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Irish Society of Gastroenterology

Summer Meeting

24 - 25 May 2018

Great Southern Hotel, Killarney

MSD

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Abbreviated Prescribing Information
INFLECTRA ▼ (Infliximab) powder for concentrate for solution for infusion.
Please refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Vial containing 100 mg of infliximab powder for concentrate for solution for infusion. **Indications:** *1) Rheumatoid arthritis (RA)* in combination with methotrexate (MTX) in adult patients with active disease with inadequate response to disease-modifying antirheumatic drugs (DMARDs) or adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs. *2) Adult Crohn's disease* (CD) a) In patients with moderately to severely active CD who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. b) In patients with fistulising, active CD who have not responded despite a full and adequate course of conventional treatment (including antibiotics, drainage and immunosuppressive therapy). *3) Paediatric* CD Severe, active CD in patients aged 6 to 17 years, who have not responded to conventional therapy including corticosteroid, immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. *4) Ulcerative colitis* (UC) In both adult patients with moderate to severely active UC, and children and adolescents aged 6 to 17 years with severely active UC and an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or those who are intolerant to, or have medical contraindications for such therapies. *5) Ankylosing spondylitis* (AS) In adult patients with severe active AS who have responded inadequately to conventional therapy. *6) Psoriatic arthritis* (PsA) In adult patients with active and progressive PsA when response to previous DMARD therapy has been inadequate. Infliectra should be administered in combination with MTX - or alone in patients who show intolerance to MTX, or for whom MTX is contraindicated. *7) Psoriasis (PsO)* In adult patients with moderate to severe plaque PsO who failed to respond to, or who have a contraindication to, or are intolerant to systemic therapy including cyclosporine, MTX or Psoralen ultra-violet A (PUVA.) **Dosage & Administration:** All doses to be administered as an intravenous (IV) infusion over 2 hours initially and monitor post-infusion for at least 1-2 hours for infusion- related reactions. *1) RA* 3 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. Inflectra must be given concomitantly with MTX. *2) Moderately to severely active CD* 5 mg/kg repeated 2 weeks after initiation. If no response after 2 doses, no additional dose should be given. In responding patients: Maintenance dose of 5 mg/kg at 6 weeks after the initial dose, followed every 8 weeks, or: Re-administration of 5 mg/kg if signs and symptoms recur. *3) Fistulising, active CD* 5 mg/kg repeated 2 and 6 weeks after initiation. If no response after 3 doses, no additional dose should be given. In responding patients: Maintenance dose of 5 mg/kg every 8 weeks or: Re-administration of 5 mg/kg if signs and symptoms recur, followed by 5 mg/kg every 8 weeks. *4) UC* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. *5) AS* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 6 to 8 weeks. If no response by 6 weeks, no additional dose should be given. *6) PsA* 5 mg/kg repeated at 2 and 6 weeks after initiation, then every 8 weeks. *7) PsO* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. If no response after 14 weeks no additional dose should be given. *8) Paediatric CD (6 to 17 years):* 5 mg/kg repeated 2 and 6 weeks later, then every 8 weeks. Data do not support further treatment in children and adolescents not responding within the first 10 weeks. *9) Paediatric UC (6 to 17 years):* 5 mg/kg repeated at 2 and 6 weeks, then every 8 weeks. Available data do not support further treatment in in patients not responding within the first 8 weeks. *Older people (≥ 65 years):* Studies have not been conducted. No major age-related differences in clearance or volume of distribution observed in clinical studies. No dose adjustment is required. *Impaired renal and/or hepatic function:* Not studied. No dose recommendations can be made. **Contraindications:** Hypersensitivity to infliximab, to other murine proteins, or to any excipients. Tuberculosis (TB) or other severe infections such as sepsis, abscesses, and opportunistic infections. Moderate or severe heart failure (NYHA class III/IV). **Warnings and Precautions:** Caution in patients with or at risk of infusion reactions and hypersensitivity. Do not administer in patients with bacterial infections, invasive fungal, viral or other opportunistic infections. Monitor for TB, and do not use in patients with TB. Test for latent/active TB prior to initiation of therapy. Do not use Inflectra in patients with active TB. In patients with latent TB, treatment with anti-TB therapy must be started before the initiation of Inflectra, and in accordance with local recommendations. Consult a physician with expertise in the treatment of TB. Monitor closely for infections, including TB before, during and for six months post-treatment. Patients with fistulising CD with acute suppurative fistulas must not initiate therapy until source of infection, specifically abscess, is excluded. Test for HBV infection before initiating treatment. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Closely monitor carriers of HBV for signs and symptoms of active HBV infection during and after therapy. In patients with HBV reactivation, stop Inflectra and initiate effective antiviral therapy with supportive treatment. Symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or ALT elevations ≥5 times the upper limit of normal develop(s), stop Inflectra and initiate thorough investigation. Concurrent administration of Inflectra with anakinra, abatacept or other biologic therapeutics is not recommended due to possible increased risk of infection and/or other potential pharmacological interactions. Live vaccines or therapeutic infectious agents should not be used concurrently with Inflectra. Patients should continue to be monitored while switching from one biologic to another. If a patient develops symptoms suggestive of lupus-like syndrome following treatment with Inflectra and is positive for antibodies against double stranded DNA, discontinue Inflectra treatment. In patients with pre-existing or recent onset of demyelinating disorders (including multiple sclerosis and Guillain Barré syndrome), the risk/benefit of anti-TNF treatment should be carefully considered before initiation of Inflectra. Discontinuation of Inflectra should be considered if these disorders develop. Caution should be exercised in considering treatment of patients with increased risk for malignancy or when considering treatment in patients that develop a dysplasia or a malignancy or with previous history of malignancy. Caution should also be exercised in patients with psoriasis and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Potential risk of development of hepatosplenic T-cell lymphoma (HSTCL) when used in combination with AZA or 6-MP, especially in adolescents and young adult males with CD or UC. Periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. Patients with UC who are at increased risk or prior history of dysplasia for dysplasia or colon carcinoma should be screened for dysplasia (including colonoscopy and biopsies) at regular intervals before therapy and throughout their disease course. Use with caution and monitor closely in mild heart failure (NYHA class I/II). Discontinue Inflectra treatment in patients who develop new or worsening symptoms of heart failure. Patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation of Inflectra should be considered in patients with confirmed significant haematologic abnormalities. For patients that require surgery, Inflectra long half-life should be taken into account and should be monitored for infections. *Special populations:* Risk of infections should be considered when treating elderly and paediatric patients. If possible, comply with vaccination program for paediatric patients prior initiating treatment with Inflectra. *Women of childbearing potential:* Use adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last Inflectra treatment. *Pregnancy:* Administration of infliximab is not recommended during pregnancy. *Breast feeding:* Unknown whether infliximab is excreted in human milk or absorbed systemically after ingestion. As human immunoglobulins are excreted in milk, women must not breast feed for at least 6 months after Inflectra treatment. **Undesirable effects:** Viral infection (e.g. influenza, herpes virus infection), bacterial infection (e.g. sepsis, cellulitis, abscess), TB, fungal infection (e.g. candidiasis), meningitis, opportunistic infection, parasitic infection, hepatitis B reactivation, vaccine breakthrough infection, lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, cervical cancer, hepatosplenic T-cell lymphoma, Merkel cell carcinoma, neutropenia, leucopenia, anaemia, lymphadenopathy, thrombocytopenia, lymphopenia, lymphocytosis, agranulocytosis, thrombotic thrombocytopenic purpura, pancytopenia, haemolytic anaemia, idiopathic thrombocytopenic purpura, allergic respiratory symptom, anaphylactic reaction/shock, lupus-like syndrome, serum sickness like reaction, vasculitis, sarcoid-like reaction, depression, insomnia, amnesia, agitation, confusion, somnolence, nervousness, apathy, headache, vertigo, dizziness, hypoaesthesia, paraesthesia, seizure, neuropathy, transverse myelitis, demyelinating disorders, conjunctivitis, keratitis, periorbital oedema, hordeolum, endophthalmitis, transient visual loss, tachycardia, palpitation, cardiac failure, arrhythmia, syncope, bradycardia, cyanosis, pericardial effusion, myocardial ischaemia/ infarction, hypotension, hypertension, ecchymosis, hot flush, flushing, peripheral ischaemia, thrombophlebitis, haematoma, circulatory failure, petechia, vasospasm, upper respiratory tract infection, sinusitis, lower respiratory tract infection, dyspnoea, epistaxis, pulmonary oedema, bronchospasm, pleurisy, pleural effusion, interstitial lung disease, abdominal pain, nausea, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, intestinal perforation/stenosis, diverticulitis, pancreatitis, cheilitis, hepatic function abnormal, transaminases increased, hepatitis, hepatocellular damage, cholecystitis, jaundice, liver failure, psoriasis (new onset or worsening), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, bullous eruption, onychomycosis, seborrhoea, rosacea, skin papilloma, hyperkeratosis, abnormal skin pigmentation, Toxic Epidermal Necrolysis, Stevens Johnson syndrome, erythema multiforme, furunculosis, worsening of symptoms of dermatomyositis, arthralgia, myalgia, back pain, urinary tract infection, pyelonephritis, vaginitis, infusion related reaction, pain, chest pain, fatigue, fever, injection site reaction, chills, oedema, impaired healing, granulomatous lesion, autoantibody positive, complement factor abnormal. **Legal category:** POM; S1A **Marketing Authorisation Number:** EU/1/13/854/001, EU/1/13/854/002, EU/1/13/854/003, EU/1/13/854/004, EU/1/13/854/005. **Marketing Authorisation Holder:** Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW, UK. **Last Revised:** August 2016.
Ref: IF 1_0 IE.
▼ 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.
For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

References:
1. INFLECTRA™. European Public Assessment Report (EPAR). June 2013. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002778/WC500151491.pdf. [Accessed June 2016]

PP-IFA-IRL-0018 October 2016

Welcome Message

Dear Colleagues and Friends,

It is my great pleasure to welcome you to the 2018 Summer Meeting of the Irish Society of Gastroenterology. I would also like to extend a very warm welcome to the members of the Irish Society of Endoscopy Nurses, HepC and IBD Nurses Association of Ireland who also hold their meetings today and tomorrow alongside the ISG.

The programme for this meeting addresses several key areas in our specialty, and links medical and surgical management of common gastroenterological diseases. In the field of inflammatory bowel diseases, we will have lectures on new surgical approaches to Crohn's disease as well as a description of the use of mesenchymal stromal cells to treat refractory perianal fistulas. This novel surgical technique looks quite promising for a difficult-to-treat subpopulation of Crohn's patients and it will be very interesting to see how this works out in real life in Ireland, after the mesenchymal stromal cell product is launched here in 2019. For the patients who are doing well, did you ever wonder when and how to stop therapy? We will get insights in that particular dilemma as well.

Pancreatic cancer remains one of the most stubborn and deadly gastroenterological diseases. A hot topics session will link medical and surgical approaches to its management. Another lecture will focus on novel surgical approaches to pelvis floor dysfunction, a common problem seen in all of our clinics.

Quality colonoscopy is a key issue in our specialty and that is why we decided to highlight the Irish Gastrointestinal Endoscopy National Quality Improvement Programme data. We will also have an invited lecture on state of the art polyp detection and removal techniques.

The meeting will finish with a look at the Irish National Hepatitis C programme and where the current and future challenges lie with this now mostly curable infection.

In keeping with a longstanding tradition of ISG meetings, we are delighted to provide trainees the opportunity to present their research findings in the oral free papers sessions. This year we also offer trainees the opportunity to present some interesting cases for discussion which is sure to be a highlight of the meeting with plenty of audience participation. I encourage you to visit the poster presentations at 13.00 Thursday and sample the exciting results on offer.

Yours sincerely,

Prof. Laurence Egan
President ISG

SIMPONI delivers long-term disease control, maintaining efficacy over 4 years[1]

Aisle Seat-itis?

Continuous clinical response: **Injecting confidence monthly**

SIMPONI (golimumab) is indicated for adult patients with moderately to severely active UC who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.[2]

6-MP = 6-mercaptopurine; AZA = azathioprine; UC = ulcerative colitis

Simponi® golimumab

SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)

ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre ffilled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **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. *Polyarticular juvenile idiopathic arthritis (pJIA):* Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **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, UC or pJIA. 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). *pJIA:* Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3 4 doses). *Missed dose:* 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):* For indications other than pJIA, Simponi is not recommended. *Patients with renal and hepatic impairment:* Simponi is not recommended. **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 for 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 and Merkel cell carcinoma (all TNF-blocking agents including Simponi) 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 thrombocytopaenia in patients receiving TNF-blockers. Cytopenias including pancytopaenia 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: Older patients (≥ 65 years):* 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. *Paediatric patients (<18 years):* Vaccinations: it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. *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, autoantibody 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, thrombocytopaenia, pancytopaenia, 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. *Paediatric population: pJIA:* The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 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:** February 2017 *Simponi/PI-IRE/02-17* Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie

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: 01-2998700)

References: 1. Reinisch W, Gibson P, Sandborn WJ, et al. Safety, efficacy, and pharmacokinetics of golimumab in patients with moderately to severely active ulcerative colitis: PURSUIT-SC long-term extension. Poster 307 presented at the 11th Congress of the European Crohn's and Colitis Organisation, March 16–19, 2016, Amsterdam, the Netherlands. **2.** Simponi SPC, available at www.medicines.ie.

Date of preparation: September 2017.

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

GAST-122848-0004

Programme for the ISG Summer Meeting
24 - 25 May 2018, Great Southern Hotel, Killarney

Thursday 24th May

9.25 **Opening Address**
Prof. Laurence Egan, President ISG

9.30 **Oral Free Papers (1-6)**

10.30 **Advances in Gastrointestinal Surgery**

Pelvic Floor Dysfunction
Ms Aisling Hogan
Consultant Surgeon
University Hospital Galway

Mesenteric Resection in Crohn's Disease
Prof. Calvin Coffey
Professor of Surgery
University Hospital Limerick

11.30 **Tea/Coffee, Posters, Visit Pharma Stands**

12.00 **Clinical Cases (1-5)**

13.05 **Lunch, Visit Posters, Visit Pharma Stands**

14.30 **Oral Free Papers (7-12)**

15.30 **Coffee/Ice Cream Break, Visit Pharma Stands**

16.00 **Endoscopy & Colon Cancer**

NQIP Endoscopic Update
Prof. Steve Patchett
Consultant Gastroenterologist
Beaumont Hospital, Dublin

Enhanced Adenoma Detection Techniques
Prof. Ralph Kiesslich
Professor of Internal Medicine/Gastroenterology
Johannes Gutenberg University of Mainz
Germany

17.10 **Close of Business**

17.15 **ISG AGM**

20.00 **ISG Gala Dinner**
featuring
Lifetime Achievement Award
to **Dr John Lennon**

Friday 25th May

8.00 AbbVie Satellite Meeting
"Calm Approach to IBD Management"
Prof. Subrata Ghosh

9.30 **What's New in IBD**

Mesenchymal Stromal Cells for the Treatment of Fistulizing Crohn's Disease
Prof. Julian Panes
Chief of Gastroenterology Department
Clinic de Barcelona, Spain

Stopping IBD Treatment - can we do it?
Prof. Glen Doherty
Consultant Gastroenterologist
St Vincent's University Hospital, Dublin

10.30 **Tea/Coffee, Visit Pharma Stands**

11.00 **Hot Topics in Pancreatic Cancer**

Pancreatic Cancer Trends and Staging
Prof. Dermot O'Toole
Consultant Gastroenterologist
St James's Hospital, Dublin

Liquid Biopsies on the Pancreas - Potential for Cancer Diagnosis and Management
Prof. Anne Marie Lennon
Associate Professor of Gastroenterology
Johns Hopkins Hospital
Baltimore, MD

Outstanding Controversies in Pancreatic Cancer
Endoscopic Stenting
Dr Finbar McCarthy
Consultant Gastroenterologist
St James's Hospital, Dublin
vs Trans-Hepatic Stenting
Dr Ronan Ryan
Consultant Radiologist
St Vincent's University Hospital, Dublin

Modern Surgical Approaches
Prof. Justin Geoghegan
Consultant Surgeon
St Vincent's University Hospital, Dublin

12.20 **Liver Session**

HCV in Ireland - where to next?
Prof. Aiden McCormick
Consultant Hepatologist
St Vincent's University Hospital, Dublin

13.15 **Presentation of Prizes/End of Meeting**

ASACOLON®

mesalazine 400mg & 800mg GR tablets

On Target for Remission

90%
of patients with mild to moderate UC maintain remission at 6 months at doses of 1.6g-2.4g/day[1]

ASACOLON® 400mg & 800mg GR tablets are indicated in adults, adolescents and children aged 6 years and over: for the treatment of mild to moderate acute ulcerative colitis (UC), for the maintenance of remission of ulcerative colitis, and for the maintenance of surgically-induced remission of Crohn's Disease (CD).

ASACOLON® 400 mg and 800 mg GR Tablets:

Reddish brown, oblong, coated tablets each containing 400 mg or 800 mg mesalazine.

INDICATIONS: Adults and children over six years: Treatment of mild to moderate acute ulcerative colitis, maintenance of remission of ulcerative colitis. Maintenance of surgically-induced remission of Crohn's disease. DOSAGE AND ADMINISTRATION: Oral use. To be swallowed whole (not chewed) with liquid before food. Adults: Ulcerative colitis: Induction of remission: 2.4 g daily in divided doses. If required the dose may be increased to 4.8 g daily. Maintenance of remission: 400 mg tablets: 1.2 to 2.4 g per day, once daily or in divided doses. 800 mg tablets: 1.6 to 2.4 g per day, once daily or in divided doses. Crohn's Disease: Maintenance of post-surgical remission: 2.4 g per day, once daily or in divided doses. Elderly: As for adults, unless renal or hepatic function is impaired. Children: Limited data. Children aged 6 years and over: Active disease: titrate to individual, initial dose 30 to 50 mg/kg/day in divided doses, maximum 75 mg/kg/day, do not exceed 4.0 g/day. Maintenance: titrate to individual, initial dose 15 to 30 mg/kg/day in divided doses, do not exceed 2.0 g/day. CONTRAINDICATIONS: Hypersensitivity to salicylates, mesalazine or any excipient. Severe renal or hepatic impairment. Children aged under two years. SPECIAL WARNINGS AND PRECAUTIONS: Conduct blood count, liver function tests, serum creatinine and urinary status (dip stick) prior to and during treatment. Follow up after 14 days, then every 4 weeks for 12 weeks, 3 monthly thereafter or immediately if signs appear. Not for use in patients with renal impairment. Caution in patients with raised serum creatinine or proteinuria. Stop treatment immediately if signs of renal impairment develop, or if there is suspicion or evidence of blood dyscrasia. Caution in patients with hepatic impairment, gastric or duodenal ulcer. Not for use in patients with a history of mesalazine-induced cardiac hypersensitivity. Caution in patients with any previous myo- and pericarditis of allergic background. Monitor closely: Patients with pulmonary disease, particularly asthma; patients sensitive to sulfasalazine. Stop treatment immediately if acute symptoms of intolerance (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Not for use in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Tablets in stools may be empty shells. Caution in elderly; use subject to renal and hepatic function. Limited data in children (aged 6 to 18 years).

INTERACTIONS: Mesalazine can increase the myelosuppressive effects of azathioprine, 6 mercaptopurine, or thioguanine. Life threatening infection can occur. Monitor closely for signs of infection and myelosuppression. Haematological parameters, especially the leukocyte, thrombocyte and lymphocyte cell counts should be monitored weekly, especially at initiation of combination therapy. May decrease the anticoagulant effect of warfarin. USE DURING PREGNANCY AND LACTATION: Limited data on use in pregnancy. One case of neonatal renal failure was reported. Mesalazine crosses the placental barrier; use only if benefit outweighs risk. Limited data on lactation are available. N-acetyl-5-aminosalicylic acid and mesalazine are excreted in breast milk. The clinical significance has not been determined. Hypersensitivity reactions such as diarrhoea in the infant cannot be excluded. Use only if the benefit outweighs the risk. If the infant develops diarrhoea, discontinue breast-feeding. UNDESIRABLE EFFECTS: Common: dyspepsia, rash. Uncommon: eosinophilia, paraesthesia, urticaria, pruritus, pyrexia, chest pain. Rare: photosensitivity (more severe in patients with atopic dermatitis or eczema), headache, dizziness, myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting. Very rare: blood dyscrasias, hypersensitivity reactions, fever, lupus erythematosus, pancolitis, peripheral neuropathy, lung reactions, pneumonia, pancreatitis, changes in hepatic and renal function, hepatitis, nephritis, nephrotic syndrome, renal failure, oligospermia, alopecia, myalgia, arthralgia. Frequency not known: pleurisy, lupus-like syndrome, mesalazine intolerance. Refer to Summary of Product Characteristics for details.

LEGAL CATEGORY: POM. MARKETING AUTHORISATION NUMBER: Asacolon® 400 mg GR Tablets PA 2018/1/1, Asacolon® 800 mg GR Tablets PA 2018/1/2. MA HOLDER: TILLOTTS PHARMA GMBH, Warmbacher Strasse 80, DE- 79618 Rheinfelden, Germany. DATE OF PREPARATION: April 2018. CODE: 2018/7. FULL PRESCRIBING INFORMATION AVAILABLE ON REQUEST FROM THE MARKETING AUTHORISATION HOLDER OR FROM TILLOTTS PHARMA LIMITED, 25 SANDYFORD OFFICE PARK, DUBLIN 18, IRELAND, TEL: (00 353 1) 294 2015. Asacolon® is a trademark.

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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Irish Society of Endoscopy Nurses
Agenda

08.30 **Registration**

09.00 Deirdre Clune, Chair
Niamh Dalton
ACNM 2
Kerry General Hospital
Welcome to Kerry

09.15 **Mary Hackett Brennan,** Chair
Hugh O Connor Msc Bsc C Eng.
Medical Physicis
St. James Hospital.
JAG Requirements for Decontamination Units.

10.15 **Glenda Hahn,** Chair
Aine Keogh
IBD ANP
Role of the IBD RANP

10.45 **COFFEE**

11.15 **Margaret O' Donnell,** Chair
Professor O' Regan
Consultant Gastroenterologist
at South Tipperary General Hospital
Barrett's oesophagus & Eosinophilic oesophagitis.

12.00 **Bridget Cafferty,** Chair
Marichu Almazan
cANP Gastroenterology
UL Hospital Group, Ennis Hospital
Telephone Based Education on Bowel Preparation for non- Screening Patients

12.45 **Mary Hackett Brennan,** Chair
Endoscopy Committee
Introduction to New Committee Members

13.00 **LUNCH**

14.00 **Devika Ghosh,** Chair
Dr Danny Cheriyan
Consultant Gastroenterologist
Beaumount Hospital
Management of Complications in Endoscopy.

15.00 **Mary Hackett Brennan,** Chair
Open Forum
The Role of the Endoscopy Nurse Endoscopy Unit

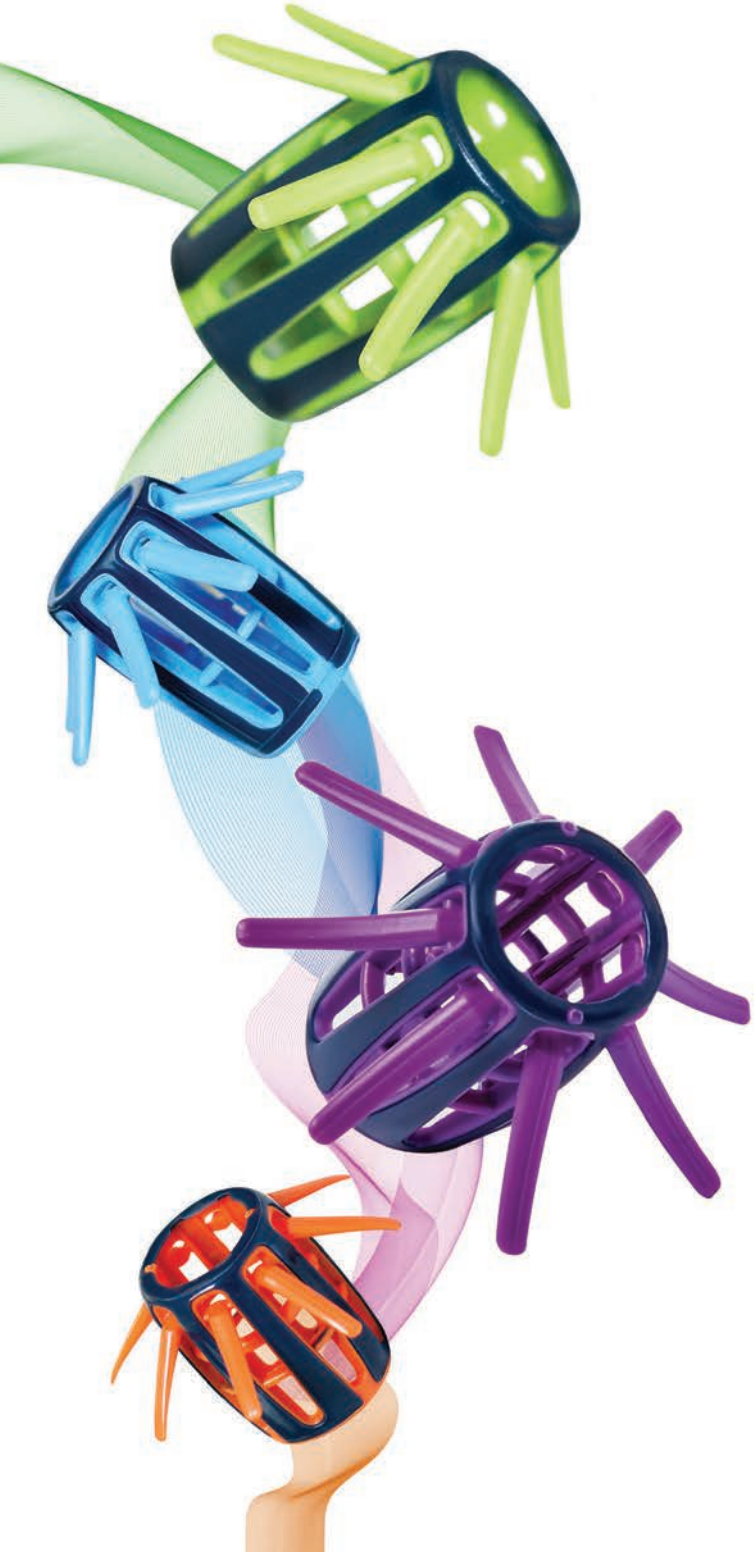
Audit

Report Findings.

15.50 **Fiona Spleeman,** Chair
Deirdre Clune
Education Opportunities within Endoscopy.

Nurses Meeting, Winter 2017

ADENOMA Study: Significant improvement in ADR* vs standard colonoscopy (40.9% vs 36.2%, p = 0.02)[1]



Presenting the innovative ENDOCUFF VISION®, a simple to use, disposable device that securely fits† around the colonoscope tip.

To find out more about how ENDOCUFF VISION® can increase the success of your colonoscopies, visit **http://hosted.bmj.com/endocuff**. Alternatively speak to your local Norgine representative or call 0800 269865 for further information.

*Adenoma detection rate

†Please refer to the Compatibility Schedule available from Norgine.

ENDOCUFF VISION®

Reference:

1. Ngu WS, *et al.* Improved adenoma detection with Endocuff Vision: the ADENOMA randomised controlled trial. Gut 2018; 66: 1-9, doi:10.1136/gutjnl-2017-314889.

Date of preparation: April 2018. UK/ECV/0418/0118.

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Biographical Sketches

Ms Aisling Hogan
Consultant Surgeon
University Hospital Galway

Aisling Hogan graduated from University College Dublin in 2004 with an honours degree in medicine. She completed her Basic Surgical Training in St. Vincent's University Hospital and was subsequently awarded an MD under the tutelage of Professors Des Winter and Alan Baird for a thesis entitled ""Pharmacological effects of oestrogens on the gastrointestinal tract". She was awarded a place on the Higher Surgical Training programme and developed a subspecialty interest in pelvic floor dysfunction. Following completion of surgical training in Ireland, she undertook a Colorectal/ Pelvic floor fellowship at Oxford University Hospital. She is currently working as a consultant colorectal surgeon in University Hospital Galway.

Prof. Calvin Coffey
Foundation Chair
Consultant General and Colorectal Surgeon
Surgery,
Graduate Entry Medical School
University Hospital Limerick

Recently appointed as Foundation Chair of Surgery at the Graduate Entry Medical School, University of Limerick and University Hospitals Limerick. Professor Coffey is a general and colorectal surgeon with a special interest in minimally invasive (keyhole) surgery. His clinical focus is in colorectal cancer, inflammatory bowel disease (ulcerative colitis and Crohn's disease), pelvic floor abnormalities.

He is the recipient of the international James IV Travelling Fellowship Award which is arguably one of the most prestigious international surgical awards. This was for his work in colorectal cancer surgery and his scientific research in the field. In 2012 he was recipient of the Cleveland Clinic Distinguished Alumnus award for which he delivered an invited lecture. He is also the recipient of over 45 national and international awards, has over 180 publications and has delivered several named national and international lectures (Millin lecture, 2012, Sir Thomas Myles Lecture 2011, inaugural Young Invertigator Lecture at the Surgical Infection Society of Europe).

After initially training in Cork University Hospital, where he received a PhD for work on cancer growth, he then trained in The Mater Misericordiae Hospital, St.Vincent's University Hospital and finally completed a fellowship in colorectal surgery at the Cleveland Clinic. He has delivered invited lectures in The Johns Hopkins, Memorial Sloan Kettering, The Cleveland Clinic and The European Institute of Oncology.

Prof. Steve Patchett
Consultant Gastroenterologist
Beaumont Hospital, Dublin

Professor Patchett is a Consultant Gastroenterologist working in Beaumont and The Bon Secours hospitals and is also an Associate Clinical Professor in the Royal College of Surgeons Dublin. Having graduated from UCD, he commenced his training in Dublin before moving to London to train in St Bartholomew's and The Royal London Hospitals.

He was appointed Senior Lecturer in Barts in 1996 and returned to take up in current position in Beaumont in November 1998. Professor Patchett's professional interests focus on diagnostic and therapeutic gastrointestinal endoscopy and therapeutics of inflammatory bowel disease. He is currently chair of the working group for the national QA programme in endoscopy and represents the College of Physicians on the QA Steering group and the Conjoint Endoscopy Curriculum development group.

Professor Patchett is also the clinical lead for endoscopy services in both Beaumont hospital and The Bon Secours.In addition he is Chair of the Medical Advisory Committee in the Bon Secours Hospital Dublin, and has served as chairman of the division of Medicine in Beaumont and as National Specialty Director in Gastroenterology.

Areas of Interest
Interventional Endoscopy, Quality Assurance in Endoscopy, Inflammatory Bowel Disease.

Prof. Ralph Kiesslich
Professor of Internal Medicine/
Gastroenterology
Johannes Gutenberg University of Mainz
Germany

Prof. Dr. Ralf Kiesslich participated in residency and fellowship training in Internal Medicine at St. Hildegardis Hospital and University of Mainz. He was board certified in Internal Medicine in 2003, and board certified in Gastroenterolog yin 2005. Dr. Kiesslich was an Assistant Professor of Internal Medicine (Gastroenterology), University of Mainz and a Visiting Professor at Massachusetts General Hospital, Boston. He was the Head of Endoscopy Unit at University of Mainz and gained Full Professorship at Johannes Gutenberg University of Mainz (founded by Pentax Europe). Dr. Kiesslich served as Head of the Department of Internal Medicine, Gastroenterology and Oncology, St. Mary's Hospital Frankfurt, Teaching hospital of the University of Frankfurt, Germany, and Head of the Department of Internal Medicine, Helios Dr. Horst Schmidt Kliniken Wiesbaden, Teaching Hospital of the University of Mainz, Germany. Since 2016, he served as Medical Director of Helios Dr. Horst Schmidt Kliniken Wiesbaden, Teaching Hospital of the University of Mainz, Germany. Dr.

Kiesslich has received the Ludwig Demling Award, German Society for Endoscopy Clinical Research Award from the Association "Gastroenterologischen Arbeitsgemeinschaft Rheinland Pfalz", Award for Best Lecture German Society for Gastroenterology (DGVS) Don Wilson Award, American Society for Gastrointestinal Endoscopy Martin Guelzow Award, Award for Clinical Science in Gastroenterology (DGVS; German Society for Gastroenterology), and the Bruce Lecturer Award in Therapeutic Endoscopy, founded by Dr. Herbert A. Bruce, Toronto, Canada.

Prof. Julian Panes
Chief of Gastroenterology Department
Clinic de Barcelona, Spain

Prof. Julián Panés is President of the European Crohn's and Colitis Organization (ECCO). Resident in Gastroenterology and Hepatology, Hospital Clinic Barcelona (1981 – 1984). Research Fellow in the Hepatology Department, Hospital Clinic Barcelona (1985). Staff member at the Department of Digestive Diseases, at Hospital Mutua in Terrassa (1985-1990). Staff member at the Gastroenterology Department, at the Hospital Clinic in Barcelona (1990-1996). Senior Specialist, Hospital Clinic Barcelona (1996-2001). Consulting Gastroenterologist, Hospital Clinic Barcelona (2001-present). Chief of the Inflammatory Bowel Diseases Unit, Hospital Clinic Barcelona (1996-present). Chief of Gastroenterology Department, Hospital Clinic Barcelona (2010-present). Associate Professor of Medicine, University of Barcelona (2001-present).
Global Adviser for the development of studies in inflammatory bowel disease for: Abbott, MSD, Novartis, Pfizer, UCB.

Prof. Dermot O'Toole
Consultant Gastroenterologist
St James's Hospital, Dublin

Dermot O'Toole is Professor in Gastroenterology and Clinical Medicine at Trinity College Dunlin (The University of Dublin) and is Consultant Gastroenterologist in St James's Hospital Dublin and the Neuroendocrine Tumour specialist in the ENETS accredited European Centre of Excellence in St Vincent's University Hospitals Dublin. He graduated from Trinity College Dublin and has postgraduate degrees from Trinity College Dublin, University of Paris and University of Angers. His major research interest is in gastrointestinal cancer biology especially focussing in neuroendocrine-related diseases and early neoplasia in the gastrointestinal tract (Barrett's oesophagus, gastric and colorectal cancers; current H-index is 50).
Professor O'Toole leads the national endoscopic interventional program for early digestive cancers and is also national clinical lead for the neuroendocrine tumour group. He also serves on the executive committee of the European Neuroendocrine Tumours Society (ENETS) and has helped develop many guidelines papers and standards of care initiatives in the field of NET as well as chairing the ENETS-driven European Centre of Excellence program. He has been principal investigator and/or coordinator in many national and international research activities in GI oncology.
Professor O'Toole is a member of several professional bodies in Europe and North America and has served as advisor on several national health care projects/initiatives and on patient advocacy groups.

Prof. Anne Marie Lennon
Associate Professor of Gastroenterology
Johns Hopkins Hospital
Baltimore, MD

Dr Lennon is the Director of the Multidisciplinary Pancreatic Cyst Clinic and an attending gastroenterologist at The Johns Hopkins Hospital. She received her medical degree from the Royal College of Surgeons in Ireland in 1996. In addition, Dr. Lennon has obtained a Ph.D degree from The National University of Ireland. She completed an internal medicine residency in Dublin and at the Cleveland Clinic, followed by a Gastroenterology Fellowship in Edinburgh, Scotland. She then completed a two year Advanced Endoscopy Fellowship in endoscopic ultrasound and ERCP at Johns Hopkins. She is certified in General Internal Medicine and Gastroenterology by the Joint Royal Colleges of Physicians Training Board (JRCPTB) of the United Kingdom and is a fellow of the Royal College of Physicians of Ireland. Dr. Lennons major interests are the workup and management of patients with pancreatic cysts, pancreatic cancer or pre-cancerous lesions and the role of endoscopic ultrasound in the diagnosis of pre-cancerous and cancerous lesions.

Dr Finbar McCarthy
Consultant Gastroenterologist, St James's Hospital, Dublin
University College Dublin
Bachelor of Medicine, Bachelor of Surgery (MBBS), Medicine
1994 – 2000

Dr Ronan Ryan
Consultant Radiologist
St Vincent's University Hospital, Dublin
Assistant Professor, UCD
Assistant Professor
Weill Cornell Medicine 2011 – 2012
UCD MB BCH BAO 1993 -1999

Prof. Justin Geoghegan
Consultant Surgeon
St Vincent's University Hospital, Dublin

Prof. Aiden McCormick
Consultant Hepatologist
St Vincent's University Hospital, Dublin

Prof Aiden McCormick graduated from UCD in 1979, and then trained in Hepatology in the Royal Free Hospital School of Medicine with Prof Dame Sheila Sherlock, Prof Neil McIntyre and Prof Andy Burroughs. Currently Hepatologist and Newman Clinical Research Professor in the National Liver Transplant Unit, St Vincent's University Hospital and University College Dublin.

His research interests are: portal hypertension, complications of chronic liver disease and liver transplantation.

Prof McCormick is a Past President of Irish Society of Gastroenterology

ISG Board Members

Professor Laurence Egan,
President ISG
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 Subhasish Sengupta,
Secretary ISG,
Consultant Gastroenterologist
Beaumount 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 Misericordae 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: Pancreatico biliary Disease and Inflammatory Bowel Disease.

Prof. 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 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.

USG Autumn Meeting
12th October 2018
Park Avenue Hotel, Belfast

Dr Tony C.K. Tham
Consultant Gastroenterologist
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 is a Consultant Physician and Gastroenterologist in the Ulster Hospital, Dundonald, Belfast.. He has more than 70 publications in peer reviewed journals. He is the first author of a book entitled "Gastrointestinal Emergencies" which has been published as a 3rd edition and translated into Polish and Chinese. He has contributed to several other book chapters. He has been co-author of guidelines on ERCP, Barretts oesophagus, perianal Crohns, non medical endoscopy workforce and UK gastroenterology services. He was the Guidelines Editor for Gut. He is on the International Editorial Board of the journal Gastrointestinal Endoscopy; Associate Editor of the World Journal of Gastrointestinal Endoscopy; Diagnostic and Therapeutic Endoscopy. He has received several awards for being a top reviewer for Gastrointestinal Endoscopy.

He was the Head of the School of Medicine, Northern Ireland Medical and Dental Training Agency (deanery). He is the Training Program Director in General Internal Medicine and Vice Chair of the Specialist Advisory Committee for general internal medicine at the Joint Royal Colleges of Physicians Training Board. He is the Deputy Chair of the British Society of Gastroenterology (BSG) Clinical Services and Standards Committee and Quality Improvement lead of the BSG. He was Secretary of the BSG committee on clinical services and standards. He is an examiner for the Royal College of Physicians of Edinburgh and also Queen's University.
He has led service improvements for patients in Northern Ireland including those with gastrointestinal consequences in pelvic radiation disease, and inflammatory bowel disease.

Mr Jürgen Mulsow
Consultant General and Colorectal Surgery
Mater Hospital, Dublin

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 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

Professor Padraic MacMathuna,
Consultant Gastroenterologist
Mater Hospital, Dublin

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 NCSS Advisory group on Colorectal Cancer Screening and a participant in the NCSS Expert Group on Herediary Cancer Risk.

Dr Susanne O'Reilly
Gastreoenterology SpR
St. Vincents Hospital, Dublin

Susanne is a Gastroenterology SpR, currently undertaking her MD entitled 'endoscopic, histological and psychosocial factors associated with a national colorectal cancer screening programme' at the Centre for Colorectal Disease, St Vincent's University Hospital. Her interests include IBD, interventional endoscopy and cystic fibrosis-related GI disease.

Dr Manus Moloney
Consultant Gastroenterologist
University of Limerick Hospital

Dr Manus Moloney graduated in 1987 from Trinity College Dublin, trained in gastroenterology at the Mater and St James Hospital Dublin before moving to the Liver unit at King's College Hospital in London, training in hepatology and completing an MD thesis on Immunogenetics of Primary Sclerosing Cholangitis. Completed training at Ashford Hospital in Kent and Guy's Hospital. Dr Moloney returned to Ireland in 2000 to take up a Consultant post at Nenagh Hospital and Limerick Regional Hospital, now the University of Limerick Hospital Group. Dr Moloney is currently serving as endoscopy lead for the group, main interests include management of Inflammatory Bowel Disease and interventional endoscopy.

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1964-1966	Professor Patrick Fitzgerald (R.I.P.)
1962-1964	Professor Oliver Fitzgerald (R.I.P.)

Oral Presentations - ISG Summer Meeting 24 May 2018

Ref:	Title of Paper	Name	Time
106	Acceptance and Commitment Therapy Improves Body Image in Inflammatory Bowel Disease Patients	Anne Fennessy	09.30
101	The Impact of the Gut Microbiota on Hepatic Drug-Metabolising Enzymes: Potential Implications for Clinical Practise of Neurogastroenterology	Jacinta Walsh	09.40
114	Effective Use Of Gastroenterology Nurse Specialist For Telephone Triage Of Direct Access Colonoscopy Referrals In An Irish Outpatient Setting	Fiona Jones	09.50
107	An Inflammation Targeted Nano-Drug Delivery System In Inflammatory Bowel Disease	Niranjan G. Kotla	10.00
147	MLH1 preservation in a cohort of Dysplastic Sessile Serrated Polyps	Susanne O'Reilly	10.10
	Clinical Case No. 1		12.00
	Clinical Case No. 1		12.13
	Clinical Case No. 3		12.26
	Clinical Case No. 4		12.39
	Clinical Case No. 5		12.52
149	Specificity of Ultrasound in Characterising Polypoid Lesions of the Gallbladder	Conor Toale	14.30
113	It's worse than you think: rates of missed upper GI cancer	Pardeep Maheshwari	14.40
117	Implementation of a minimally invasive oesophagectomy programme: Results of 108 consecutive cases	Jessie A Elliott	14.50
126	Medium-term outcomes from the Irish Early Access Programme of Direct Acting Antiviral (DAA) Therapy for HCV in patients with decompensated cirrhosis: High risk but high reward	Omar El-Sherif	15.00
146	Increasing age and survival after orthotopic liver transplantation. Should age be a contraindications?	Aisling Murphy	15.10
142	A Multicentre Study on Response Rates to Ursodeoxycholic Acid in Primary Biliary Cholangitis	Andrew Carroll	15.20

ORAL PRESENTATIONS

(ISG S'2018 106)

Acceptance and Commitment Therapy Improves Body Image in Inflammatory Bowel Disease Patients

Author(s)
Fennessy AM (1), McHugh L (2), Rowan C (1), Wynne B (2), Keegan D (1), Byrne K (1), Hartery K (1), Dooley B (2), Mulcahy H (1)

Department(s)/Institutions
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Introduction
Body image dissatisfaction is common in Inflammatory Bowel Disease (IBD). Acceptance and Commitment Therapy (ACT) involves exercises which promote psychological flexibility. ACT positively impacts stress in IBD patients and has also been utilised for other psychological disorders, including body image dissatisfaction in the general population. ACT has not previously been assessed as a treatment for body image dissatisfaction in IBD.

Aims/Background
To identify the effect of ACT on body image in IBD subjects.

Method
122 subjects were randomised to an eight-week ACT course (n=61) or standard care (n=61) with the original trial outcome being stress (ClinicalTrials.gov RegNo: NCT02350920). Body image was a secondary outcome in the original trial. Baseline data were available for 122 patients, while the follow-up study included 77 who attended five or more ACT sessions and had a baseline body image score of three or more. The Hopwood Body Image Scale was completed at baseline and after 8 and 20 weeks.

Results
Baseline body image dissatisfaction was greater in females (p=0.007), younger subjects (p=0.006) and those who had undergone previous surgery (p=0.03). Body image dissatisfaction decreased by 14% and 37% in the ACT group from baseline to 8 and 20 weeks and by 10% and 9% in the control group with a significant treatment x group interaction (p=0.001). ACT also impacted favourably on a range of other psychological variables including stress (p<0.001), anxiety (p=0.02) and depression (p=0.002).

Conclusions
An eight-week ACT therapy course improves body image in IBD subjects with body image dissatisfaction.

(ISG S'2018 101)

The Impact of the Gut Microbiota on Hepatic Drug-Metabolising Enzymes: Potential Implications for Clinical Practise of Neurogastroenterology

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Introduction
Although the direct microbial metabolism of xenobiotics is increasingly appreciated as an important factor for drug activity and toxicity, indirect microbial modulation of drug metabolism remains a neglected topic of research. The cytochrome P450 (CYPs) enzyme superfamily is implicated in the metabolism of 70-80% of all drugs in clinical use. Microbial regulation of hepatic CYP expression could be an important and modifiable source of the inter-individual variation in pharmacotherapy.

Aims/Background
Using germ-free (GF) mice, we sought to investigate whether supplementation with butyrate, a microbial metabolite, and histone deacetylase inhibitor, could normalise microbially-regulated hepatic CYP gene expression.

Method
Sodium butyrate or sodium-matched saline was administered for 21 days via the drinking water (3g/L) to conventional and GF male C57BL/6 mice (n=15/group). Mice were euthanised by decapitation and total RNA was isolated from harvested liver tissue. Reverse-transcriptase PCR was employed to compare the mRNA expression of 12 drug-metabolising CYP1-3 family isoenzymes.

Results
Expression of CYP2a4 (7.81 fold; P<0.001), CYP2b10 (7.3 fold; P<0.001) and CYP 3a11 (36.9 fold; P<0.001) were all significantly increased in the livers of GF mice. These enzymes are important for the metabolism of psychostimulants, anaesthetics and analgesics, and antipsychotics respectively. Notably, butyrate supplementation further potentiated the induction of these particular enzymes in GF mice but had no significant impact on the CYP expression in conventional animals.

Conclusions
These results may thus have important implications for clinical neurogastroenterology and may provide the impetus to consider the gut microbiota as an additional source of variation in patient response to neuroactive and gastrointestinal therapies.

(ISG S'2018 114)

Effective Use of Gastroenterology Nurse Specialist for Telephone Triage of Direct Access Colonoscopy Referrals in an Irish Outpatient Setting

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Introduction
Direct access colonoscopy (DAC) avoids clinical consultation prior to colonoscopy aiming to provide timely patient access. Limitations include inappropriate referrals and failure to identify high-risk patients. Demand for colonoscopy in Ireland has increased by 67% from 2005-2012 putting a strain on endoscopy resources and increasing waiting lists.

Aims/Background
We evaluated the appointment of a GI nurse specialist to triage DAC referrals in our endoscopy unit in a tertiary referral hospital.

Method
We carried out a prospective study evaluating adjustments to colonoscopy rates following telephone triage. DAC referrals from July 2017-January 2018 were reviewed and patients were contacted regarding indications and suitability for colonoscopy. Available clinical information, NICE and hospital guidelines were used to identify inappropriate referrals. These were declined or re-directed to either OPD, GP follow-up or an alternative procedure.

Results
1166 DAC referrals were received over 7 months (mean=167/mo). 86% were GP referrals (n=1006). Following triage, 521 patients (44.7%) did not proceed to DAC. Of 1166 referrals, 20% were re-directed to sigmoidoscopy and 2.7% to gastroscopy. 9.9% were re-directed to OPD (105 GI, 10 other). 6% were declined and directed to their GP. Based on local colonoscopy pricing, we estimated cost savings of €651,250 over 7 months, offset by €217,890 for alternative procedures.

Conclusions
Our initial data highlights that nearly half of DAC referrals were inappropriate. Many patients required more limited or alternative examinations or clinical review. We demonstrated the successful appointment of a GI nurse specialist reducing costs and unnecessary procedures, which will clearly have a significant impact on our waiting lists.

(ISG S'2018 107)

An Inflammation Targeted Nano-Drug Delivery System In Inflammatory Bowel Disease

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Introduction
There is a pressing clinical need for inflammation targeted drug delivery systems for inflammatory bowel disease (IBD) including Crohn's and ulcerative colitis. Targeting drugs selectively to the local inflamed intestine may improve therapeutic outcomes and minimize associated systemic toxicity.

Aims/Background
Inflammation of the colonic mucosa is accompanied by depletion of the mucus layer and in situ accumulation of positively charged proteins (transferrin, BPIs, AMPs, eosinophil cationic proteins) resulting in the buildup of positive charges at the damaged epithelial surface. Hyaluronan (HA) functionalized anionic nano drug particles selectively target to positive inflamed colon mucosa in colitis via electrostatic and receptor interactions.

Method
In the current investigation, hydrophobic model drug (curcumin) loaded HA nanoparticles were fabricated for inflammation-specific colon targeting. Nanoparticles were characterized for size, surface charge, stability, encapsulation/loading efficiencies, drug release studies, uptake studies in HT-29 cells and adhesion studies on simulated positive inflammatory surfaces in vitro, ex vivo.

Results
Drug-HA nanoparticles were found to be spherical in shape and of 200-400 nm in size, with high negative surface charge -51.3 mV and 56.0% drug released after 72 hrs. HA functionalization increased cellular uptake in HT-29 cells over that of uncoated nanoparticles. Further, nanoparticles were preferentially adhered (30 folds high) to transferrin, polyallylamine, amine-coated positive surfaces than those of mucin (negative) coated surfaces.

Conclusions
By understanding the pharmacological colitis tissue surface characteristics, we successfully fabricated drug-HA nanoparticles with negative surface charge and showed preferential adhesion on simulated positive surfaces, in vitro. Further in vivo (DSS/TNBS mice) studies are to be conducted to prove the hypothesis in terms of targetability, local drug delivery and biodistribution and kinetics.

(ISG S'2018 147)

MLH1 preservation in a cohort of Dysplastic Sessile Serrated Polyps

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Introduction
Sessile serrated polyps (SSPs) were first described histologically in 1990 by Longacre et al. Between 5 and 10% are dysplastic, with malignant potential. MLH1 loss and BRAF mutation are seen in >80% of dysplastic SSPs.

Aims/Background
We sought to describe the pattern of MLH1 loss in our dysplastic SSPs.

Method
The histology database was searched using the key words 'serrated adenoma'. All specimens identified (n=520) between 2004 and 2016 were reviewed by one or two pathologists. Immunohistochemical analysis of MLH1 protein was performed.

Results
35 dysplastic SSPs were identified (6.7%), of which 24 cases had adequate staining and were included. 50% were male, with a median age of 70 years old. Adenomatous dysplasia was present in 15/24 (62.5%), serrated dysplasia in 14/24 (58.3%), minimal deviation dysplasia in 2/28 (7.1%) and dysplasia of not-otherwise-specified (NOS) type in 12/24 (50%). 13/24 (54.2%) exhibited more than one type of dysplasia. MLH1 was preserved in 13/15 (86.6%) SSPs with adenomatous dysplasia, 12/14 (85.7%)with serrated type dysplasia, 1/2 (50%) exhibiting minimal deviation dysplasia, and 8/12 (66.6%) exhibiting NOS dysplasia. Overall, loss of MLH1 was only seen in 5/24 (20.8%). 4/5 of these were in the right colon (80%), and 2/5 (40%) were >1cm in size. There was no difference in location or size when compared to the 19 specimens showing MLH1 preservation.

Conclusions
Contrary to published literature, our analysis has demonstrated preservation of MLH1 in the majority of dysplastic SSPs studied. A study of a larger population would be required in order to explore this further.

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References: 1. Feagan BG *et al,* N Engl J Med 2016;375:1946-60. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. **2.** Sands BE *et al,* Oral Presentation OP005, United European Gastroenterology Week (UEGW): 15-19 October 2016; Vienna, Austria. **3.** Sandborn, WJ. *et al.* ECCO 2017. OP010. **4.** Papp K *et al,* J Drugs Dermatol 2015; 14(7): 706-714. **5.** Kalb RE et al, JAMA Dermatol 2015; 151(9): 961-969. **6.** Stelara® 90 mg pre-filled syringe. Summary of Product Characteristics. Available at www.medicines.ie. **7.** Stelara® 130 mg concentrate for solution for infusion. Summary of Product Characteristics. Available at www.medicines.ie.

PHIR/STE/0417/0009(2) | Date of Preparation: May 2018

(ISG S'2018 108)

Gastrointestinal Serotonergic Responses to an Acute Stressor are Altered in the Absence of the Microbiota

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Introduction
Gut-derived serotonin (5-HT) produced following stress can exert physiologically and clinically-important local and systemic effects. We have previously demonstrated a murine strain-dependent temporal response of the gastrointestinal serotonergic system following acute stress, but the role of the gut microbiome in modulating this profile is unknown.

Aims/Background
We therefore sought to define the role of the gut microbiome in the gastrointestinal serotonergic system response to acute stress.

Method
Adult male and female C57/BL6 conventional and germ-free, mice were randomly allocated to the unstressed control or stress group. Stressed animals were subjected to 15min of restraint stress and sacrificed immediately or 45min post-stressor. Plasma corticosterone was assayed using ELISA. Gastrointestinal 5-HT and 5-HIAA concentrations were determined using HPLC. Results were analyzed by student's t-test or ANOVA, where applicable, and statistical significance was set at $p<0.05$.

Results
In the control group, germ-free corticosterone levels were significantly greater than in conventional mice. However, corticosterone levels were significantly elevated in all mice immediately after restraint stress. Germ-free ileal 5-HIAA was significantly greater compared to conventional animals at baseline and 45min post-stress, as was ileal 5-HT in male germ-free mice. Male germ-free colonic 5-HIAA, but not 5-HT, was significantly lower relative to conventional animals at baseline and 45min post-stressor.

Conclusions
The gut microbiome defines the set point of the gastrointestinal serotonergic system and its response to acute stress in a region-dependent manner. Further studies are required to understand the impact of colonization and the implications of these findings for the control of stress-induced 5-HT-mediated gastrointestinal symptoms.

(ISG S'2018 149)

Specificity of Ultrasound in Characterising Polypoid Lesions of the Gallbladder

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Introduction
Current guidelines recommend cholecystectomy for polyps exceeding 8mm on ultrasound, due to the risk of malignant change above this threshold.

Aims/Background
This study sought to assess the impact of this policy on the yield of true polypoid lesions of the gallbladder.

Method
Patients undergoing cholecystectomy from January 2015 to March 2018 were eligible for inclusion. Clinico-pathological features were retrospectively reviewed from a prospectively maintained database. Histological analysis of patient gallbladders in whom gallbladder polyps were the primary indication for surgery were further assessed. Patients in whom incidental polyps were identified only on histology were not included.

Results
815 patients underwent cholecystectomy in the study time period. Of these, 70 (8.8%) were identified pre-operatively as having polypoid gallbladder lesions on ultrasound. Histological analysis confirmed the presence of polyps in 32 (46%) of patients. 38 (54%) did not have identifiable polyps. Of the 32 patients in whom polypoid lesions were histologically identified, 29 (91%) were shown to have benign 'pseudopolyps' (polypoid cholesterolosis, papillary hyperplasia, adenomyomatosis). Three patients were diagnosed with neoplastic polyps. Of the 32 patients in whom no polyps were identified, 13 (41%) had gallstones, and 8 (25%) had evidence of chronic cholecystitis. The remainder had no identifiable pathology. Polyp size on US was not predictive of finding a polypoid lesion on histology ($p=0.2113$). However, all malignant polyps were larger than 8mm on imaging.

Conclusions
Ultrasound overestimates the prevalence of gallbladder polyps. This study calls into question the rationale of current guidelines in the management of gallbladder polyps detected with ultrasonography.

(ISG S'2018 113)

It's worse than you think: rates of missed upper GI cancer

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Introduction
Missed upper GI cancer is defined as a new diagnosis of upper GI cancer in an individual with a normal upper endoscopy in the preceding 3 years. The literature suggest the rate of missed upper GI cancer ranges from 4- 14%. The BSG position statement (2017) has included missed upper GI cancer as a key performance indicator, recommending that the rates should not exceed 10%. It also stipulates that each unit should audit upper GI cancer miss rates every 3 years.

Aims/Background
To assess the missed upper GI cancer rate in a single tertiary care centre.

Method
Data from all upper GI cancers diagnosed over a three year periods in Beaumont hospital were evaluated. Recurrent and metastatic cancers were excluded.

Results
164 cases of upper GI cancers were assessed, of which 34 had an OGD in the preceding three years. 11 patients were excluded. 19 (11.5%) were missed cancers (11 oesophageal and 8 gastric). 7/19 (37%) missed cancers were metastatic at diagnosis. Appropriate, high quality photo documentation was absent in all missed cancers.

Conclusions
Our high volume, tertiary referral centre had a missed upper GI cancer rate in line with published data; however, it does not meet the relevant KPI as outlined by the BSG. Miss rates can be lowered further by appropriate training and strict adherence to quality measures.

(ISG S'2018 117)

Implementation of a minimally invasive oesophagectomy programme: Results of 108 consecutive cases

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Introduction
Open Ivor-Lewis oesophagectomy has traditionally been the standard treatment for resectable oesophageal cancer, but is associated with significant postoperative morbidity. Minimally invasive oesophagectomy (MIO) is increasingly adopted, with reduced pulmonary morbidity and improved quality of life in survivorship as demonstrated in two recent European randomised controlled trials.

Aims/Background
To describe short term outcomes with implementation of an MIO programme in Ireland.

Method
Consecutive patients undergoing minimally invasive Ivor-Lewis oesophagectomy for oesophageal cancer from 2011 – 2017 were prospectively studied. Neoadjuvant therapy was utilised for ≥cT2 and/or ≥N1 disease. All patients underwent radical abdominothoracic en bloc oesophagectomy with two-field lymphadenectomy and high intrathoracic end-to-side circular stapled oesophagogastric anastomosis, and a postoperative ERAS protocol was utilised.

Results
108 patients (age 61.7±8.7 years; female, 22%; adenocarcinoma, 83%) were studied. 78% of patients had neoadjuvant therapy (chemotherapy 10%, chemoradiation 68%). One patient required conversion to an open procedure. 93% had an R0 resection. The median lymph node count was 29 (7-58). The median in- hospital and critical care lengths of stay were 8 (6-34) and 3 (1-28) days, respectively. Grade II, III and IV morbidity occurred in 19%, 19% and 3%, with pneumonia, atrial fibrillation and anastomotic leak in 19.4%, 20.3% and 4.6% of patients. The ICU readmission rate was 2.7%, and 30-day hospital readmission rate was 11.1%. 30-day/ in-hospital mortality and 90-day mortality were 3.7% and 4.5%, respectively.

Conclusions
The implementation of a minimally invasive oesophagectomy programme was successful, feasible and safe. Perioperative and oncologic outcomes compared favourably with published benchmarks. Minimally invasive oesophagectomy should be considered the standard of care for resectable oesophageal cancer.

(ISG S'2018 126)

Medium-term outcomes from the Irish Early Access Programme of Direct Acting Antiviral (DAA) Therapy for HCV in patients with decompensated cirrhosis: High risk but high reward

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Department(s)/Institutions
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Introduction
DAA therapy can improve liver function in some patients with decompensated HCV cirrhosis. However, treatment benefit must be balanced against the risks of adverse events such as death or liver transplantation.

Aims/Background
There are limited data on medium term outcomes following DAA therapy for decompensated HCV.

Method
Patients with decompensated cirrhosis or a history of decompensation were treated for 12 weeks with ledipasvir/sofosbuvir + ribavirin as part of the Irish Early Access Programme for DAA therapy. The primary outcome was survival following therapy. Secondary outcomes were death, improvement to CP class A cirrhosis or liver transplantation.

Results
In all, 101 patients underwent treatment (Baseline CP B/C – 66.3%/18.8%). The rate of sustained virological response (SVR12) was 74.3%. Two patients were lost to follow-up following SVR. The overall survival rate in our cohort was 70.7% (median follow-up 3 years). Survival rates at 1, 2 and 3 years from the start of treatment were 86.8%, 79.7% and 70.7% respectively. During the follow-up period, 7 patients were transplanted (3 year transplant free survival 63.6%). Failure to achieve SVR was associated with a significant increased risk of death (OR 3.35, 95% CI 1.903 – 5.891, $p < 0.0005$). At the end of follow-up, 75% (47/63) of surviving non-transplanted patients had CP class A compensated cirrhosis.

Conclusions
SVR is associated with medium-term survival in patients with

decompensated HCV cirrhosis treated with DAA. Despite the previously reported high mortality rate in CP B and C patients undergoing DAA therapy, a high proportion of the total cohort improved to CP class A cirrhosis.

(ISG S'2018 146)

Increasing age and survival after orthotopic liver transplantation. Should age be a contraindications?

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Introduction
The mean age of patients receiving liver transplantation is increasing worldwide. There is increasing demand for liver transplantation among the elderly, however despite the shortage of organs, the outcome for this population is not well defined.

Aims/Background
Our aim was to evaluate the short and long term survival rates of patients over 65 who underwent orthotopic liver transplantation (OLT) and to compare them to a younger cohort aged 15-64 in a single national transplant center.

Method
Data from 1070 patients who underwent OLT between January 1993 and December 2017 was obtained from national liver transplant database. Patients under and over 65 years of age were compared with respect to 1 year, 5 year and 10 year survival. Baseline characteristics, length of ICU stay, length of hospital admission and cause of death were also compared.

Results
Of the 1070 patients who received a liver transplantation, 90 patients (8.4%) were over 65 years of age. The one year, five year and ten year survival were 81% (n=69), 71.9% (n=41) and 51% (n=19) respectively. This was not significantly different to the younger under 65 cohort with 86% (n=814) one year survival (p=2306), 76.2% (n=562) five years survival (p=3971) and 63% (n=307) 10 years survival (p=1472). There was no significant difference in the length of ICU stay or length of hospital admission post transplant. Patients over 65 were more frequently transplanted for HCC (p=<0.001) and NASH (p=<0.001). There was no significant difference in the causes of death between the older and younger cohort.

Conclusions
Carefully selected patients over 65 have similar survival rates after OLT compared to younger counterparts. Age over 65 alone should not be considered a contraindication for OLT.

(ISG S'2018 142)

A Multicentre Study on Response Rates to Ursodeoxycholic Acid in Primary Biliary Cholangitis

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Introduction
Primary biliary cholangitis (PBC) is a chronic, destructive cholangiopathy. Failure of response to treatment can result in progression to cirrhosis, liver transplantation or death. Until recently, ursodeoxycholic acid (UDCA) was the only approved therapy. Obeticholic acid (OCA) has now been licensed but not reimbursed as a potential second-line therapy for PBC patients with an inadequate response to UDCA.

Aims/Background
To assess the numbers of non-responders who may benefit from OCA.

Method
Patients attending any of three Irish hepatology centres with a confirmed diagnosis of PBC over the age of 16 were included. Patients were excluded if there was insufficient data, if they were transplanted or if they were deceased. Data was analysed using SPSS. The modified Toronto criteria (ALP>1.67x ULN after 6 months of UDCA) was used to determine non-response.

Results
201 patients were included for analysis. 90% were female. The mean age was 61.4 years. 93.2% of patients were receiving UDCA. The median UDCA dose was 750mg/day (0-1500mg/day). 69.3% of patients were responders. Weights were available for 55 out of 201 patients. Of these, 56.4% were on the correct weight-based dosing of UDCA. 34.2% of the non-responders who had data for their weight recorded were receiving sub-therapeutic dosing of UDCA.

Conclusions
In 201 adults with PBC we saw UDCA response rates of 69.3%. Of the patients with weight recorded, 43.6% were under-dosed. UDCA dose should be optimised in all non-responders, but up to 30% of patients may benefit from a second line therapy.

POSTER PRESENTATIONS

(ISG S'2018 102)

Host and environmental factors influencing the expression of bacterial-derived metabolic enzymes in faeces: Potential implications for microbiota-mediated drug metabolism

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Introduction
The gastrointestinal tract houses a reservoir of bacterial-derived enzymes, including β-glucuronidase and β-glucosidase, which can directly catalyse the metabolism of drugs. It is important to investigate the host and environmental factors, which may influence the expression and activity of these enzymes, to explore novel mechanisms driving inter-individual variation in drug metabolism.

Aims/Background
Our aim was to investigate the effects of age, sex, genetic background, germ-free (GF) status, antibiotic treatment, and species on enzymatic activity.

Method
Fecalase, a cell-free extract of faeces, was prepared from mouse, rat and human faeces, according to a modified **method** previously described by Lee et al. To quantify the enzymatic activity in fecalase, we utilised a colorimetric-based assay. Enzyme activity was indicated as the amount required to catalyse the formation of 1nmole of p-nitrophenol per minute and expressed as U/mg protein. Two different antibiotic cocktails, previously found to ablate the gut microbiota, were administered via the drinking water for 21 days to adolescent and adult C57/BL6 male mice (n=8-12/group).

Results
The absence of enzyme activity in GF animals confirmed these enzymes are microbial-derived. Our data show that the activity of β-glucuronidase and β-glucosidase depends on the sex, host genetics, age, and species of the experimental animal. The antibiotic-cocktails depleted enzymatic activity during treatment, which recovered one week after stopping antibiotic administration.

Conclusions
Antibiotic-treated animals may thus serve as a possible alternative to the GF model in pharmacokinetic studies. The implications of these findings for drug metabolism and pharmacokinetics warrant further investigation.

(ISG S'2018 103)

Comparison of biopsy sites for diagnostic accuracy of Helicobacter pylori infection: a retrospective study.

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Introduction
Helicobacter pylori infection is very common worldwide, occurring in 40% to 50% of the population in developed countries. The infection causes chronic gastritis which significantly increases the risk of developing gastric or duodenal ulcer, gastric adenocarcinoma, and mucosa-associated lymphoid tissue (MALT) lymphoma. Eradication of H. pylori infection has been shown to improve the outcome of peptic ulcer disease in terms of recurrence and complications. Hence, accurate diagnosis of H. pylori infection is of clinical importance.

Aims/Background
To assess the optimal site for biopsy for detection of H.pylori infection and whether different sites provide different accuracy.

Method
We did a retrospective study on 943 patient who underwent upper GI endoscopy for dyspepsia at Monaghan General Hospital between March 2009 and July 2013. Biopsies were obtained from two sites in antrum and corpus respectively during upper endoscopy .The biopsy specimen were taken immediately for the CLO rapid urease test. Two biopsies were sent for histology and the results were followed to compare the CLO test result and biopsy results.

Results
Sensitivity of RUT in the body vs antrum was 73% vs 68% respectively specificity of RUT in the body vs antrum was 96% vs 97% respectively

Conclusions
Both biopsy sites had an almost similar results in the detection of H.pylori infection. The RUT should be combined with other endoscopic or nonendoscopic modalities to establish the presence or absence of this infection. Increasing the number of biopsies and the number of sites will increase accuracy. However, this prolongs endoscopy time and adds to the discomfort of the patient.

(ISG S'2018 104)

The prevalence of alcohol use disorders in medical admissions to the Mater Misericordiae University Hospital

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Introduction
Alcohol consumption can contribute directly or indirectly to the need for medical admission to hospital. The impact of alcohol consumption and the drinking patterns of medical admissions to the Mater hospital are not known.

Aims/Background
We sought to quantify alcohol consumption and determine the prevalence of alcohol use disorders in patients admitted to our hospital. We also aimed to determine whether the admission was alcohol attributable, alcohol associated or unrelated.

Method
We determined the alcohol consumption for every patient admitted medically over one whole week and then classified them as abstinent, low risk, hazardous, harmful or dependent. Every patient that was not low risk was asked to complete an AUDIT (Alcohol Use Disorders Identification Test) questionnaire. Patients were divided into three age groups; ≤40, 41-65, ≥66 years old.

Results
We collected data on 199 patients. Alcohol use disorders were uncommon in patients ≤40 or ≥66. 40% (19/48) of patients in the 41-65 year old group had an alcohol use disorder (mean AUDIT score = 20) and 17% (8) were dependent (mean AUDIT score = 32). There were more dependent women than men. In this age group 10% had an admission that was directly alcohol attributable and in 25% it was alcohol associated.

Conclusions
Alcohol use disorders are common in patients aged between 41 and 65 admitted medically to the Mater Hospital. It is important to screen this population and deliver targeted interventions.

(ISG S'2018 105)

The diagnostic yield of EUS guided FNA in a tertiary referral center.

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Introduction
Endoscopic ultrasound-guided fine needle aspiration cytology (EUS-FNAC) is a minimally invasive technique widely used for the evaluation of deep-seated benign and malignant lesions. The advantages of EUS include real-time puncture, reduced risk of complications due to the proximity of the needle to the lesion, and the ability to sample small lesions that might be hard to sample using other methods.

Aims/Background
Compare the diagnostic yield of EUS guided FNA in our unit with international standards.

Method
The histological reports of the list of the patients who had EUS guided FNA in 1 year reviewed and results were recorded.

Results
Of total 553 total EUS done in 1 year, 74 patients had EUS guided FNA, the diagnosis of malignancy was made in 53%, and the sample size was enough to exclude malignancy in 28%

Conclusions
EUS guided FNA has relatively high diagnostic yields compared to other imaging-guided biopsies. Our diagnostic yield is compatible with international standards. The presence of cytopathologist in the procedure room may increase the diagnostic yield.

(ISG S'2018 109)

"GAL-SWITCH: A Prospective Observational study of planned switch from bio-originator Infliximab to biosimilar Inflectra."

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Introduction
Recent studies have shown that the efficacy of Infliximab (IFX) biosimilars appears similar to Remicade when patients were switched without significant increase in adverse drug reactions and immunogenicity.

Aims/Background
To prospectively assess the efficacy, safety and patient satisfaction (using patient reported outcome measures) when switching patients from Remicade to biosimilar Inflectra in our Inflammatory Bowel Disease Cohort.

Method
In this open-label prospective cohort study all patients with IBD receiving Remicade were switched to biosimilar Inflectra in October 2017. Data was collected 6 months and 3 months prior to the switch, at the time of the switch and 3 months after. Data collected includes CRP, fecal calprotectin, Infliximab trough levels, antibodies to infliximab and patient symptom scores (IBD-control, Visual Analogue scale, Harvey-Bradshaw Index and partial Mayo score).

Results
53 patients are included in the study. 55% of patients are male and 75% are Crohn's patients. 98% of patients were still receiving Inflectra at 3 months. There were no crisis admissions for IBD flares and no serious ADRs reported. On average, there was a cost reduction of 56% annually per patient. There was no significant difference in PROMs or mean CRP pre-switch and at 3 months after. Pre-switch median IFX trough level was 4.6mg/L compared to a median of 5.2mg/L 3 months post switch. None of our patients have developed antibodies to IFX to date.

Conclusions
From our preliminary data, there is no concern regarding safety, efficacy, immunogenicity or patient satisfaction having switch from Remicade to Inflectra. Longer term post switch data is currently being collected.

(ISG S'2018 110)

Follow up of the awareness and education of the vaccinations in IBD cohort in tertiary center as ECCO guidelines

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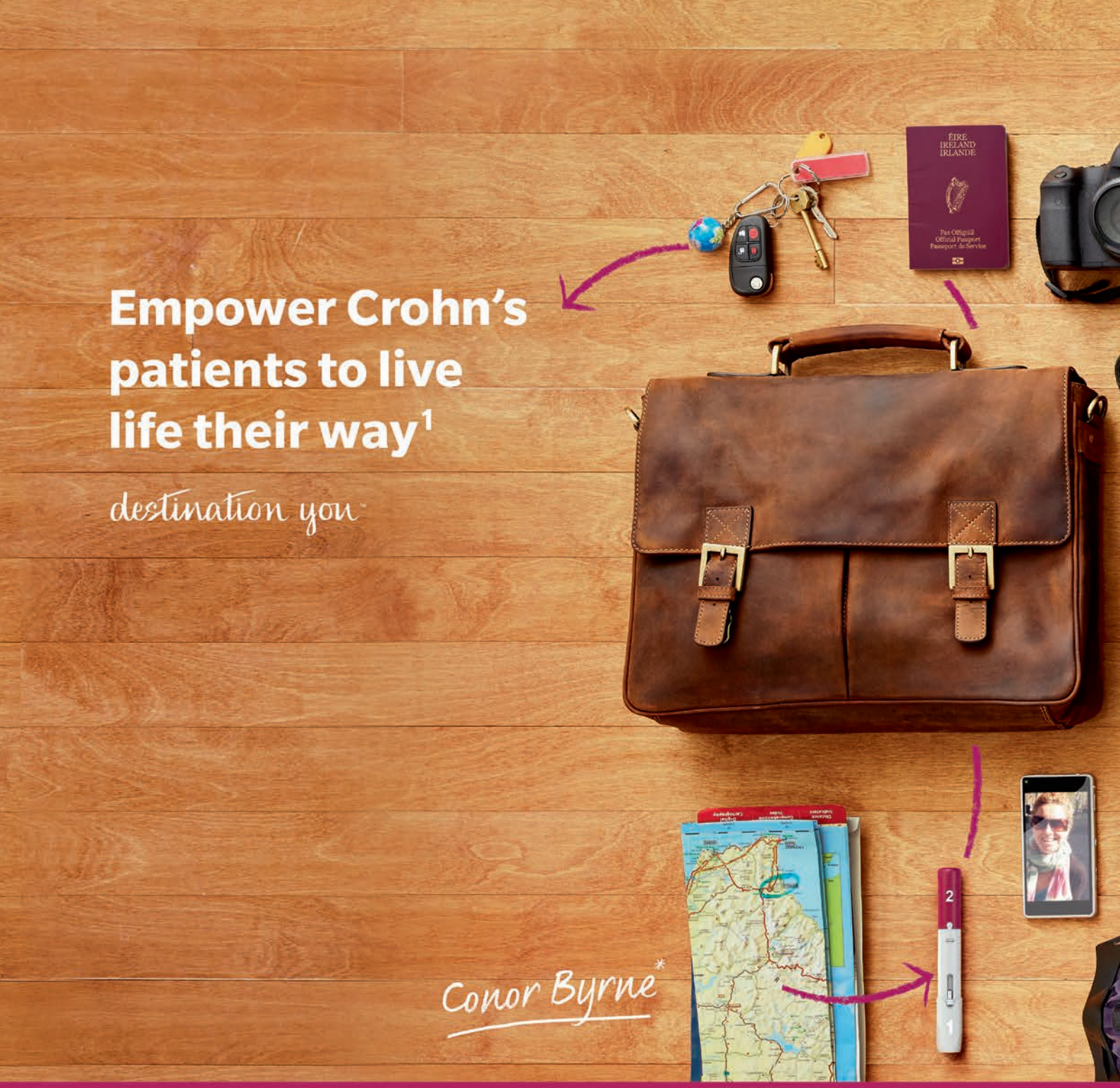
Introduction
Chronic diseases increases the risk of opportunistic infections and specially patients with inflammatory bowel disease who are on long term immunosuppressive and biologic medications. In 2016 we studied the vaccination status and knowledge regarding vaccination in our IBD cohort and in keeping with other studies we found that vaccination uptake was very poor. We provide individual and quarterly group patient education sessions, provide written literature and document in letters to primary care providers the need for vaccination to prevent opportunistic infection

Aims/Background
The aim was the reassess the awareness of the vaccination in our IBD cohort based on ECCO guidelines following our intervention

Method
A written questionnaire with simple Yes/No answers given to IBD patients at the outpatient clinics , Infusion suite and in the community

Results
A total of 92 patient replied the questionnaire, 52(56%) were male and 44(47%) have with Crohn's Disease (CD). Average duration of disease was 9 years (range 6 months to 30 years). 58% were exposed to immunomodulators or steroids and 52% to biologics .



Empower Crohn's patients to live life their way[1]

destination you™

*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 0.4ml single dose pre-filled pen or pre-filled syringe contains 40mg of adalimumab. Each 0.8ml 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. Enthesitis-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). Uveitis, adults: For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in need of corticosteroid-sparing, or where corticosteroid treatment is inappropriate. Uveitis, paediatrics 2 years and above: For chronic non-infectious anterior uveitis with inadequate response or intolerance to conventional therapy, or where conventional therapy 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: 80mg Week 0, 40mg at Week 2. For a more rapid response: 160mg 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: 40mg every other week. If insufficient response, consider 40mg 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 40mg every week. If adequate response is achieved with an increased dosing frequency, dose may subsequently be reduced to 40mg every other week. If there is inadequate response to the increased frequency, carefully reconsider treatment. Psoriasis, Paediatrics 4 years and above: 0.8mg per kg body weight (maximum of 40mg/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 80mg two weeks later at Day 15 (two 40mg injections in one day). Two weeks later (Day 29) continue with a dose of 40mg 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: 40mg 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: 80mg initially at week 0 (given as two 40mg injections on day one). 40mg 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 dosing frequency to 40mg 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

*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.
2. HUMIRA® Summary of Product Characteristics. Available on www.medicines.ie
Date of Preparation: September 2017 IREHUG160187d(2)

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: 80mg induction dose at week 0, 40mg 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. Uveitis, paediatrics 2 years and above < 30 kg: 20mg every other week in combination with MTX. When Humira is initiated, a loading dose of 40mg may be administered one week prior to the start of maintenance therapy. No clinical data available on the use of a Humira loading dose in children < 6 years of age. Uveitis, paediatrics 2 years and above ≥ 30 kg: 40mg every other week in combination with MTX. When Humira is initiated, a loading dose of 80mg may be administered one week prior to the start of maintenance therapy. In paediatric uveitis, there is no experience in the treatment with Humira without concomitant treatment with MTX. No relevant use of Humira in children aged less than 2 years in paediatric uveitis. 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 noninfectious 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 doublestranded 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 ≥ 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:** September 2017, PI/256/019.

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Only 9% reported they have knowledge about the vaccination and 10% reported they were educated about the vaccinations. Forty percent reported they have up-to-date influenza vaccine and only 15% have their Pneumococcal vaccine. Fifteen percent have their vaccine against the hep B. Sixty percent of the women were having their regular cervical smear checked

Conclusions
Despite all efforts uptake is low and we advocate that vaccination should now be proactively administered by the IBD physicians

(ISG S'2018 111)

EUS guided gallbladder drainage with the hot AXIOS stent: The first Irish experience

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Introduction
The management of gallbladder disease is particularly challenging in patients who are elderly or poor surgical candidates. Current standard of care for acute cholecystitis in this cohort involves antibiotics and possible percutaneous drainage via interventional radiology. External drains are uncomfortable, may dislodge, and can result in delayed hospital discharge.

Aims/Background
We report the first six cases in Ireland of EUS guided placement of a lumen apposing metal stent between the gallbladder and stomach or duodenum using the hot AXIOS system

Method
6 patients with acute or recurrent cholecystitis were prospectively selected as appropriate candidates. Each patient was deemed unsuitable for surgical intervention given advanced age or co-morbidities. Under conscious sedation in the endoscopy unit, EUS guided gallbladder drainage (EUS-GBD) was performed

Results
EUS- GBD was performed in 6 patients (4 male, 2 female, mean age 78, range 65-95).3 patients had recurrent cholecystitis requiring multiple admissions. 1 patient, with a history of recurrent cholecystitis, presented with a gallbladder perforation. 2 patient with hilar cholangiocarcinoma developed acute cholecystitis following percutaneous transheptatic biliary stenting . Stent placement was successful in 100% of patients, with no immediate complications. All patients were discharged well.At mean follow up of 5 months, no patient has re-presented to hospital with cholecystitis

Conclusions
EUS- GBD in carefully selected patients is safe, and may reduce the morbidity and long term care issues associated with percutaneous drains

(ISG S'2018 112)

Measures of predicting inflammatory and fibrotic strictures in Crohn's disease patients using magnetic resonance

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Introduction
Small bowel (SB) Crohn's disease (CD) strictures can comprise of both inflammation and fibrosis. Dense fibrotic matrix exhibits delayed gadolinium enhancement on MRI. Relative contrast enhancement (REC) of >24% on delayed MRI sequences may accurately detect fibrosis.

Aims/Background
To determine the feasibility of Magnetic Resonance Enterography, MRE, SB stricture assessment with early (70s) and late (7mins) phase post gadolinium imaging.

Method
A retrospective study on 208 MREs for patient with suspected and known CD. Disease status, demographics and biochemical markers were recorded. MREs assessed by 2 radiologist for evidence of RCE, T2 signal intensity(SI), MaRIA score and evidence of stenosis.

Results
Median age 40.5years; male n= 83(39.9%). 117, 72 and 19 patients had known CD, suspected CD and indeterminate IBD, respectively. 119(57%) MREs were normal. Ileitis, strictures and fistulas were found in 40(19%), 49(24%) and 1(0.5%), respectively. 69 MREs were further assessed on patients with stricturing and inflammatory ileal CD. Median age = 42 years. Male n= 26(38%). RCE >24% and high T2SI occurred in 26(38%) and 35/69 (51%)respectively. MaRIA score comprised of: Mild<7; 5(7%), moderate 7-11; 11(16%), severe>11; 53(77%). No significant change in MaRIA score between 70sec and 7mins. 36(52%) had stenosis on MRE. RCE, T2SI and MaRIA score for patients with stenosis versus no stenosis were: RCE>24%; 13v13. High T2 SI: 30v5. MaRIA < 7; 2v3. MaRIA 7-11; 6v5. MaRIA >11; 28v25. RCE<24% and high T2SI; 23(33.3%). 20(30.3%) had neither High T2SI nor RCE>24%. 12(17%) had both RCE>24% and high T2SI while 14(20%) had RCE>24% without high T2SI.

Conclusions
MaRIA scores do not differentiate between inflammatory and stenotic disease. T2SI may be a useful marker of stenosis. RCE>24% was comparable in groups with both stenosis and without, further analysis is required into patients who have isolated RCE>24% and where this may be a marker of fibrotic versus inflammatory disease.

(ISG S'2018 116)

Minimally invasive surgical management of spontaneous oesophageal perforation (Boerhaave's syndrome)

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Introduction
Spontaneous esophageal perforation (Boerhaave's syndrome) is a highly morbid condition traditionally associated with poor outcomes.

Aims/Background
The Pittsburgh perforation severity score (PSS) accurately predicts risk of morbidity, length of stay (LOS) and mortality. Operative management is indicated among patients with intermediate (3 – 5) or high (>5) PSS, however the role of minimally invasive surgery remains uncertain.

Method
Consecutive patients presenting with Boerhaave's syndrome with intermediate or high PSS to a single oesophagogastric unit from 2012-2017 were reviewed. Demographic, clinical presentation, management and outcomes were analysed.

Results
Ten patients (80% male) with a mean age of 61.2 years (range: 37–81) were included. Three patients had intermediate and seven patients had high PSS (7.3±2.9, range: 4–12). The mean time from onset of symptoms to diagnosis was 25±15 hours and APACHE II score was 12.4±6.7. Nine patients were managed operatively and one conservatively. Thoracoscopic debridement and primary repair was performed in seven patients, with two perforations repaired primarily over a T-tube. Laparoscopic feeding jejunostomy was performed in all cases, and decompressing gastrostomy in five patients. Critical care LOS was 8.1±7.5 days (range: 0–26), while inpatient LOS was 22.1±12.3 days (range: 8–46), significantly associated with PSS (P=0.01, R2 =0.63). Median comprehensive complications index was 34.6 (range: 0 – 69.6), with grade IIIa and IV morbidity in 50% and 10%, respectively. One patient developed dehiscence at the primary repair, which was managed non-operatively. In-hospital and 90-day mortality was 10%.

Conclusions
Minimally invasive surgical management of spontaneous oesophageal perforation with high perforation severity scores is feasible and safe, with outcomes which compare favourably to the published literature.

(ISG S'2018 122)

Lymph node yield from pancreaticoduodenectomy (Whipple) specimens; a three year audit from 2015-2017

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Introduction
The surgical management of neoplasms of the pancreas, ampulla and distal bile duct is pancreaticoduodenectomy (Whipple procedure). Identification and histological examination of the lymph nodes is a key staging and prognostic element of the pathological evaluation of these specimens in cases of malignancy

Aims/Background
A LND yield of ≥10 in pancreaticoduodenectomy specimens is a key performance indicators (KPI) set by the National Cancer Control Program. Our primary aim was to determine if lymph node dissection in these specimens in our laboratory has met this KPI.

Method
Details of all pancreaticoduodenectomy specimens reported in St Vincent's University Hospital from 2015-2017 were retrieved via a search of the laboratory information system. Pathology reports of cases of invasive malignancy were reviewed to obtain the lymph node yield and the mean, median and percentage of cases that met the KPI were calculated. Data was stratified yearly to obtain a trend and was also compared to a previous similar audit from 2012-2014

Results
A total of 189 cases were reviewed. The mean number of lymph nodes retrieved was 17.15(range 2-55) and the median was 16. There was a yearly improvement in the mean lymph node yield and an improvement since the previous audit of 2012-2014 (mean 13.45). 89.4% (n=169) cases had a lymph node yield of ≥10

Conclusions
This audit confirmed that lymph node retrieval in pancreaticoduodenectomy specimens for invasive malignancy met the key performance indicators set by the National Cancer Control Program of ≥10 in 89.4% of cases (mean 17.15), with a yearly improvement in lymph node yield since 2012

(ISG S'2018 125)

Microbial Regulation of Hepatic Gene Expression: Implications for Tryptophan Metabolism

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Introduction
Communication along the microbiome-gut-brain axis exerts a marked impact on brain function and behaviour. Microbial regulation of tryptophan metabolism, an essential amino acid and precursor to serotonin and neuroactive kynurenine pathway metabolites, represents a potential mechanism underpinning this influence.

Aims/Background
The liver is a major site of tryptophan metabolism to kynurenine by tryptophan 2,3-dioxygenase (TDO2) and other enzymes. The gut microbiome influences hepatic gene expression but the contribution of this crosstalk to the circulating availability of tryptophan and its metabolites is currently unknown.

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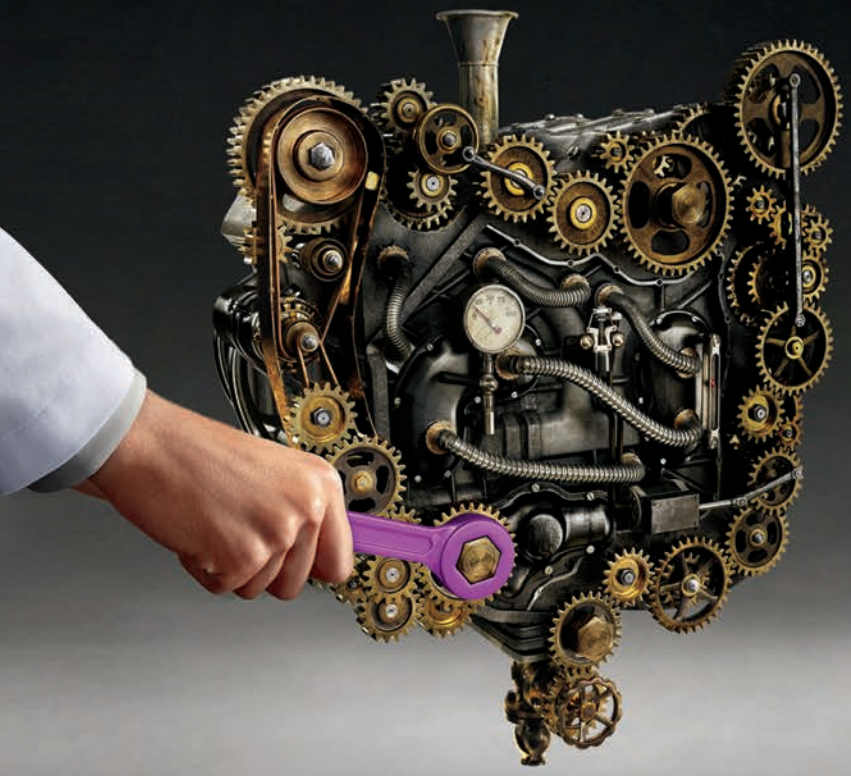

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  - 39% of CD patients vs 22% for placebo in patients responding at Week 6 ($P<0.001$)[1]
- Targeted mechanism of action[1] different from anti-TNFα therapies
- No weight based dosing[1]. 300-mg IV infusion

References: 1. Entyvio Summary of Product Characteristics. Takeda Pharmaceuticals Ireland Ltd. www.medicines.ie

ITEM CODE: IRE/VED/14/0008c(2)
DATE OF PREPARATION: January 2018

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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, upper respiratory tract infection, 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:* respiratory tract infection, infusion site reaction, infusion-related reaction, pneumonia. **Refer to the SmPC for details on full side effect profile and interactions. Legal Classification:** POM. **Marketing Authorisation:** EU/1/14/923/001 **Additional information is available on request from:** Full prescribing information is available from Takeda UK Ltd. Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Buckinghamshire, HP10 0DF. Tel **1800 937 970**. Fax +44 1628 526617. Takeda Products Ireland Ltd. 3013 Lake Drive, Citywest Business Campus, Dublin 24. Tel: +353 (0)1 642 0021 Fax: +353 (0)1 642 0020. **PI Approval Code:** IRE/VED/17/0012 **Date of revision:** December 2017.

Ireland: Adverse Events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority (medsafety@hpra.ie). Information about Adverse Event reporting can be found on the HPRA website (www.hpra.ie). Adverse events should also be reported to Takeda UK Ltd 1800 937 970

Method
Butyrate or saline was administered via the drinking water (3g/L) for 21 days to conventional and germ-free male C57BL/6 mice (n=15/group). Mice were euthanised by decapitation and total RNA was isolated from harvested liver tissue. Quantitative reverse-transcription polymerase chain reaction (qRT-PCR) was used to examine the expression of relevant hepatic tryptophan-metabolising enzymes.

Results
The expression of TDO2 was reduced in germ-free mice compared to conventionally colonised animals ($p<0.05$). Butyrate supplementation was unable to normalise the expression of this enzyme in germ-free animals nor did it have an effect in conventional controls. A similar pattern of hepatic gene expression was also observed for indoleamine 2,3-dioxygenase 1 (IDO1).

Conclusions
Microbial regulation of hepatic gene expression may represent an important mechanism though which the gut microbiome regulates the availability of tryptophan and its metabolites. Further studies are required to understand the microbial mediators involved in this crosstalk between the gut microbiome and the liver and to determine if is possible to manipulate this relationship to control gut-brain axis signalling.

(ISG S'2018 127)

To evaluate Photographic confirmation of complete colonoscopy

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Introduction
Colonoscopy is the gold standard investigation for examining the lower GI tract. Colonoscopy must be high quality in order to maximize its benefit. BSG and ESGE guidelines recommend photographic and written documentation of caecal intubation. such photo-documentation includes images of both the ileocecal valve and the cecum with views of the appendiceal orifice.

Aims/Background
Establishing reliability of photo documentation of caecum as evidence of caecal intubation in our hospital.

Method
A retrospective study of consecutive colonoscopies in endoscopy unit from 29/01/2018 to 07/02/2018 by gastroenterology registrars, surgical registrars and consultants . Data was collected from endoraad. Total of 112 colonoscopies were performed in above period. 18 colonoscopies were excluded from audit(no photograph due to technical reason, failed colonoscopies and previous surgery). 94 included in the audit. 5 endoscopists then independently scored the photographs ranging from 1-4. Score 1 is definitely caecum, 2 likely caecum, 3 maybe caecum and 4 not caecum.

Results
Inter observer variability (number of caecal picture with the difference of more than 1 point) was 4 of 94 (4.2%) . Photographs assessed as either definitely caecum or likely caecum was 63 (72.3%) and 22 (23.4%)was assessed as may be caecum or not caecum.

Conclusions
Photographic documentation of caecum is well establish KPI of colonoscopy. As evident from this audit 23.4% caecal photo docoumentation by experienced endoscopist was not established. This audit evaluate the need for adherence with established KPI's.A further alternative to the above is video-documentation of the cecal landmarks if available.

(ISG S'2018 128)

Barrett's Oesophagus Surveillance in a Tertiary Centre

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Introduction
Guidelines regarding interval surveillance endoscopy for Barrett's oesophagus(BO) are well established. Novel techniques including narrow band imaging(NBI), ascetic acid chromoendoscopy(AACE) and transparent cap(TC) use have shown better accuracy in detecting dysplasia . These techniques remain outside international guidelines, potentially leading to a wide variation in assessment.

Aims/Background
To review BO assessment techniques and variation in practice within a tertiary endoscopy centre.

Method
A retrospective review of 180 OGDs identified 21 OGDs with BO. Techniques including NBI, AACE and TC use were documented. Use of Prague Criteria, Seattle Protocol or targeted biopsies were noted.

Results
Median age 61 years (Male n=14).Indication for endoscopy: previous dysplasia(5); BO follow-up(6); other(10). There was no significant difference in use of lidocaine spray and midazolam. Fentanyl use by registrars was 66%(8) and consultants 44%(4). Prague Criteria was documented in 19(90%) cases, registrar= 12(100%) and consultant=7(77%). Short BO (<3cm)=10(47%). Long BO=11(53%). NBI was performed in 15/21(71%) cases: previous dysplasia 5/5(100%), known BO 6/6(100%); new BO 4/10(40%); short BO 7/10(70%); long BO 8/11(73%). AACE was performed in 5/21(24%); short BO 0/10(0%); long BO 5/11(45%); previous dysplasia 2/5(40%), known BO 3/6(50%); new BO 0/10(0%). TC was performed in 5/21(24%) short BO 2/10(20%); long BO 3/11(27%); previous dysplasia 3/5(60%), known BO 2/6(33%); new BO 0/10(0%). There was no significant difference between registrar and consultant endoscopists. Quandrantic biopsies were taken in 100%, with no targeted biopsies.

Conclusions
We found wide variation in BO assessment techniques in a single unit. Local and international guidelines are required to standardise BO assessment and improve dysplasia detection.

(ISG S'2018 130)

Endoscopic Colonic Polyps Reporting. Are we doing it right?

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Introduction
Approximately 3-6% of colorectal adenomas detected at colonoscopy are large sessile polyps and up to 20% of all polyps are flat or minimally elevated. The detection of these lesions is likely to increase with the **introduction** of population screening for colorectal cancer. Polyp description (size, location), procedure performed (excision and methodology) and the use of internationally recognized Paris or NICE (NBI-Narrow Band Imaging International Colorectal Endoscopic) classifications ideally should be documented in a standard endoscopy report.

Aims/Background
The aim of this retrospective observational study is to assess endoscopists' approach on colonic polyps reporting in our institution.

Method
Endoscopy reporting is performed using the Unisoft Software. A total of 100 colonoscopy reports generated from mid-January to February 2018 involving detection and management of colonic polyps were reviewed.

Results
There were 93 (93%) reports documenting measurements of polyps' size with 7 describing polyps as small without measurement. 99% reports documenting colonic segments of polyps encountered. 99% reports documented method of excision (forceps biopsy/ snare/endoscopic mucosal resection (EMR). There was one case documented only biopsy performed with the other 99 cases managed with polypectomy. 4 reports commented on the polyps having hyperplastic appearance. Of the 100 colonoscopies, 63% were performed by non-consultant hospital doctors (43 medical, 20 surgical) with 37% performed by consultants (30 medical, 7 surgical). 18% endoscopists applied Paris classification in their reports (all medical endoscopists).

Conclusions
This single centre observational study has shown good reporting manner with high percentage amongst endoscopists including details on polyps' size, site and methodology of polypectomy in reports. However, there was a low utilization of internationally recognized polyp classifications. A number of variables may account for this.

(ISG S'2018 131)

Hepatitis C success rates and improvement in liver enzymes at St Luke's Hospital Kilkenny

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Introduction
Historical treatment of Hepatitis C with interferon had high drop out rates and high recurrence rates. The novel direct acting antiviral agents(DAAs) are now widely available in Ireland and are easier and more successful than interferon based treatment. They are however expensive and real world data is needed to ensure efficiency and efficacy.

Aims/Background
To retrospectively analyse all hepatitis C patients treated at our institute with novel direct acting antiviral agents to assess success rates

Method
All patients with hepatitis C at our institute are followed up at a specialised nurse led clinic. Patients who have been treated at our institute since February 2017 with DAAs were entered into a specific database and analysed. Our primary measure was the number of patients pcr negative 3 months post treatment. We also measured changes in liver enzymes during and after treatment.

Results
Thirty eight patients were treated at our institute since February 2017. 26(68%) males and 12 females. Mean age 47.3 (28-68). Genotype 1a (14). Genotype 1b (12). Genotype 2 (2). Genotype 3 (10). 30 non-cirrhotic, 8 cirrhotic. Mean treatment duration was 12.2 weeks (8-24) with 32 patients prescribed the 12 week programme. One patient was not fully compliant with treatment and has since stopped attending. Only one patient was pcr positive at 3 months. Therefore in intention to treat we had a 95% success rate. Mean ALT pre-treatment was 81 (16-307) and the mean at end of treatment was 21(12-51). Mean GGT pre-treatment was 84 (7-687) and the mean at end of treatment was 33(12-449).

Conclusions
Our data shows that treatment with the new DAAs at our institute is effective and safe resulting in 95% viral clearance and significant improvement in liver enzymes

(ISG S'2018 132)

Individualised Prescribing for H. pylori Eradication, Proven Efficacy in Practice

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Introduction
Current best practice guidelines state that 14-day triple therapy or Bismuth quadruple therapy should be adopted as first line treatment of H. pylori.

Aims/Background
This study aims to evaluate the effectiveness of switching from a 7-day triple therapy regimen to 14-day triple or quadruple therapy in terms of H pylori eradication rates.

Method
From September 2016 to December 2017 patients undergoing OGD at the Bon Secours Hospital, Cork had H. pylori status determined by CLO test (BioHIT). All patients undergoing OGD also had biopsies sent for H. pylori culture. H. pylori positive patients were treated with 7-day triple therapy, 14-day triple therapy or 14-day quadruple therapy. Patients were offered urea breath test (Diabact UBT) 3-4 months after completing treatment. Patients were excluded if they did not attend follow-up breath testing or if data was unavailable. Eradication rates in the different treatment groups were compared.

Results
Of 1891 patients undergoing OGD, 146 (7.7%) had positive CLO tests. 28 patients had negative CLO tests on OGD but went on to have positive H. pylori biopsies. Of the total 174 patients identified as H pylori positive, 112 went on to have urea breath testing. 5 patients were excluded due to incomplete prescription details. 42 received triple therapy for 7 days, 54 received triple therapy for 14 days and 11 received quadruple therapy for 14 days. The overall eradication rate was 89/107 (83.2%). The eradication rates per group were 36/42 (85.7%) in the 7-day triple therapy group, 46/54 (85.2%) in the 14-day triple therapy group and 7/11 (63.6%) in the quadruple therapy group.

Conclusions
Implementation of the new guidelines and individualised prescribing has lead to an improvement in H. pylori eradication rates from 71.4% in a previous audit (Bon Secours, 2017) to 83.2%.

(ISG S'2018 135)

An Analysis of Sessile Serrated Polyp Detection over a 13 year period

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Introduction
Sessile serrated polyps (SSPs) were first described in 1990. Their recognition and detection at endoscopy has increased exponentially since then and is a potential colonscopy quality indicator. We sought to decribe the detection and characteristics of SSPs over a 13 year period in a single institution.

Aims/Background
N/A

Method
We identified all SSPs diagnosed in SVHG between 2004 and 2017 through pathology records and obtained clinical information from medical records.

Results
560 patients were diagnosed with SSPs 2004-2017. Clinical data were available in 395, the remainder were excluded. 77% of SSPs were in the symptomatic (non-screening) population. 26.3% were >1cm in size. Dysplasia was present in 6.7% and was more likely to occur in over 50s (89% vs 11%, p=0.036) and the right colon (69.4%). Concurrent adenomas were more common in men (45%, p=0.013) and BowelScreen patients (66% Vs 32%, p<0.01). 61% of procedures were carried out by a consultant gastroenterologist, 20.5% by a gastroenterology trainee, and 18.2% by a surgical consultant or trainee. Overall, the number of SSPs detected doubled year on year between 2014 and 2017.

Conclusions
The diagnosis of SSPs has increased substatially since 2013 and this is possibly reflective of an enhanced focus on pathological diagnosis and colonoscopy quality that occurred alongside the **introduction** of colorectal cancer screening in Ireland.

(ISG S'2018 136)

Forced Diuresis In Patients With Decompensated Liver Disease – Is There Significant Benefit To Be Gained?

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Introduction
Human albumin solution (HAS) has traditionally been used in patients with liver disease to prevent renal failure in spontaneous bacterial peritonitis, circulatory collapse following paracentesis and in the treatment of hepatorenal syndrome. The ANSWER trial recently suggested that administration of HAS alongside diuretics infers significant survival benefit in decompensated liver cirrhosis as well as improving quality of life.

Aims/Background
We evaluated the effectiveness of forced diuresis in the management of cirrhotic patients with peripheral oedema aiming to show improvement in functional status.

Method
Prospective assessment of patients admitted to the Regional Liver Unit from August 2017 until January 2018. Inclusion criteria comprised confirmed cirrhosis (Fibroscan, radiology or histology), peripheral oedema restricting mobility, failure of oral diuretics and absence of tense ascites or hepatorenal syndrome. All received

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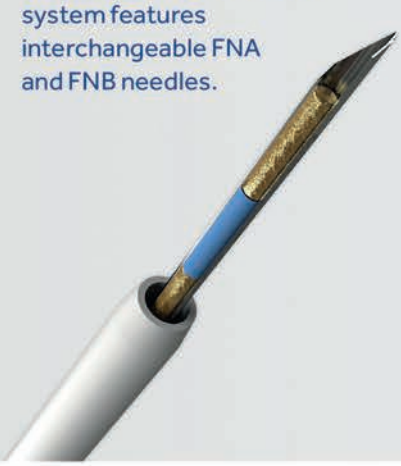

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treatment with 20g HAS daily alongside IV furosemide (40mg to 80mg daily) or IV bumetanide 1-2mg. Inpatient days, weight, renal function and ECOG score were assessed.

Results
22 patients were assessed. With the exception of two palliative patients all showed significant improvement in ECOG scores from 1-3 to 0-1. Mean inpatient stay was 13.9 days. Renal function was maintained in all cases. Only 14 patients had accurate weights throughout treatment. Of this cohort the mean total weight loss was 9kg (range 3.5kg–17.1kg).

Conclusions
For a subset of patients with liver cirrhosis, forced diuresis offers significant symptomatic relief and optimisation of functional status whilst preserving renal function. In light of inpatient days required, consideration should be given to development of an ambulatory pathway.

(ISG S'2018 139)

Attitudes towards Treatment Withdrawal in IBD

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Introduction
A recently published ECCO topical review on exit strategies in IBD has underlined the role of treatment withdrawal in selected cohorts with stable disease. Select patients may no longer require immunosuppression once disease remission is achieved and maintained.

Aims/Background
To assess patients' attitudes towards immunosuppresive therapy and to potential treatment withdrawal.

Method
We invited patients undergoing immunosuppressive therapy, attending out-patients or the infusion suite during a 4-week period, to participate in this prospective observational study. Participants were asked a series of questions regarding their disease and treatment history, compliance with treatment, awareness of risks of immunosuppression, concerns regarding long term treatment, concerns regarding treatment withdrawal and willingness to switch to generic medication.

Results
In total, 88 (female = 48%) patients participated. Mean age 42.6 years (16 - 72). Crohn's 77%%. Treatment – 28% Infliximab, 13% Combination therapy, 17% Adalimumab, 10% Imuran, 4% Ustekinumab, 2% Vedolizumab, 1% Golimumab. Mean duration of therapy 5 years (0.5-18). 35% required steroids in the past 12 months. 16% smokers. 29% ex-smokers. Missed dose reported in 80% Imuran, 35% Infusions, 78% Subcutaneous. Mean HBI = 6.3. Mean partial Mayo = 1. 97% aware therapy affected immune system. 70% concerned regarding same. 84% agreeable to life-long therapy. 54% happy to stop treatment if advised by their Physician, rising to 87% if decision based on drug levels. 68% happy to switch to biosimilar. Main concerns regarding treatment withdrawal include relapse (68%), loss of response (16%) none (16%).

Conclusions
Patients are aware of the risks of long term immunosuppression and are interested in treatment withdrawal if advised by their Physician.

(ISG S'2018 140)

PBC Management in a Regional Liver Unit – Establishing the Role for a PBC MDM

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Introduction
Primary Biliary Cholangitis (PBC) is a progressive autoimmune disease that destroys the small interlobular bile ducts leading to cirrhosis. The goals of treatment are to delay/avoid the need for transplantation. The current mainstay of treatment is ursodeoxycholic acid (UDCA). New medications have recently received NICE approval for second line treatment of PBC.

Aims/Background
To identify PBC patients under follow up with the Liver Unit of the Royal Victoria Hospital (RVH), who are not on appropriate weight-based treatment of UDCA or are non-responders to UDCA who may be eligible for second line agents.

Method
A retrospective, cross-sectional evaluation of consecutive PBC patients attending the RVH liver clinic between September 2016 and June 2017.Written consent was obtained during outpatient clinic consultations and anonymized data was collected from hospital databases and medical notes including patient demographics, management and outcomes i.e. biochemical response.

Results
103 patients were included. 85% of patients were female; mean age 51.2 years at diagnosis; 93% (96/103) were on UDCA. Of 96 patients (93%) on UDCA, 13 (14%) were on the recommended dose (13 – 15 mg/kg), 65 (68%) were on the incorrect dose and 18 (19%) had no weight recorded. 60% (58/96) were deemed to be UDCA responders (ALP ≤1.67 upper limit of normal (ULN) and bilirubin<="" p="" style="box-sizing: border-box;">

Conclusions
Overall a significant proportion of PBC patients attending for follow-up at the RVH liver clinic were on an incorrect dose of UDCA based on their weight. Despite this 60% of patients on UDCA were deemed to be responders indicating a favourable prognosis. 38% of patients on UDCA were non-responders and therefore may be appropriate for consideration of a second line medication such as bezafibrate or obeticholic acid. This suggests a regional PBC MDM would be beneficial to identify patients suitable for escalation of treatment.

(ISG S'2018 143)

Measuring Compliance with Adalimumab using Smart Sharps Bin Technology

Author(s)
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Department(s)/Institutions
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Introduction
Adalimumab is a patient-administered subcutaneous anti-TNF agent used in both Crohn's Disease and Ulcerative Colitis. It has previously been shown that there is significant non-compliance with patient-administered subcutaneous therapies.

Aims/Background
To evaluate compliance with Adalimumab among our patient cohort enrolled in the Health Beacon programme.

Method
We collated data supplied by Health Beacon on a monthly basis to determine rates of non-compliance with Adalimumab therapy including, early, late and missed dosing. A drop is counted as administration of Adalimumab and placement of the pre-filled pen or syringe into the smart sharps bin.

Results
A total of 496 drops were counted among 26 patients. 15 males and 11 females are currently enrolled in the programme with an average age of 40.6 years. 17 patients have a diagnosis of Crohn's Disease and 9 with Ulcerative Colitis. 355 drops were recorded as being on-time, giving an overall compliance rate of 71.5%. Compliance among males is 76.8% and females 63.8%. Compliance is 71.7% and 70.6 in Crohn's Disease and Ulcerative Colitis, respectively. 46.2% of patients have missed at least two doses.

Conclusions
We have shown high rates of non-compliance with Adalimumab therapy in patients who have agreed to have their compliance tracked. This may be attributed to the administration of the medication by the patient at home. In this case, infusion therapy may show benefit over subcutaneous therapy. Further correlation with inflammatory markers, endoscopic findings and faecal calprotectin may aid in deescalating therapy in those patients who are non-compliant, yielding significant savings for our department.

(ISG S'2018 144)

Pancreatic cystic lesions (PCLs): Are we risk-stratifying the lesions and complying with international surveillance guidelines?

Author(s)
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Introduction
PCLs are being increasingly detected on imaging. PCLs can be pseudocysts, serous (harmless) or mucinous. IPMNs, the more common mucinous PCL have a 40% malignant risk. EUS is a vital tool in assessment of PCLs. Several consensus guidelines for PCL diagnosis and surveillance exist but compliance is often poor.

Aims/Background
To retrospectively review our EUS database to identify all cases of PCL over a 6-year period. To characterise the PCLs and to establish if patients are undergoing appropriate surveillance.

Method
2180 EUS procedures performed from 2011-2017 were reviewed and all PCLs were included. PCL characteristics and worrisome features (dilated PD, solid component or size >2cm were recorded. FNA data (cyst fluid, CEA, amylase,cytology) were recorded. Post-EUS surveillance of PCLs by EUS, MRCP or CT is under review.

Results
256/2180(13.0%) patients had PCLs at index EUS. Based on EUS characteristics, PCLs were classified as follows: IPMN/mucinous cystadenoma 94(36.7%), serous 40(15.6%), pseudocyst 73(28.5%) and 49(19%) indeterminate. Size was recorded in 233(91%) of patients and was categorised as; < 1cm 59(23%), 1-2cm 68(26.6%), and >2cm in 106(41.4%) of patients. Worrisome features including dilated PD, solid component, size>2cm were identified in 75(29%). PCL FNA was performed in 72(28%). Surveillance data following index EUS are currently being reviewed.

Conclusions
56% of PCLs were IPMNs or indeterminate in this study. These have a significant risk of malignant transformation and require on-going surveillance. 29% had worrisome features. We are currently assessing the subsequent surveillance of our PCL population for compliance with consensus guidelines.

(ISG S'2018 145)

Management Of Pbc Patients Pre-Obeticholic Acid Era

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Introduction
Primary Biliary Cholangitis is a chronic autoimmune disease characterised by progressive damage of interlobular bile ducts leading to end-stage liver disease in some cases.

Aims/Background
To evaluate the management of PBC patients attending Tallaght University Hospital over the last 2 decades, in comparison to 2017 EASL guidelines.

Method
We performed a retrospective study of 39 PBC patients attending our institution using chart review, NIMIS electronic radiology system, and our local blood/pathology electronic system.

Results
The mean age of our cohort was 57.92 (range 33 – 78). 87.2% (n=34) of patients were female, and 76.92% (n=30) were above age fifty. 26 (66.7%) patients were treated with Ursodeoxycholic acid (UDCA), with 18 (69.2%) on suboptimal doses (<13 -15 mg/kg/day). Of the 26, 11 (42.3%) were non-responders based on Toronto criteria with an Alkaline phosphatase (ALP) > 1.67 x upper limit of normal. 8 (72.7%) of the 11 non-responders were on suboptimal dose of UDCA. 15 patients responded to UDCA based on Toronto criteria, 7 (26.9%) of these had ALP<1.67 x ULN before commencing treatment with UDCA, with ALP remaining <1.67 x ULN over 24 - 36 months.

Conclusions
Most patients were on suboptimal doses of UDCA, especially non-responders. This reflects previous uncertainty about the efficacy of UDCA. The dose is being optimised for these patients. True non responders will be considered for obeticholic acid. All patients with ALP<1.67 x ULN who were treated with UDCA had a non-progressive disease course, which may relate to early treatment.

(ISG S'2018 148)

The Adult Kasai: perspectives from the adult physician to guide management

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Aims/Background
To describe the relevant clinical course for adult patients with biliary atresia who underwent a Kasai operation in childhood and who have not been transplanted at the time of transition to adult services ("adult Kasai")

Method
Retrospective audit of the adult care of patients from a single centre programme embedded in a large transplant unit (1999-2016)

Results
Of 95 patients (54 female- mean age 26.2± 0.69 years) reported with a Kasai procedure as a child, 63 had undergone liver transplantation (LT). Eight patients had LT post transition to adult care. 32 remained with their native liver –two were lost to follow-up- (19 female, mean age of 26±0.75 years) with median follow up 63.8 months. Portal hypertension was present in 22 patients: 13 (43%) with varices and splenomegaly. Variceal bleeding occurred in 4 patients; 1 patient developed ascites and 1 hepatocellular carcinoma. Pruritus and abdominal pain affected 11 patients (36.6%). Cholangitis (1-10 episodes) appeared in 12. 16 patients (53%) were admitted to hospital at least once due to their liver disease. Malabsorption appeared in 2, and 5 had underlying bone disease. MRI performed in 9 (30%) included features of sclerosing cholangitis and bile dilatation. A total of 9 patients underwent a liver biopsy, only 5 presented advanced fibrosis. 10 patients were on long term UDCA and 10 required rotating antibiotics

Conclusions
The "adult Kasai" patient has a heterogeneous course that includes: cirrhosis, portal hypertension, symptomatic cholangitis and pain. Clinical care of patients needs to account for this

(ISG S'2018 150)

Use of endoscopy services by cystic fibrosis patients in a national cohort

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Introduction
Cystic fibrosis is a genetic chronic disease affecting approximately 1300 people in Ireland. There are a myriad of gastrointestinal manifestations of CF, including pancreatic insufficiency, CF-related liver disease, distal intestinal obstruction syndrome, and gastro-oesophageal reflux.

Aims/Background
We sought to examine use of endoscopy and its findings in a large cohort at our centre.

Method
The CF patient database (n=341) was used to review all endoscopic records 2008-2018 at our centre. Date of procedure, indication, and findings were recorded. An age-matched control population of patients who underwent colonoscopy at our centre was used for comparison (1:1).

Results
169/341 were genotype ΔF508, 131 (38.4%) male, with a median age of 32. 84/341(25%) underwent gastroscopy, and 38/341 (11.4%) underwent colonoscopy. Commonest indications were reflux symptoms (25.3%), PEG insertion (21.7%), investigation of anaemia (13.3%) and assessment/banding of varices (18.1%). 35/84 (42.2%) had a normal OGD. 18% were found to have a hiatus hernia, 8.4% Barrett's oesophagus, 13.3% oesophagitis, 27.7% gastritis, 6% a duodenal ulcer, and 24.5% oesophageal varices. ΔF508 patients were more likely to have Barrett's (15.6% vs 0%, p=0.014). There were no differences between genders. The commonest indications for colonoscopy in CF patients were rectal bleeding (38%) and anaemia (18%). Patients with CF were more likely to have a polyp identified at colonoscopy (23.7% versus 12.4%, p=0.05).

Conclusions
CF patients are more likely to have colonic polyps than age-matched controls. Genotype may be significantly related to the presence of Barrett's oesophagus, but further study is required.

(ISG S'2018 151)

Outcomes of patients treated with upfront cholecystostomy for severe acute cholecystitis in a tertiary referral centre.

Author(s)
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Introduction
Cholecystostomy insertion is an important temporising adjunct in treatment of severe cholecystitis, especially in the co-morbid patient.

Aims/Background
The aim was to assess short and long term outcomes of patients post cholecystostomy at a single medical centre.

Method
A review of consecutive patients who underwent percutaneous ultrasound and fluoroscopic guided cholecystostomy tube insertion over a 3 year period (01/01/2015-31/12/2017) was performed. Patients were identified using NIMIS and the hospital internal computer system. Outcomes assessed included; cholecystectomy, cholecystostomy reinsertion, no further interventions, and mortality.

Results
There were 63 patients in total (45 male, 19 female). Patient age range was 29 to 93, mean 70 years. Acute cholecystitis was the most

common indication. 49 were transhepatic drain insertions, 2 were direct gallbladder punctures. Route of insertion was not specified in 13 cases. 45 (69%) had a subsequent tubogram to assess patency of the cystic duct prior to catheter removal (37) or to assess position (8). 16 patients subsequently underwent cholecystectomy (12 laparoscopic, 4 open). 7 (11%) had a cholecystostomy reinserted (2 were due to recurrence of symptoms, 5 were due to inadvertent catheter dislodgement). Time to reinsertion ranged from 2 to 107 days, average 33 days. 29 (35%) had no further intervention post removal of cholecystostomy. 1 required subsequent drainage of a hepatic abscess. 9 patients (14%) died during the recruitment period

Conclusions
Cholecystostomy remains an important treatment method of acute cholecystitis in the short term, or as an alternative treatment option in those unsuitable for surgery. 11% of those that did not proceed to cholecystectomy required reinsertion of a cholecystostomy.

(ISG S'2018 152)

Cross-Specialty Analysis of Infliximab Dosing

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Introduction
Infliximab is prescribed for numerous conditions, including IBD and Rheumatoid Arthritis (RA). Numerous biologic agents are licensed for the treatment of RA. However, IFX remains a stalwart of IBD therapy as few alternatives exist.

Aim
To compare the overall use and dosing of Infliximab by relevant specialties.

Methods
The study was performed in a single academic centre between January and March 2018. Data regarding the dose(mg) and number of vials per infusion of Infliximab, and prescribing specialty for each individual infusion were retrieved from the Pharmacy database.

Results
405 Infliximab infusions were administered in the study period. 75.8% were prescribed by Gastroenterology, compared with 19.3% by Rheumatology, the second largest cohort. Dermatology and Neurology accounted for 3.7% and 1.2% respectively. The median dose/infusion was 430mg (IQR 350-620mg); median number of vials/infusion was 5 (IQR 4-7).
The median dose of Infliximab prescribed by Gastroenterology was significantly higher compared with the Rheumatology service. (440mg; IQR 360-630mg vs 400mg; IQR 300-472mg; p=0.001). There was no significant difference in dose/infusion between the Gastroenterology service and Dermatology or Neurology prescribers. (p=0.29 and p=0.15 respectively)

Conclusion
Gastroenterology represent the largest proportion of Infliximab prescribers in this tertiary referral centre, administering over 3 times as many infusions as the Rheumatology service in the same study period. Gastroenterology patients were administered a significantly higher dose of Infliximab/infusion. IFX trough levels can be used to safely reduce IFX dose. The adequate resourcing of IBD specialty nurses and biologic registries could have a significant impact on hospital expenditure on Infliximab.

Audience view

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The two doses should be separated by a minimum of 1 hour. Day before dosing schedule: Both doses taken the evening before the procedure. The two doses should be separated by a minimum of 1 hour. No solid food should be taken from the start of the course of treatment until after the clinical procedure. Consumption of all fluids should be stopped at least 2 hours prior to a procedure under general anaesthesia or 1 hour prior to a procedure without general anaesthesia. Children: Not recommended for use in children below 18 years of age. No special dosage adjustment is deemed necessary in patients with mild to moderate renal or hepatic impairment. Patients should be advised to allow adequate time after bowel movements have subsided to travel to the clinical unit. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients, gastrointestinal obstruction or perforation, ileus, disorders of gastric emptying (gastroparesis, gastric retention), phenylketonuria, glucose-6-phosphate dehydrogenase deficiency, toxic megacolon. **Warnings and precautions:** The fluid content of reconstituted Plenvu does not replace regular fluid intake. Adequate fluid intake must be maintained. As with other macrogol containing products, allergic reactions including rash, urticaria, pruritus, angioedema and anaphylaxis are a possibility. Caution should be used with administration to frail or debilitated patients, in patients with impaired gag reflex, with the possibility of regurgitation or aspiration, or with diminished levels of consciousness, severe renal impairment, cardiac failure (grade III or IV of NYHA), those at risk of arrhythmia, dehydration or severe acute inflammatory bowel disease. 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 a baseline and post-treatment electrolyte, renal function test and ECG as appropriate. Any suspected dehydration should be corrected for before use of Plenvu. There have been rare reports of serious arrhythmias including atrial fibrillation associated with the use of ionic osmotic laxatives for bowel preparation, predominantly in patients with underlying cardiac risk factors and electrolyte disturbance. If patients develop any symptoms indicating arrhythmia or shifts of fluid/electrolytes during or after treatment, plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately. If patients experience severe bloating, abdominal distension, or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms subside. The sodium content, 458.5mmol (10.5g), should be taken into consideration for patients on a controlled sodium diet. The potassium content, 29.4mmol (1.1g), should be taken into consideration by patients with reduced kidney function or those on a controlled potassium diet. **Interactions:** Medicinal products taken orally within one hour of starting colonic lavage with Plenvu may be flushed from the gastrointestinal tract unabsorbed. The therapeutic effect of drugs with a narrow therapeutic index or short half-life may be particularly affected. **Fertility, pregnancy and lactation:** There are no data on the effects of Plenvu on fertility in humans. There were no effects on fertility in studies in male and female rats. It is preferable to avoid the use of Plenvu during pregnancy. It is unknown whether Plenvu active ingredients/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain from Plenvu therapy. **Undesirable effects:** Diarrhoea is an expected outcome. Common: vomiting, nausea, dehydration. Uncommon: abdominal distension, anorectal discomfort, abdominal pain, drug hypersensitivity, headache, migraine, somnolence, thirst, fatigue, asthenia, chills, pains, aches, palpitation, sinus tachycardia, transient increase in blood pressure, hot flush, transient increase in liver enzymes, hypernatraemia, hypercalcaemia, hypophosphataemia, hypokalaemia, decreased bicarbonate, anion gap increased/ decreased, hyperosmolar state. Refer to the Summary of Product Characteristics (SmPC) for a full list and frequency of adverse events. **Legal category:** Prescription medicine **For further information contact:** Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, United Kingdom UB9 6NS. Telephone: +44(0)1895 826606. E-mail: medinfo@norgine.com **Product licence number:** PA 1336/005/001 **Date:** March 2018 **Company reference:** UK/PLV/0318/0061

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References: 1. Bisschops R, *et al*. Presented at UEGW 2016, poster number P0179. **2.** Schreiber S, *et al*. Presented at UEGW 2016, poster number P1266. **3.** DeMicco MP, *et al*. Gastrointest Endosc 2018;87(3):677-687.e3; doi: 10.1016/j.gie.2017.07.047. **4.** Norgine Ltd. DOF-PLENV-008 version 1.0. August 2017. **5.** PLENVU® IE Summary of Product Characteristics. October 2017. **6.** MOVIPREP® IE Summary of Product Characteristics. August 2017; **7.** MOVIPREP® Orange IE Summary of Product Characteristics. August 2017.

Winter Meeting 2017

Michael Stafford, Cara Dunne, John Halpin

Grace Harkin, Pardeep Maheshwari, You Yi Hong, Jim O'Connell

Padraic MacMathuna, Garret Cullen, Diarmuid O'Donoghue

Winter Meeting 2017

Margaret Walshe, Mairead McNally, Ciara Egan

Audrea Kennedy, Deirdre O'Donovan, Hilary King, Maureen Moore

Vitthal R. Wadekar and Anne Liyanage

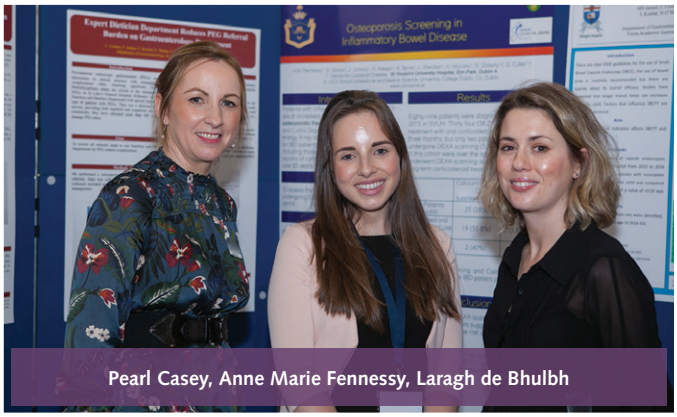
Aman Shah Afridi and Fayyaz Janjua

Lunch Break

Winter Meeting 2017

Caroline Conlon, Olga Fagan, Elaine Houlihan

Dr Nap Keeling and Prof Fergus Gleeson



Pearl Casey, Anne Marie Fennessy, Laragh de Bhulbh

Nerissa Oller, Archana Sasidharan Nair, Nerissa Noche, Christina Ducusin

You Yi Hong, Ronan Leen, Vikrant Parihar

Takeda Team, Shane Ryan, Michelle Condell, Eileen Phillips, Declan Ruth.

Prof Laurence Egan and Guest Speaker Dr Ken Wang

Loretta O'Brien, Neil Power, Angela Mullan

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Karen O'Driscoll, Mary Hamzawi, Mary Forry, Caroline Lardner, Annie Coe

Eimear Gibbons, Orlaith Kelly, Claire Smyth, Karl Hazel

Cathal Clifford, Eoin Keating, Paul Armstrong

Sinead Cabben and Mai Hanlon, Tillotts

Dr Susan McKiernan

Dr Diarmuid Houlihan

Dr Christian Maaser with Audience

Prof. Glen Doherty

Winter Meeting 2017

Gavin Forde and Caroline Eyre, Pfizer


Poster Winner - Loretta O'Brien, Winner Dr Ciaran Judge collected by Dr David Kevans and Prof Laurence Egan.


Poster Winner - Loretta O'Brien AbbVie, Dr Jane Doherty and Prof Laurence Egan.


Poster Winner - Loretta O'Brien, Dr Sara Naimimohasses and Prof Laurence Egan


Oral Winner - Robert Felton, Norgine, Dr Paul Armstrong and Prof Laurence Egan


Oral Winner - Robert Felton Norgine, Dr Fintan O'Hara and Prof Laurence Egan


Oral Winner - Robert Felton Norgine, Dr Margaret Walshe and Prof Laurence Egan

Winter Meeting 2017

Gala Dinner Groups

L to R: Eoin Slattery, Garret Cullen, David Kevans,
Aoibhlinn O'Toole, Susan McKiernan, Diarmuid Houlihan

Winter Meeting 2017

Best Video Clip, Margaret Shaughnessy – Takeda , M. Syafie Ismail receiving award on behalf of Catriona Gallagher and Prof Laurence Egan

Conor and the Fleetwood Team

Dr Subhasish Sengupta and Dr Jan Leyden

Prof Paud O'Regan

Audience

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Please refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Vial containing 100 mg of infliximab powder for concentrate for solution for infusion. **Indications:** *1) Rheumatoid arthritis (RA)* in combination with methotrexate (MTX) in adult patients with active disease with inadequate response to disease-modifying antirheumatic drugs (DMARDs) or adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs. *2) Adult Crohn's disease* (CD) a) In patients with moderately to severely active CD who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. b) In patients with fistulising, active CD who have not responded despite a full and adequate course of conventional treatment (including antibiotics, drainage and immunosuppressive therapy). *3) Paediatric* CD Severe, active CD in patients aged 6 to 17 years, who have not responded to conventional therapy including corticosteroid, immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. *4) Ulcerative colitis* (UC) In both adult patients with moderate to severely active UC, and children and adolescents aged 6 to 17 years with severely active UC and an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or those who are intolerant to, or have medical contraindications for such therapies. *5) Ankylosing spondylitis* (AS) In adult patients with severe active AS who have responded inadequately to conventional therapy. *6) Psoriatic arthritis* (PsA) In adult patients with active and progressive PsA when response to previous DMARD therapy has been inadequate. Inflectra should be administered in combination with MTX - or alone in patients who show intolerance to MTX, or for whom MTX is contraindicated. *7) Psoriasis (PsO)* In adult patients with moderate to severe plaque PsO who failed to respond to, or who have a contraindication to, or are intolerant to systemic therapy including cyclosporine, MTX or Psoralen ultra-violet A (PUVA.) **Dosage & Administration:** All doses to be administered as an intravenous (IV) infusion over 2 hours initially and monitor post-infusion for at least 1–2 hours for infusion- related reactions. *1) RA* 3 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. Inflectra must be given concomitantly with MTX. *2) Moderately to severely active CD* 5 mg/kg repeated 2 weeks after initiation. If no response after 2 doses, no additional dose should be given. In responding patients: Maintenance dose of 5 mg/kg at 6 weeks after the initial dose, followed every 8 weeks, or: Re-administration of 5 mg/kg if signs and symptoms recur. *3) Fistulising, active CD* 5 mg/kg repeated 2 and 6 weeks after initiation. If no response after 3 doses, no additional dose should be given. In responding patients: Maintenance dose of 5 mg/kg every 8 weeks or: Re-administration of 5 mg/kg if signs and symptoms recur, followed by 5 mg/kg every 8 weeks. *4) UC* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. *5) AS* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 6 to 8 weeks. If no response by 6 weeks, no additional dose should be given. *6) PsA* 5 mg/kg repeated at 2 and 6 weeks after initiation, then every 8 weeks. *7) PsO* 5 mg/kg repeated 2 and 6 weeks after initiation, then every 8 weeks. If no response after 14 weeks no additional dose should be given. *8) Paediatric CD (6 to 17 years):* 5 mg/kg repeated 2 and 6 weeks later, then every 8 weeks. Data do not support further treatment in children and adolescents not responding within the first 10 weeks. *9) Paediatric UC (6 to 17 years):* 5 mg/kg repeated at 2 and 6 weeks, then every 8 weeks. Available data do not support further treatment in in patients not responding within the first 8 weeks. *Older people (≥ 65 years):* Studies have not been conducted. No major age-related differences in clearance or volume of distribution observed in clinical studies. No dose adjustment is required. *Impaired renal and/or hepatic function:* Not studied. No dose recommendations can be made. **Contraindications:** Hypersensitivity to infliximab, to other murine proteins, or to any excipients. Tuberculosis (TB) or other severe infections such as sepsis, abscesses, and opportunistic infections. Moderate or severe heart failure (NYHA class III/IV). **Warnings and Precautions:** Caution in patients with or at risk of infusion reactions and hypersensitivity. Do not administer in patients with bacterial infections, invasive fungal, viral or other opportunistic infections. Monitor for TB, and do not use in patients with TB. Test for latent/active TB prior to initiation of therapy. Do not use Inflectra in patients with active TB. In patients with latent TB, treatment with anti-TB therapy must be started before the initiation of Inflectra, and in accordance with local recommendations. Consult a physician with expertise in the treatment of TB. Monitor closely for infections, including TB before, during and for six months post-treatment. Patients with fistulising CD with acute suppurative fistulas must not initiate therapy until source of infection, specifically abscess, is excluded. Test for HBV infection before initiating treatment. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Closely monitor carriers of HBV for signs and symptoms of active HBV infection during and after therapy. In patients with HBV reactivation, stop Inflectra and initiate effective antiviral therapy with supportive treatment. Symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or ALT elevations ≥5 times the upper limit of normal develop(s), stop Inflectra and initiate thorough investigation. Concurrent administration of Inflectra with anakinra, abatacept or other biologic therapeutics is not recommended due to possible increased risk of infection and/or other potential pharmacological interactions. Live vaccines or therapeutic infectious agents should not be used concurrently with Inflectra. Patients should continue to be monitored while switching from one biologic to another. If a patient develops symptoms suggestive of lupus-like syndrome following treatment with Inflectra and is positive for antibodies against double stranded DNA, discontinue Inflectra treatment. In patients with pre-existing or recent onset of demyelinating disorders (including multiple sclerosis and Guillain Barré syndrome), the risk/benefit of anti-TNF treatment should be carefully considered before initiation of Inflectra. Discontinuation of Inflectra should be considered if these disorders develop. Caution should be exercised in considering treatment of patients with increased risk for malignancy or when considering treatment in patients that develop a dysplasia or a malignancy or with previous history of malignancy. Caution should also be exercised in patients with psoriasis and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Potential risk of development of hepatosplenic T-cell lymphoma (HSTCL) when used in combination with AZA or 6-MP, especially in adolescents and young adult males with CD or UC. Periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. Patients with UC who are at increased risk or prior history of dysplasia for dysplasia or colon carcinoma should be screened for dysplasia (including colonoscopy and biopsies) at regular intervals before therapy and throughout their disease course. Use with caution and monitor closely in mild heart failure (NYHA class I/II). Discontinue Inflectra treatment in patients who develop new or worsening symptoms of heart failure. Patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation of Inflectra should be considered in patients with confirmed significant haematologic abnormalities. For patients that require surgery, Inflectra long half-life should be taken into account and should be monitored for infections. *Special populations:* Risk of infections should be considered when treating elderly and paediatric patients. If possible, comply with vaccination program for paediatric patients prior initiating treatment with Inflectra. *Women of childbearing potential:* Use adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last Inflectra treatment. *Pregnancy:* Administration of infliximab is not recommended during pregnancy. *Breast feeding:* Unknown whether infliximab is excreted in human milk or absorbed systemically after ingestion. As human immunoglobulins are excreted in milk, women must not breast feed for at least 6 months after Inflectra treatment. **Undesirable effects:** Viral infection (e.g. influenza, herpes virus infection), bacterial infection (e.g. sepsis, cellulitis, abscess), TB, fungal infection (e.g. candidiasis), meningitis, opportunistic infection, parasitic infection, hepatitis B reactivation, vaccine breakthrough infection, lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, cervical cancer, hepatosplenic T-cell lymphoma, Merkel cell carcinoma, neutropenia, leucopenia, anaemia, lymphadenopathy, thrombocytopenia, lymphopenia, lymphocytosis, agranulocytosis, thrombotic thrombocytopenic purpura, pancytopenia, haemolytic anaemia, idiopathic thrombocytopenic purpura, allergic respiratory symptom, anaphylactic reaction/shock, lupus-like syndrome, serum sickness like reaction, vasculitis, sarcoid-like reaction, depression, insomnia, amnesia, agitation, confusion, somnolence, nervousness, apathy, headache, vertigo, dizziness, hypoaesthesia, paraesthesia, seizure, neuropathy, transverse myelitis, demyelinating disorders, conjunctivitis, keratitis, periorbital oedema, hordeolum, endophthalmitis, transient visual loss, tachycardia, palpitation, cardiac failure, arrhythmia, syncope, bradycardia, cyanosis, pericardial effusion, myocardial ischaemia/ infarction, hypotension, hypertension, ecchymosis, hot flush, flushing, peripheral ischaemia, thrombophlebitis, haematoma, circulatory failure, petechia, vasospasm, upper respiratory tract infection, sinusitis, lower respiratory tract infection, dyspnoea, epistaxis, pulmonary oedema, bronchospasm, pleurisy, pleural effusion, interstitial lung disease, abdominal pain, nausea, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, intestinal perforation/stenosis, diverticulitis, pancreatitis, cheilitis, hepatic function abnormal, transaminases increased, hepatitis, hepatocellular damage, cholecystitis, jaundice, liver failure, psoriasis (new onset or worsening), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, bullous eruption, onychomycosis, seborrhoea, rosacea, skin papilloma, hyperkeratosis, abnormal skin pigmentation, Toxic Epidermal Necrolysis, Stevens Johnson syndrome, erythema multiforme, furunculosis, worsening of symptoms of dermatomyositis, arthralgia, myalgia, back pain, urinary tract infection, pyelonephritis, vaginitis, infusion related reaction, pain, chest pain, fatigue, fever, injection site reaction, chills, oedema, impaired healing, granulomatous lesion, autoantibody positive, complement factor abnormal. **Legal category:** POM; S1A **Marketing Authorisation Number:** EU/1/13/854/001, EU/1/13/854/002, EU/1/13/854/003, EU/1/13/854/004, EU/1/13/854/005. **Marketing Authorisation Holder:** Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW, UK. **Last Revised:** August 2016.
Ref: IF 1_0 IE.
▼ 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.
For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

References:
1. INFLECTRA™. European Public Assessment Report (EPAR). June 2013. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002778/WC500151491.pdf. [Accessed June 2016]

PP-IFA-IRL-0018 October 2016

NEW IN HCV

MAVIRET®▼

glecaprevir/pibrentasvir

DON'T LOOK BACK

ONE REGIMEN ALL GENOTYPES 8-WEEKS

FOR TREATMENT-NAÏVE, NON-CIRRHOTIC PATIENTS[1]

8 WEEK TREATMENT[1]

- TREATMENT-NAÏVE NON-CIRRHOTIC GT 1-6
- TREATMENT-EXPERIENCED* NON-CIRRHOTIC GT 1, 2, 4, 5, 6

12 WEEK TREATMENT[1]

- TREATMENT-NAÏVE CIRRHOTIC GT 1-6
- TREATMENT-EXPERIENCED* CIRRHOTIC GT 1, 2, 4, 5, 6

16 WEEK TREATMENT[1]

- TREATMENT-EXPERIENCED NON-CIRRHOTIC GT 3
- TREATMENT-EXPERIENCED* CIRRHOTIC GT 3

**Treatment-experienced refers to patients who failed prior therapy with peg-IFN + ribavirin +/- sofosbuvir, or sofosbuvir + ribavirin. Cirrhotic refers to compensated cirrhotic (Child-Pugh A).*

STRAIGHTFORWARD ONCE-DAILY REGIMEN[1]

- No baseline resistance or viral load testing required
- No ribavirin required
- 0.1% discontinuation of treatment due to adverse reactions
- The most common adverse reactions (≥10% of patients) were headache and fatigue

Maviret® ▼ 100mg/40mg film-coated tablets PRESCRIBING INFORMATION
PRESENTATION: Each film-coated tablet contains 100 mg glecaprevir and 40 mg pibrentasvir. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **INDICATION:** For treatment of Chronic Hepatitis C Virus (HCV) in adults. **DOSAGE AND ADMINISTRATION:** Oral. Treatment to be initiated and monitored by physician experienced in the management of patients with HCV infection. See SmPC for full posology. **Dosage:** The recommended dose of Maviret is 300 mg/120 mg (three 100 mg/40 mg tablets), taken orally, once daily with food. **Treatment Duration:** Patients without prior HCV therapy (GT 1-6): **No cirrhosis:** 8 weeks. **Cirrhosis:** 12 weeks. Patients who failed prior therapy with peg-IFN + ribavirin +/- sofosbuvir, or sofosbuvir + ribavirin: GT 1, 2, 4-6: **No cirrhosis:** 8 weeks. **Cirrhosis:** 12 weeks. GT 3: **No cirrhosis:** 16 weeks. **Cirrhosis:** 16 weeks. **Special Populations:** HIV-1 Co-infection: Follow the dosing recommendations as above. For dosing recommendations with HIV antiviral agents, refer to SmPC for additional information. Elderly: No dose adjustment required. Renal impairment: No dose adjustment required. Hepatic impairment: No dose adjustment recommended in patients with mild hepatic impairment (Child-Pugh A). Maviret is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and is contraindicated in patients with severe hepatic impairment (Child-Pugh C). Liver transplant patients: 12 weeks minimum in liver transplant recipients, with 16 week treatment duration to be considered for GT 3-infected patients who are treatment experienced with peg-IFN + ribavirin +/- sofosbuvir, or sofosbuvir + ribavirin. Paediatric Population: No data available. **CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients. Patients with severe hepatic impairment (Child-Pugh C). Concomitant use with atazanavir containing products, atorvastatin, simvastatin, dabigatran etexilate, ethinyl oestradiol-containing products, strong P-gp and CYP3A inducers (e.g., rifampicin, carbamazepine, St. John's wort (Hypericum perforatum), phenobarbital, phenytoin, and primidone). **SPECIAL WARNINGS AND PRECAUTIONS:** Hepatitis B Virus reactivation: HBV screening should be performed in all patients before initiation of treatment. HBV/HCV co-infected patients are at risk of HBV reactivation, and should, therefore, be monitored and managed according to current clinical guidelines. Liver transplant patients: The safety and efficacy of Maviret in patients who are post-liver transplant have not yet been assessed. Treatment with Maviret in this population in accordance with the recommended posology should be guided by an assessment of the potential benefits and risks for the individual patient. Hepatic impairment: Maviret is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and is contraindicated in patients with severe hepatic impairment (Child-Pugh C). Patients who failed a prior regimen containing an NS5A- and/or an NS3/4A-inhibitor: GT 1-infected (and a very limited number of GT 4-infected) patients with prior failure on regimens that may confer resistance to glecaprevir/pibrentasvir were studied in the MAGELLAN-1 study. The risk of failure was, as expected, highest for those exposed to both classes. A resistance algorithm predictive of the risk for failure by baseline resistance has not been established. Accumulating double class resistance was a general finding for patients who failed re-treatment with glecaprevir/pibrentasvir in MAGELLAN-1. No re-treatment data is available for patients infected with GT 2, 3, 5 or 6. Maviret is not recommended for the re-treatment of patients with prior exposure to NS3/4A- and/or NS5A-inhibitors. Lactose: Maviret contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **INTERACTIONS:** See SmPC for full details. Contraindicated: Dabigatran etexilate, carbamazepine, phenytoin, phenobarbital, primidone, rifampicin, ethinyloestradiol-containing products, St. John's wort, atazanavir, atorvastatin, simvastatin. Not Recommended: darunavir, efavirenz, lopinavir/ritonavir, lovastatin, ciclosporin doses > 100 mg per day. Use Caution: digoxin, pravastatin, rosuvastatin, fluvastatin, pitavastatin, tacrolimus. Monitor Levels: Digoxin, Monitor INR with all vitamin K antagonists. No dose adjustment: Losartan, valsartan, sofosbuvir, raltegravir, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, levonorgestrel, norethidrone or norgestimate as contraceptive progestogen. **FERTILITY, PREGNANCY AND LACTATION:** Maviret is not recommended in pregnancy. It is not known whether Maviret and its metabolites are excreted in breast milk. No human data on the effect of glecaprevir and/or pibrentasvir on fertility are available. **SIDE EFFECTS:** See SmPC for full details. ***Very common side effects*** (≥1/10): headache, fatigue. ***Common side effects*** (≥1/100 to <1/10): diarrhoea, nausea, asthenia. **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. Suspected adverse events should also be reported to AbbVie Limited on 01-4287900. LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBER/ PRESENTATIONS:** EU/1/17/1213/001 – blister packs containing 84 (4 x 21) 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:** February 2018. PI/1213/002

REFERENCE: 1. MAVIRET Summary of Product Characteristics, available on www.medicines.ie

IREMAV170618(1) **Date of Preparation:** March 2018

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