnl-2017-314127.60

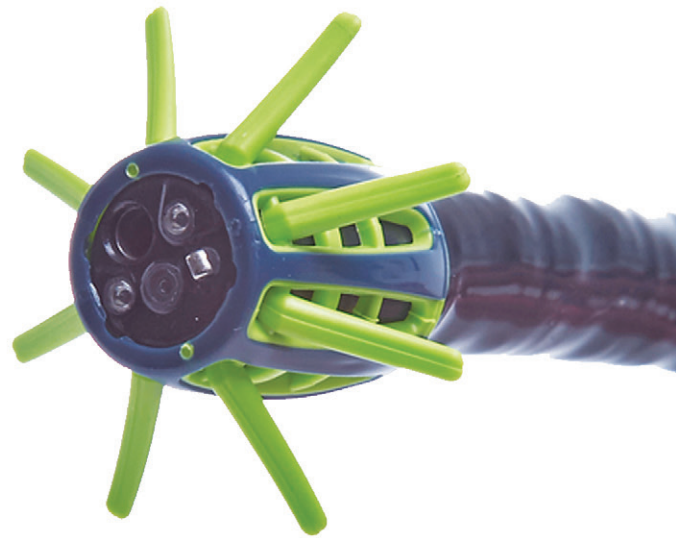
Background Due to increasing prevalence of antibiotic resistant *Helicobacter pylori*, the number of patients who require rescue treatment (after >1 failed eradication attempts) is increasing. First-line treatment for *H. pylori* is not standardised, therefore it's difficult to recommend a specific rescue treatment. Prescribing a tailored regimen based on antibiotic sensitivities upon first eradication failure may be most effective.

Aim To examine the efficacy of a tailored regimen based on antimicrobial susceptibility as a rescue treatment for *H. pylori*. **Method** Patients previously treated for *H. pylori* and undergoing endoscopy were prospectively recruited. Biopsies from *H. pylori*-positive patients (CLO test) were processed for sensitivity testing. Patients received treatment based on antibiotic sensitivities, for 7/14 days. A follow-up breath test was performed 8 weeks post-treatment.

Results Of 881 gastroscopies done between April 2013- February 2017, 190 (22%) were *H. pylori* positive. Of these, 76 (40%) were previously treated: 41 (54%) received one prior treatment and 35 (46%) received >1. To date, 44 (58%) patients have completed the study; 20 (45%) received levofloxacin triple therapy; 10 (23%) a PPI and 2 antibiotics based on their sensitivities; 10 (23%) bismuth quadruple and 4 (9%) clarithromycin triple therapy. The efficacy of tailored treatment by intention-to-treat and per protocol analysis was poor, at 47.3% (26/55) and 59.1% (26/44) respectively. Patients who received one previous treatment were significantly more likely to achieve eradication than those who received >1 previous treatment (76.2% vs 43.5%, $p=0.04$).

Conclusions Rescue eradication rates are disappointing and emphasise the importance of eradicating *H. pylori* infection the first time round.

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ratio should be carefully monitored with the addition or withdrawal of treatment with rifaximin. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation. Cloisporin may increase the rifaximin C_{max} .
Pregnancy and lactation: Rifaximin is not recommended during pregnancy. The benefits of rifaximin treatment should be assessed against the need to continue breastfeeding.
Side effects: Common effects reported in clinical trials are dizziness, headache, depression, dyspnoea, upper abdominal pain, abdominal distension, diarrhoea, nausea, vomiting, ascites, rashes, pruritus, muscle spasms, arthralgia and peripheral oedema. Other effects that have been reported include: Clostridial infections, urinary tract infections, candidiasis, pneumonia cellulitis, upper respiratory tract infection and rhinitis. Blood disorders (e.g. anaemia, thrombocytopenia). Anaphylactic reactions, angioedemas, hypersensitivity. Anorexia, hyperkalaemia and dehydration. Confusion, sleep disorders, balance disorders, convulsions, hypoesthesia, memory impairment and attention disorders. Hypotension, hypertension and fainting. Hot flushes. Breathing difficulty, pleural effusion, COPD. Gastrointestinal disorders and skin reactions. Liver function test abnormalities. Dysuria, pollakiuria and proteinuria. Oedema. Pyrexia. INR abnormalities.
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References:

1. TARGAXAN[®] 550 Summary of Product Characteristics. Available for the UK from: <https://www.medicines.org.uk/emc/medicine/27427> [Accessed October 2016]. Available for Ireland from: <http://www.medicines.ie/medicine/15936/SPC/TARGAXAN+550mg+film-coated+tablets/> [Accessed October 2016].
2. Mullen KD, et al. Clin Gastroenterol Hepatol 2014;12(8): 1390-97.

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Date of preparation: October 2016.



61 PREVALENCE OF RAS/RAF MUTATIONS IN PANCREATIC CYSTIC LESIONS AND CORRELATION WITH MALIGNANT POTENTIAL

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10.1136/gutjnl-2017-314127.61

Background Incidence of pancreatic cystic lesions (PCL) is increasing due to ageing populations and increasing cross-sectional imaging. PCL are often benign but have potential for malignant transformation, particularly mucinous cysts. Surveillance strategies and surgical intervention have implications for health economics and patient morbidity/mortality. Despite multimodality investigation, establishing that a PCL is mucinous and its potential for malignant transformation is frequently inaccurate. Molecular characterisation of these lesions may improve classification.

Aim This exploratory study aims to: determine the prevalence of BRAF, KRAS and NRAS mutations in a cohort of PCL and to correlate these mutations with standard clinicopathological features and patient outcomes.

Method PCR and Sanger sequencing were used to determine KRAS, NRAS and BRAF mutational status of 20 patients with PCL. Patients were identified sequentially from MDM meetings as having PCL and undergoing diagnostic work-up including imaging, cytology and tumour marker measurement.

Results The majority of PCL were incidental findings; 10% (n=2) underwent malignant transformation during the follow-up period. Mutations in BRAF and NRAS were not identified. KRAS mutations were found in 10%. No clear association could be found between mutational status, biochemical markers and clinicopathological characteristics or patient outcome at this stage.

Conclusions There is potential to use mutational status to determine if PCLs are mucinous and likelihood of malignant transformation, however further investigation in a larger sample set with mature outcome data is required. It is likely that mutational status will be helpful as part of a multimodality classification process that also incorporates radiological, cytological and biochemical assessments.

62 FOLLOW-UP OF PATIENTS WITH ISOLATED ACTIVE ILEITIS: INCREASING DEVELOPMENT OF OVERT CROHN'S DISEASE OVER TIME

R Stack*, S O'Donnell, N O'Morain, M Hussey, A O'Connor, N Breslin, A Alakkari, D McNamara, BM Ryan. *Gastroenterology, AMNCH, Tallaght, Dublin, Clinical Medicine, Trinity College Dublin, Ireland*

10.1136/gutjnl-2017-314127.62

Background Increased TI intubation at colonoscopy had led to increased identification of mild ileal inflammation. Patients with co-called Isolated Active ileitis (IAI) have mild TI inflammation, no chronicity on histology, and do not fulfil criteria for a diagnosis of Crohn's Disease (CD). Causes include CD, NSAID use or infection. The natural history of IAI has remained unclear.

Aim Long term follow up of a cohort of patients diagnosed as IAI, to assess evolution to CD, persistent IAI and Self-Limiting Ileitis (SLI).

Method IAI patients were reviewed at a 10 year interval by means of clinical follow up, endoscopy, histology and small bowel imaging (SBI).

Results 50 patients; Median age 48 years; 16/50 (32%) male. At time of follow up, 29/50 (58%) had a follow up ileocolonoscopy with 16/29 (55%) showing persistent ileitis on histology. 38/50 had formal SBI with inflammatory changes on 11/38 (29%). Of the original cohort, SLI, persistent IAI and CD was reported in 7/50 (14%), 7/50 (14%) and 14/50 (28%), respectively. 22/50 patients were lost to follow up. 4 patients developed strictures and 3 required surgery. Predominant presenting symptoms included pain and diarrhoea in all groups, with no statistical difference in smoking, NSAID use and family history amongst the 3 subgroups.

Conclusions Over time a significant portion of patients with IAI evolve to overt small bowel CD. Neither presenting complaint nor clinical risk factors were predictive of disease progression, suggesting these all patients should be under surveillance for disease progression.

63 10 YEAR FOLLOW-UP STUDY OF THE LONG TERM EFFECTS OF ANTI-TNF THERAPY ON BONE METABOLISM IN A COHORT OF ANTI-TNF NAÏVE IBD PATIENTS

N O'Morain*, G Farrell, R Stack, M Hussey, Y Bailey, C Kiat, S Veerappan, D McNamara, A O'Connor, N Breslin, C O'Morain, BM Ryan. *Department of Gastroenterology, Tallaght Hospital, and Clinical Medicine, Trinity College Dublin, Ireland*

10.1136/gutjnl-2017-314127.63

Background Anti-TNF therapy (ATT) has been shown to have beneficial effects on bone metabolism in the short term, but there is a dearth of long term prospective data.

Aim To evaluate the long term effects of ATT on bone metabolism.

Method Retrospective observational cohort study of ATT naïve IBD patients first evaluated in 2007 by DXA scan and by metabolic bone markers prior to, and one year post commencement of ATT. Patients were invited to undergo repeat DXA scan and serum bone marker measurement.

Results To date, 73% (n=38/52) patients from the original study have been recruited for 10 year follow up. There were 3 deaths, 4 refusals, 7 uncontactable. DXA scans and serum samples have been collected on 24/38 patients. 50% were female, mean age of 44.5 years (range 27-80). 67% (n=16) Crohn's, 33% (n=8) UC. 6 patients continued with immunomodulator (IMM), 11 with ATT (Adalimumab (n=5), Infliximab (n=6)), 2 with combination therapy (ATT/IMM), 1 with 5-ASA, 4 no treatment.

Mean T score prior to ATT in 2007 was -1.46 (SD ± 1.24), and 0.81 (SD ± 1.04) at 10 years. The baseline and 10 year mean T-scores were -1.53 (SD ± 1.26) and -0.70 (SD ± 1.13) for patients remaining on ATT and -0.97 (SD ± 1.27) and -0.66 (SD ± 1.01) for those off ATT. Serum analyses are in process.

Conclusions In this ongoing 10 year follow up study, results suggest that long term (>10 years) treatment with anti-TNF therapy has a beneficial effect on bone metabolism.

64 MAGNETIC RESONANCE OF THE SMALL BOWEL WITH EARLY (70S) AND LATE (7MINS) PHASE POST GADOLINIUM IMAGING TO IDENTIFY FIBROSIS IN STRICTURING SMALL BOWEL CROHN'S DISEASE

R Stack*, C O'Brien, T Nuzum, S Cummins, M Hussey, N O'Morain, A O'Connor, N Breslin, B Ryan, I Murphy, D McNamara. *Gastroenterology, AMNCH, Tallaght, Dublin. Trinity College Dublin, Ireland*

10.1136/gutjnl-2017-314127.64

Background Strictures are a serious complication of Ileal Crohn's disease (CD). Current assessment tools poorly differentiate fibrotic from inflammatory lesions and do not predict response. The magnetic resonance index of activity (MaRIA) is a validated means to assess activity. Its ability to characterise fibrosis remains unclear. Recent evidence suggests relative contrast enhancement (REC) of >24% on delayed MRI sequences may accurately detect fibrosis.

Aim Compare MaRIA, RCE and biochemical activity in patients with Ileal CD.

Method Prospective study of patients undergoing MRE for known CD. MRE was performed as standard with additional coronal T1 sequences 7 min post gadolinium administration. Two independent blinded Radiologists calculated RCE and MaRIA's at 70 s and 7 min. Demographics and CRP were recorded.

Results 26/29 MRE's performed had ileal CD, median age=41 years, male=10 (38%). RCE >24% and high T2 signal intensity (SI); 6/26 (23%) and 11/26 (42.3%). REC >24% occurred in only 1/10 with a visible stenosis. Average MaRIA's: 2/26 (7.7%)<7 mild; 3/26 (11.5%) 7-11 moderate; 21/26 (80.7%)>11 severe. MaRIA's did not change significantly between 70 s and 7 min. As expected T2 SI increased with MaRIA's>11, 26 v 13 (p<0.001, 95% CI 7.73 to 17.27). RCE did not correlate with MaRIA group, ? 0.09. Consistent with MRE findings, CRP was higher in patients with MaRAI >11 (13.3 vs 5.2) and lower in patients with RCE >24% (3.9 vs 14), p<0.04 95% CI 0.37 to 15.71 and p<0.01 95% CI 2.5 to 19.05 respectively.

Conclusions RCE may be a useful adjunct to current MRE and help detect fibrosis in small bowel lesions and warrants further investigation.

65 LOCALISED CAVITY FORMATION IN OESOPHAGEAL CARCINOMA

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10.1136/gutjnl-2017-314127.65

Background Oesophageal cavity formation secondary to oesophageal carcinoma is a rare complication, with significant morbidity and mortality.

We describe two cases treated with a partially covered Cook stent for symptom control and palliation.

Aim To describe the management of oesophageal cavity formation secondary to oesophageal carcinoma.

Method Retrospective case notes review.

Results Case 1-A 67 year old gentleman presented with dysphagia. OGD showed a squamous cell carcinoma in the lower oesophagus with imaging showing no metastatic disease. Four weeks after diagnosis he deteriorated rapidly with pyrexia and malaise.

Repeat OGD showed a large cavity with mediastinal structures seen. A 12 cm partially covered Cook stent was deployed. Subsequent CT Chest revealed no distal leak/fistula, and he was discharged after 5 days with nutritional optimisation. He was palliated in the community and died almost 4 months after his stent insertion.

Case 2-A 84 year old gentleman with known metastatic oesophageal adenocarcinoma who had undergone palliative chemo/radiotherapy presented with regurgitation of food.

OGD showed a cavity with mediastinal structures seen. A 12 cm partially covered Cook stent was deployed. Subsequent CT Chest revealed a small cavity with no distal leak/fistula, and was discharged after 4 days. He was palliated in the community, and died 13 months after his procedure.

Conclusions Oesophageal cavity formation is a rare complication of oesophageal carcinoma. Management options include surgical and none surgical conservation options.

We describe successful none operative management via partially covered stent insertion, facilitating palliation and reducing morbidity with significant improvement in quality of life.

66 OESOPHAGEAL GRANULAR CELL TUMOURS-A LOCAL CASE SERIES

¹EA Gorman EA, ²D McManus, ¹JBM Doyle, ¹D McKernan, ¹L Mainie. ¹Department of Gastroenterology, Belfast City Hospital, Belfast, UK; ²Department of Pathology, Belfast City Hospital, Belfast, UK

10.1136/gutjnl-2017-314127.66

Background Granular cell tumours (GCT) are soft tissue tumours that present in the skin/oral cavity, with 5% presenting in the gastrointestinal tract.

We present a local case series, illustrating endoscopic, ultrasonographic and histological appearances of GCT in the oesophagus and subsequent management.

Aim Describing clinicopathological characteristics of oesophageal GCT with follow up.

Method Retrospective case notes review.

Results Case 1-A 51 year old female presented with dysphagia. OGD showed two small oesophageal lesions (<1 cm) at 30/32 cm. Endoscopic Ultrasound (EUS) revealed a submucosal lesion. MDT discussion recommended a conservative approach, with yearly endoscopy and EUS.

Case 2-A 55 year old female presented with lethargy. OGD showed a small oesophageal lesion (0.6 cm) at 34 cm. EUS revealed a mucosal lesion with minimal submucosal involvement. MDT discussion for both patients recommended a conservative approach, follow up for >3 years has shown no ultrasonographic change.

Case 3-A 31 year old male presented with dyspepsia. OGD showed a small oesophageal lesion (<1 cm) at 34 cm. EUS revealed a submucosal lesion. MDT discussion adopted a conservative approach, with yearly endoscopy and EUS, and follow up at 2 years has shown no ultrasonographic change.

Case 4-A 67 year old female presented with dyspepsia. OGD revealed a small oesophageal lesion (<1 cm) in the distal oesophagus. EUS is awaited.

Conclusions GCT's are rare, with low malignant potential. They are usually asymptomatic, and have a classical endoscopic appearance of a firm, yellow, submucosal lesion. EUS is critical in staging, with MDT discussion. A conservative approach appears justified, with yearly endoscopy and EUS for surveillance.

67 CONSCIOUS SEDATION PRACTICE IN ERCP: A SINGLE CENTRE REVIEW

A Monged*, D Cheriyan. *Beaumont Hospital, Dublin, Ireland*

10.1136/gutjnl-2017-314127.67

Background ERCP is a complex endoscopic procedure which requires adequate sedation to increase patient tolerance and improve procedural success. Achieving the desired level of conscious sedation which allows for satisfactory completion of a therapeutic ERCP can be challenging. Few guidelines exist to support appropriate conscious sedation practice in ERCP.

Aim The aim of the study is to evaluate conscious sedation practices for ERCP in a single, tertiary referral centre in Dublin, Ireland.

Method A retrospective analysis was conducted for ERCPs performed from October 2014 to October 2016. ENDORAAD software was utilised to collect data.

Abstract 67 Table 1 Overall drug dosage

Drug	Mean	Range	Stand Dev	Total (% of 905)
Midazolam (mg)	5.7	15–1 mg	2.7	232 (25%)
Diazepam (mg)	9.8	30–2 mg	4.6	803 (89%)
Fentanyl (mcg)	83.2	125–25 mg	23	870 (96%)
Pethidine (mg)	47	100–25 mg	11	204 (23%)

Abstract 67 Table 2 Patients ≥ 70 years

Drug	Mean	Range	Stand Dev	Total (% of 419)
Midazolam (mg)	5	10–1	2	55 (13%)
Diazepam (mg)	8	20–2	3.5	329 (79%)
Midazolam	3.8	10–2	2	35 (8.4%)
and Diazepam	7.8	17–2	3.6	
Fentanyl (mcg)	75	100–25	24	384 (92%)
Pethidine (mg)	50	50		1 (0.2%)
Fentanyl	87	25–100	24	27 (6.5%)
and Pethidine	42.6	25–50	11.6	

Abstract 67 Table 3 Patients <70 years

Drug	Mean	Range	Stand Dev	Total (% of 485)
Midazolam (mg)	8	3–15	2.8	46 (9.5%)
Diazepam (mg)	11.6	3–30	4.8	343 (70.5%)
Midazolam	5.6	2–10	2.5	96 (20%)
and Diazepam	10.0	2–30	4.4	
Fentanyl (mcg)	87.8	25–125	20	309 (63.7%)
Pethidine (mg)	50.9	100–25	11.1	26 (5.4%)
Fentanyl	93.5	25–100	17	149 (30.7%)
and Pethidine	47	25–100	10	

Results 904 patients had ERCPs in Beaumont hospital under conscious sedation between 2014-2016. The median age was

65.6 (range 19-89). 419 were ≥ 70 years. The most frequently used benzodiazepine and opiate used for ERCPs in our review was diazepam (89% of all patients), and Fentanyl (96% of all patients). 51% of patients <70 years received more than one benzodiazepine or opiate, compared to 14.8% of patients ≥ 70 years. In total 14 patients required reversal of sedation due to respiratory compromise, of which 11 were ≥ 70 years.

Conclusion The use of more than one benzodiazepine or opiate was more common in patients <70 years of age. Our data should be compared to that of other tertiary referral centres in Ireland, with the ultimate aim of developing guidelines for conscious sedation practice for ERCP.

68 THE BIFIDOBACTERIUM LONGUM 35624® CULTURE TRANSITS IN HIGH NUMBERS THROUGH THE HUMAN GUT

¹S Healy, ¹M Casey, ¹B Kiely, ²EM Quigley, ³F Shanahan, ¹EF Murphy. ¹Alimentary Health Ltd. Building 4400, Cork Airport Business Park, Cork; ²APC Microbiome Institute, University College Cork, Ireland; ³Division of Gastroenterology and Hepatology, Lynda K and David M Underwood Centre for Digestive Disorders, Houston Methodist Hospital, Weill Cornell Medical College, Houston, USA

10.1136/gutjnl-2017-314127.68

Background Most probiotic products rely on *in vitro* laboratory tests to assess transit and lack data on survival through the human gastrointestinal tract (GIT). However, *in vitro* tests are not representative of the multiple physiological states of the gut.

Aim To confirm transit of the *Bifidobacterium longum* 35 624 strain, found in Alflorex®, in different formats in humans.

Method 35 624 strain was administered in a capsule, straw, sachet or milk format to volunteers for 7 days at doses ranging from 1×10^7 – 1×10^{10} CFU/day (n=1–6) followed by a wash-out period. The transit of viable 35 624 strain through the human GIT was assessed from stool collected at various timepoints by bifidobacteria selective agar plates and/or typing representative colonies using strain-specific PCR.

Results Independent of form, the 35 624 strain transited in humans to high numbers, ranging from 1×10^4 – 1×10^8 CFU/g of stool in a dose-dependent manner at Day 7. Furthermore, despite antibiotic use in a 10-year-old cystic fibrosis sufferer (250 mg Zithromax 3 times/week), the 35 624 strain transited well ($\geq 1 \times 10^6$ CFU/g). Co-administration of the antibiotic and probiotic resulted in a 1 log decrease in levels recovered from stool compared to administration of the probiotic 12 hour post antibiotic.

Conclusion Independent of delivery format, the 35 624® strain was detected in stool at day 7 in a viable form at levels greater than 1×10^4 CFU/g of stool. Transit of viable 35 624® strain in a patient with long term antibiotic use was confirmed demonstrating that the Zithromax did not affect the 35 624® viability under the conditions of the experiment.

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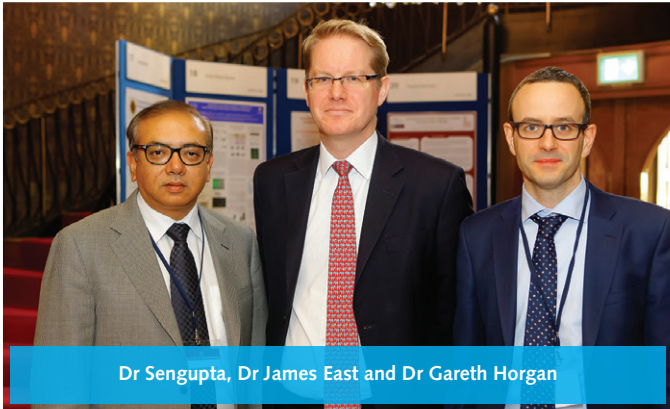


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Audience View

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Michelle Condell Takeda and Prof Padraic MacMathuna presenting 1st Clinical Oral Prize to Dr Lillian Barry

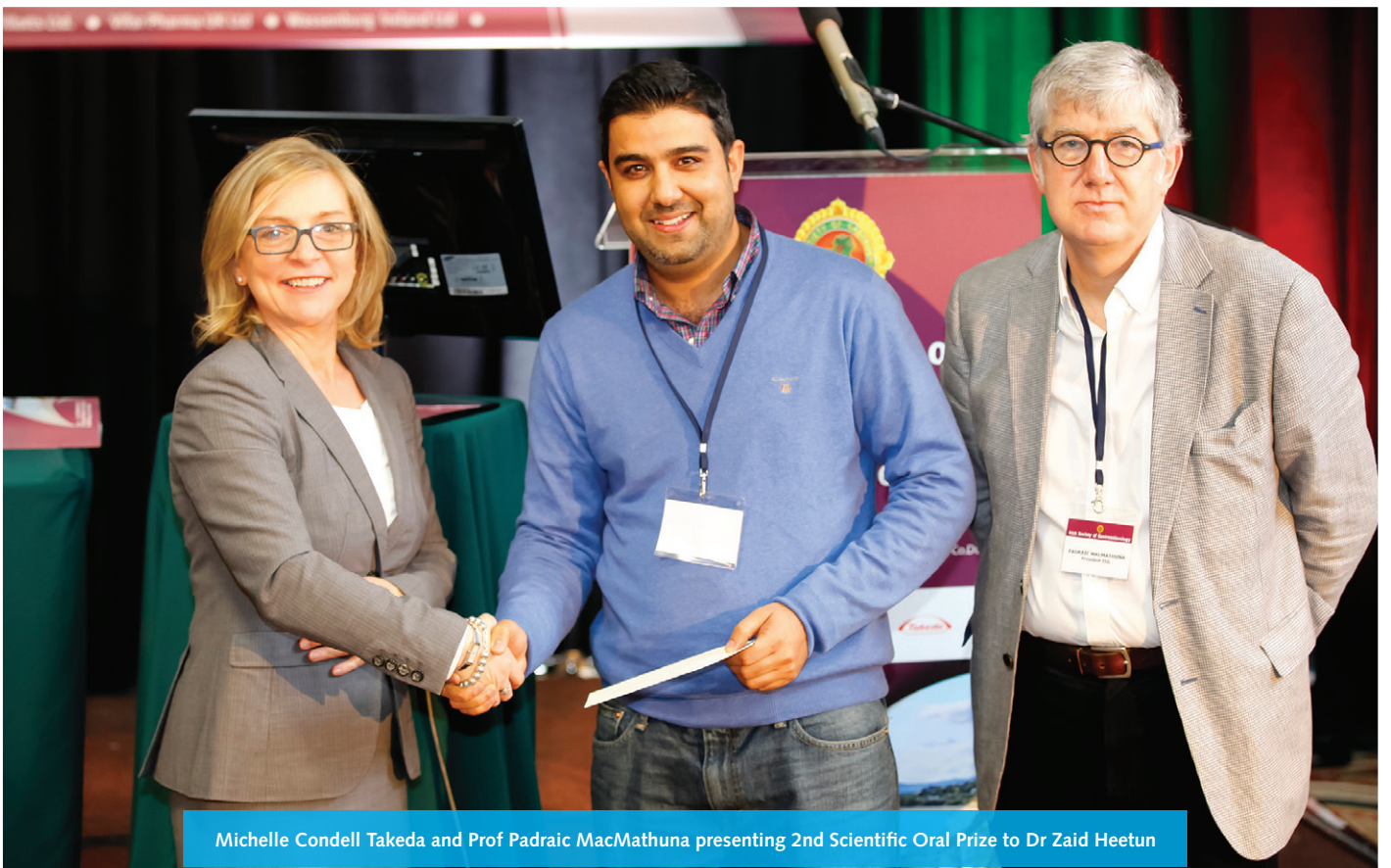


Michelle Condell Takeda and Prof Padraic MacMathuna presenting 2nd Clinical Oral Prize to Dr Mary Hussey

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Michelle Condell Takeda and Prof Padraic MacMathuna presenting 1st Scientific Oral Prize to Dr Anne Marie Byrne



Michelle Condell Takeda and Prof Padraic MacMathuna presenting 2nd Scientific Oral Prize to Dr Zaid Heetun

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Laragh DeBhulbh AbbVie and Prof Padraic MacMathuna presenting 1st Poster Prize to Dr Catherine Rowan



Laragh DeBhulbh AbbVie and Prof Padraic MacMathuna presenting 2nd Poster Prize to Dr Neil O'Morain

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Prof Deirdre McNamara



Catherine Rowan and Jun Liang Chin



Danielle at the Initiative Stand



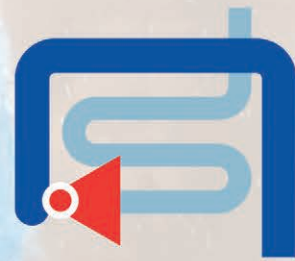
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LEGAL CATEGORY: POM.

MARKETING AUTHORISATION NUMBER: Asacolon® 400 mg GR Tablets PA 2018/1/1, Asacolon® 800 mg GR Tablets PA 2018/1/2

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1. Sandborn, WJ et al. Once-daily dosing of delayed-release oral mesalamine (400-mg tablet) is as effective as twice-daily dosing for maintenance of remission of ulcerative colitis. *Gastroenterology*. 2010 Apr;138(4):1286-96.

The referenced study relates to Allergan's Eudragit S-coated mesalazine. Allergan markets mesalazine products in the USA, Canada and the UK. Tillotts Pharma markets its own Eudragit S-coated mesalazine products under the trademark Asacolon® in Ireland, and under other trademarks in continental Europe (other than Switzerland, Italy, Belgium, the Netherlands and Luxembourg) and other countries. Allergan and Tillotts Pharma are not related companies.

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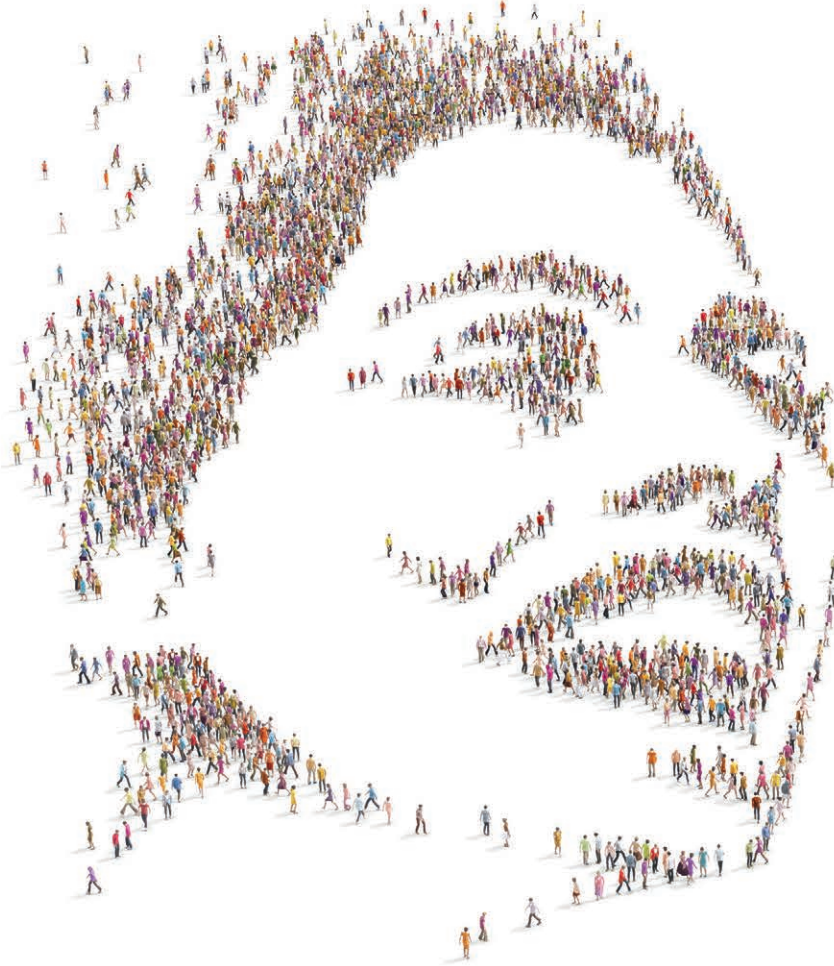


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WITH VIEKIRAX® +
EXVIERA® +/- RBV*^{1,2}**

When selecting a treatment, optimise the opportunity for cure*

RBV=ribavirin. *SVR was the primary endpoint to determine the HCV cure rate in the Phase 3 studies and was defined as unquantifiable or undetectable HCV RNA 12 weeks after the end of treatment (SVR₁₂).^{1,2}
*In patients who received the recommended regimen. †In Phase 2 and 3 clinical trials.

VIEKIRAX® ▽ 12.5 mg/75 mg/50 mg film-coated tablets & EXVIERA® ▽ 250 mg film-coated tablets **PRESCRIBING INFORMATION PRESENTATION:** Each Viekirax film-coated tablet contains 12.5 mg of ombitasvir, 75 mg of paritaprevir and 50 mg of ritonavir. Each Exviera tablet contains 250 mg of dasabuvir. Please refer to the respective Summary of Product Characteristics (SmPC) before prescribing. **INDICATION:** For treatment of Chronic Hepatitis C (CHC) in combination with other medicinal products in adults. **DOSE AND ADMINISTRATION:** Oral. Treatment to be initiated and monitored by physician experienced in CHC management. See SmPC for full posology. **Dosage:** The recommended dose of Viekirax is two 12.5 mg/75 mg/50 mg tablets once daily with food. The recommended dose of Exviera is one 250 mg tablet twice daily (morning and evening) with food. **Recommended Co-administered medicinal product(s) and Treatment Duration:** Genotype 1b without cirrhosis or with compensated cirrhosis: Viekirax + Exviera for 12 weeks. Genotype 1a without cirrhosis: Viekirax + Exviera + ribavirin for 12 weeks. Genotypes 1a with compensated cirrhosis: Viekirax + Exviera + ribavirin for 24 weeks. See SmPC for details. Genotype 4 without cirrhosis or with compensated cirrhosis: Viekirax + ribavirin for 12 weeks. See ribavirin SmPC for dosing instructions. **Special Populations:** HIV-1 Co-infection: No dose adjustment required. For dosing with HIV antiviral agents refer to SmPC for additional information. Liver Transplant recipients: Viekirax + Exviera + ribavirin for 24 weeks in liver transplant recipients with genotype 1 HCV infection. Viekirax + ribavirin in genotype 4 infected recipients. Elderly: No dose adjustment required. Renal impairment: No dose adjustment required. For patients that require ribavirin, refer to the ribavirin SmPC for information regarding use in patients with renal impairment. Hepatic impairment: No dose adjustment recommended in patients with mild hepatic impairment (Child-Pugh A). Viekirax is contraindicated and Exviera should not be used in patients with severe hepatic impairment (Child-Pugh C). **Paediatric Population:** No data available. **CONTRAINDICATIONS:** Hypersensitivity to any of the active substances or excipients. Ethnyllestadiol-containing medicinal products such as those in most combined oral contraceptives or contraceptive vaginal rings. Viekirax is contraindicated in patients with severe hepatic impairment (Child-Pugh C). Viekirax in combination with CYP3A4 substrates, examples include: alfuzosin hydrochloride, amiodarone, astemizole, terfenadine, cisapride, colchicine in patients with renal or hepatic impairment, ergotamine, dihydroergotamine, ergonovine, methylergometrine, fusidic acid, lovastatin, simvastatin, atorvastatin, oral midazolam, triazolam, pimozide, quetiapine, quinine, salmeterol, sildenafil (when used for the treatment of pulmonary arterial hypertension) and ticagrelor. Viekirax with or without Exviera in combination with enzyme inducers: examples include: carbamazepine, phenytoin, phenobarbital, efavirenz, nevirapine, etravirine, enzalutamide, mitotane, rifampicin, St. John's Wort (*Hypericum perforatum*). Viekirax with or without Exviera in combination with CYP3A4 inhibitors: examples include: cobicistat, indinavir, lopinavir/ritonavir, saquinavir, tipranavir, itraconazole, ketoconazole, posaconazole, voriconazole, clarithromycin, telithromycin and cobicistat. Exviera is contraindicated in combination with CYP2C8 inhibitors: example includes: gemfibrozil. **SPECIAL WARNINGS AND PRECAUTIONS:** Viekirax and Exviera are not recommended as monotherapies. Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported postmarketing in patients treated with Viekirax with and without Exviera and with and without ribavirin. Most patients with these severe outcomes had evidence of advanced or decompensated cirrhosis prior to initiating therapy. Although causality is difficult to establish due to background advanced liver disease, a potential risk cannot be excluded. The efficacy of Viekirax has only been established in patients with Hepatitis C Virus (HCV) genotypes 1 and 4. The efficacy of Exviera has only been established in patients with HCV genotype 1 only. Co-administration of Viekirax with other antivirals other than Exviera and/or ribavirin has not been evaluated. For patients with cirrhosis: Monitor for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal haemorrhage) hepatic laboratory testing including direct bilirubin levels should be performed at baseline, during the first 4 weeks of starting treatment and as clinically indicated thereafter. Discontinue treatment in patients who develop evidence of hepatic decompensation. When used in combination with ribavirin, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and for 6 months after the treatment as recommended in the SmPC for ribavirin. Refer to the SmPC for ribavirin for additional information. Although ALT elevations associated with Viekirax and Exviera have been asymptomatic, patients should be instructed to watch for early warning signs of liver inflammation, such as fatigue, weakness, lack of appetite, nausea and vomiting, as well as later signs such as jaundice and discoloured faeces, and to consult a doctor without delay if such symptoms occur. Routine monitoring of liver enzymes is not necessary in patients that do not have cirrhosis. Early discontinuation may result in drug resistance, but implications for future therapy are not known. Use caution when administering Viekirax with fluticasone or other glucocorticoids that are metabolised by CYP3A4. Concomitant use of inhaled glucocorticoids metabolised with CYP3A4 can increase systemic exposures of the glucocorticoids, and cases of Cushing's syndrome and subsequent adrenal suppression have been reported with ritonavir-containing regimens. The safety and efficacy of Viekirax and Exviera have not been established in Hepatitis B co-infection patients. **INTERACTIONS:** See SmPC for full details. Viekirax in combination with Exviera: Not Recommended; darunavir in patients with extensive PI resistance, fluvastatin and pitavastatin not recommended. Use caution and dose decrease may be needed for ropinirole. **Use Caution:** sulfasalazine, erythromycin, trazodone (lower dose of trazodone may be considered), fexofenadine, lidiazem, verapamil, rilpivirine once daily should only be used in patients without known QT prolongation, and without other QT prolongation co-medications. **Monitor Levels:** digoxin, warfarin and other vitamin K antagonists (INR). **Adjust Dose:** Monitoring and dose reduction recommended for valsartan, losartan, candesartan and iratrinol. Monitoring and dose adjustment may be needed for s-mephenytoin and levothyroxine. Reduction in colchicine dose or interruption of colchicine treatment is recommended in patients with normal renal or hepatic function. Decrease amlodipine dose by 50% and monitor. Decrease nifedipine dose and monitor. Furosemide decrease of up to 50% may be required upon monitoring. 300 mg dose of atazanavir recommended to be administered at the same time as Viekirax with Exviera, 800 mg darunavir once-daily without ritonavir recommended to be administered at the same time as Viekirax with Exviera in the absence of extensive PI resistance. Do not exceed 5 mg/day rosvastatin. Reduce pravastatin dose by 50%. When starting co-administration, give one fifth of the total daily dose of ciclosporin once daily, monitor ciclosporin levels and adjust dose and/or dosing frequency as needed. When starting co-dosing, administer 0.5 mg tacrolimus once every week, monitor and adjust dose and/or dosing frequency as needed. Use higher doses of omeprazole if clinically indicated. Higher doses of esomeprazole/lansoprazole may be needed if clinically indicated. A decrease in alprazolam dose can be considered based on clinical monitoring. Carisoprodol, cyclobenzaprine, diazepam; no dose adjustment required, increase dose if clinically indicated. Reduction of hydrocodone dose by 50% and/or clinical monitoring should be considered. Viekirax without Exviera: As per combination with Exviera with following exceptions. **Use Caution:** dabigatran etexilate. **Not Recommended:** Atazanavir and darunavir are not recommended with Viekirax without Exviera. **Adjust Dose:** Decrease digoxin dose by 30–50% and monitor. Do not exceed 10 mg/day rosvastatin. **PREGNANCY AND LACTATION:** Extreme caution must be taken to avoid pregnancy in female patients and female partners of male patients when co-administered with ribavirin. See the ribavirin SmPC for information. There is only limited data on the use of Viekirax and Exviera in pregnant women. The potential risk to humans is unknown. Viekirax and Exviera should not be used in pregnancy. It is not known whether Viekirax, Exviera and their metabolites are excreted in human breast milk. **SIDE EFFECTS:** See SmPC for full details on side effects. **Side effects identified with Viekirax in combination with Exviera Common side effects (≥1/100 to <1/10):** pruritus Side-effects identified with Viekirax in combination with Exviera and ribavirin **Very common side effects (≥1/10):** insomnia, nausea, pruritus, asthenia and fatigue. **Common side effects (≥1/100 to <1/10):** anaemia. HCPs are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. **Website:** www.hpria.ie; **E-mail:** mdsafety@hpria.ie. **Suspected adverse events should also be reported to AbbVie Limited on 01-4287900. LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBERS/PRESENTATIONS:** EU/1/14/0982/001 - Viekirax 12.5mg/75 mg/50 mg film-coated tablets, daily blister packs containing 2 film-coated tablets, inner cartons containing 14 film-coated tablets in multipack presentation containing 56 (4 packs of 14) film-coated tablets. EU/1/14/0983/001 - Exviera 250 mg film-coated tablets, daily blister packs containing 2 film-coated tablets, inner cartons containing 14 film-coated tablets in multipack presentation containing 56 (4 packs of 14) film-coated tablets. **MARKETING AUTHORISATION HOLDER:** AbbVie Ltd, Maidenhead, SL6 4UB, UK. Further information is available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **DATE OF REVISION:** November 2016. PI/982+983/006.

References: 1. viekirax® Summary of Product Characteristics, available on www.medicines.ie 2. exviera® Summary of Product Characteristics, available on www.medicines.ie
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