



# Autumn Meeting

Park Avenue Hotel, Belfast  
Friday October 12th, 2018

**usg** Ulster Society  
of  
Gastroenterology

# DEC™ Video Duodenoscope ED34-i10T2

*New Elevator Every Time.*



Disposable Elevator Cap (DEC™) allows simplified reprocessing and increased cleaning capability.



## Setting the new standard in ERCP

### The PENTAX Medical Solution

The innovative design of the PENTAX Medical DEC Duodenoscope introduces a unique solution in the market and simplifies the overall reprocessing process.

### Distal end with open access incorporating Single Use Elevator

The DEC™ Duodenoscope distal end, a crucial element for the prevention of patient infection, has been designed to offer easier access for brushing.



**35%**

reduction in steps for distal end reprocessing\*

In comparison to the standard duodenoscopes of major manufacturers. Source: PENTAX Medical internal benchmarking.

**Sword Medical**  
ADVANCED HEALTHCARE SOLUTIONS

## Welcome to Autumn USG 2018



**Dear Colleagues and Friends,**

It is a great pleasure to welcome you to the Autumn USG. It is a real extravaganza with a number of highly relevant and important topics being considered: missed early lesions at endoscopy by the BSG leaders in this field (Nigel Trudgill and John Anderson); a debate on the roles of Medicine and Surgery in IBD by Jill Somerville and Aidan Armstrong, and a headline talk by Dr John Morris on what to do when things go wrong at endoscopy. Last but not least Mark Taylor is going to challenge us with his talk "Time for change". This meeting also incorporates abstracts on local research and a research-based talk on the evaluation of Barrett's dysplasia by Dr Myrtle van der Wel from Amsterdam, who is working on the international BOLERO study along with participants from Northern Ireland, including Helen Coleman. There is also a very interesting parallel programme for nurses during the morning.

The committee hopes that you will find the day informative and relevant to your work in gastroenterology. It is also a great chance to meet your colleagues and representatives from the pharma industry who so generously support our meetings. Please make a point of interacting with them.

If there are any topic(s) or format that you would particularly like to see at future USG's please discuss with one of the committee and maybe you would like to consider coming on the committee yourself-we are always happy to welcome new talent.

Enjoy the day.

**Peter Watson**  
President USG



# APPROACHING PBC DIFFERENTLY AFTER 20 YEARS<sup>1,2</sup>

## Introducing OCALIVA

OCALIVA offers an option for patients with inadequately controlled PBC on UDCA or as monotherapy for those who are unable to tolerate UDCA<sup>1</sup>

## Engage with the pathway

OCALIVA is a first-in-class selective and potent FXR agonist. FXR is thought to play a crucial role in bile acid homeostasis and pathways controlling inflammation and fibrosis<sup>3</sup>

## Proven efficacy

When OCALIVA was given in combination with UDCA,<sup>4</sup> almost 5 times as many patients achieved reductions in ALP and stabilisation of bilirubin levels at 12 months compared with UDCA alone.<sup>4</sup> The effects of OCALIVA were sustained over an additional 12 months of therapy in the open-label extension study<sup>4</sup>

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

<sup>1</sup>UDCA was withheld from patients intolerant to UDCA.<sup>4</sup>

<sup>2</sup>35 patients receiving OCALIVA 10 mg + UDCA (48%) and 46 patients receiving OCALIVA titration + UDCA (46%) achieved the primary composite endpoint of ALP <1.67 x ULN with a ≥15% reduction from baseline and total bilirubin ≤ULN compared with 7 patients on placebo + UDCA (10%).<sup>4</sup>



### Abbreviated Prescribing Information

OCALIVA ▼ (obeticholic acid)

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

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

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

**Dosage and administration:** Oral administration. Hepatic status must be known before initiating treatment. In patients with normal or mildly impaired (Child Pugh Class A) hepatic function, the starting dose is 5 mg once daily. Based on an assessment of tolerability after 6 months, the dose should be increased to 10 mg once daily if adequate reduction of alkaline phosphatase (ALP) and/or total bilirubin have not been achieved. No dose adjustment of concomitant UDCA is required in patients receiving obeticholic acid. For cases of severe pruritus, dose management includes reduction, temporal interruption or discontinuation for persistent intolerable pruritus; use of bile acid binding agents or antihistamines (see SmPC).

**Moderate to Severe Hepatic Impairment:** In patients with Child-Pugh B or C hepatic impairment, a reduced starting dose of 5 mg once weekly is required. After 3 months, depending on response and tolerability, the starting dose may be titrated to 5 mg twice weekly and subsequently to 10 mg twice weekly (at least 3 days between doses) if adequate reductions in ALP and/or total bilirubin have not been achieved. No dose adjustment required in Child Pugh Class A function. **Mild or moderate renal impairment:** No dose adjustments are required. **Paediatric population:** No data.

**Elderly:** No dose adjustment required; limited data exists.

**Contraindications:** Hypersensitivity to the active substance or any excipients. Complete biliary obstruction.

**Special warnings and precautions for use:** After initiation, patients should be monitored for progression of PBC with frequent clinical and laboratory assessment of those at increased risk of hepatic decompensation. Dose frequency should be reduced in patients who progress from Child Pugh A to Child Pugh B or C Class disease. Serious liver injury and death have been reported in patients with moderate/severe impairment who did not receive appropriate dose reduction. Liver-related adverse events have been observed within the first month of treatment and have included elevations in alanine amino transferase (ALT), aspartate aminotransferase (AST) and hepatic decompensation.

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

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

**Undesirable effects:** Very common (≥1/10) adverse

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

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

**Legal category:** POM

**Marketing authorisation numbers:** EU/1/16/1139/001 & 002. **Marketing authorisation holder:** Intercept Pharma Ltd, 2 Pancras Square, London, N1C 4AG, United Kingdom.

**Package Quantities and Basic NHS cost:** OCALIVA 5 mg and 10 mg £2,384.04 per bottle of 30 tablets.

**Date of revision:** 11th April 2018

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

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

References: 1. OCALIVA (obeticholic acid). Summary of Product Characteristics, 2018. 2. FDA Drug Approval Package: Ocaz (obeticholic acid) NDA 141-2017-01. 3. Ding L, et al. Bile acid nuclear receptor FXR and digestive system diseases. *Acta Pharm Sin* 2015;36:125-34. 4. Newsis P, et al. A Placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *N Engl J Med* 2016;375:331-43.

**Ulster Society of Gastroenterology Autumn Meeting**  
***Quality Improvement in Gastroenterology***  
**12th October 2018**

**Programme**

08.30 Registration

12.30 **LUNCH - MEET-THE-INDUSTRY  
& POSTER VIEWING**

**SESSION 1**

**Early diagnosis of GI cancers**

**SESSION 3**

**It's all about quality**

Chairs: **Dr Peter Watson and Mr Eamon Mackle**

Chairs: **Mr Tim McAdam and Dr Shivaram Bhat**

09.30 **Post OGD Upper GI Cancer**  
**Dr Nigel Trudgill,**  
 Consultant Gastroenterologist,  
 Sandwell and West Birmingham Hospitals

13.30 **IBD Treatment Debate:  
Endoscopist v. Surgeon**  
**Dr Jill Somerville,**  
 Northern HSCT  
**Mr Aidan Armstrong,**  
 Consultant Surgeon,  
 Belfast City Hospital.

10.00 **Post colonoscopy colorectal cancer**  
**Dr John Anderson,**  
 Consultant Gastroenterologist,  
 Cheltenham General Hospital.

14.00 **Endoscopy:  
What to do when things go wrong?**  
**Dr John Morris,**  
 Consultant Gastroenterologist,  
 Glasgow Royal Infirmary.

10.30 **3 Free papers (8min+2min questions)**

11.00 **COFFEE - MEET-THE-INDUSTRY  
& POSTER VIEWING**

**SESSION 2**

**Research and innovation**

14.45 **Time for change**  
**Mr Mark Taylor,**  
 Consultant Surgeon,  
 Mater Hospital, Belfast HSCT

Chairs: **Dr Helen Coleman and Dr Philip Hall**

11.30 **3 free papers (8min+2min questions)**

15.15 **DEBATE AND PANEL DISCUSSION**

12.00 **What makes an expert?**  
**The Global BOLERO Study**  
**in Barrett's dysplasia**  
**Dr Myrtle van der Wel,**  
 Academic Medical Centre,  
 Amsterdam, The Netherlands

**CLOSE OF MEETING**

**FEEDBACK**

12.20 **USG Bursary 2018 recipients:  
outline of planned work**  
**Dr Andy Spence,**  
 Gastroenterology SpR  
**Mr Stephen McCain,**  
 Surgical SpR

# Spot<sup>®</sup> Ex Endoscopic Tattoo

Take The Next Step In The Fight Against Colon Cancer

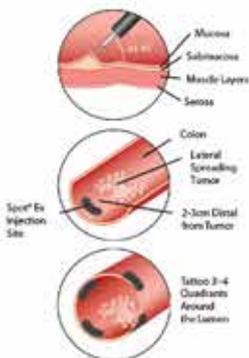
**Preparation**

- Shake it
- Attach it
- Prime it

**Storage**

- Store upright or on its side
- Keep at room temperature
- 2 year shelf life

## Submucosal Injection<sup>1</sup>



1. Place injection 2-3cm distal (downstream) of the area of interest.
2. Inject tangentially, at a 30-45° angle to the mucosa.<sup>1</sup>
3. Create a saline bleb to find the submucosal plane prior to injecting Spot Ex to reduce risk of transmural injection.<sup>1</sup>
4. Place Spot Ex tattoos in 3-4 quadrants around the lumen to increase likelihood of seeing it at follow-up.<sup>1</sup>
5. Use 0.5-0.75 mL per injection site, and no more than 8 mL per patient.<sup>1</sup>

- Ex** panded indications support adoption of guidelines<sup>1,2</sup>
- Ex** pedite localisation at follow-up procedures<sup>3</sup>
- Ex** tra efficiency from new features

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<sup>1</sup> Spot Ex Instructions For Use. G45-006 Rev 03. May 2018.  
<sup>2</sup> Ferlitsch M, Moss A, Hassan C, et al. Colorectal polypectomy and endoscopic mucosal resection (EMR): ESGE Clinical Guideline. 2017.  
<sup>3</sup> Easier identification at follow-up procedures as compared to no tattoo

## Nurses Programme

### USG 12 October 2018 at Park Ave Hotel, Belfast

9.30 - 10.10	<p><b>Alan Wilson</b> Gastroenterology Pharmacist Belfast Trust <i>"Overview of biologic therapy in IBD- Challenges &amp; Opportunities"</i></p>
10.10 - 10.50	<p><b>Dr Tracey Owen</b> Consultant in public health medicine at the PHA <i>"Making bowel cancer screening bigger and better"</i></p>
10.50 - 11.10	Tea/Coffee Break
11.10 - 11.50	<p><b>Dr Conor Braniff</b> Consultant Hepatologist, Belfast Trust. <i>"TIPSS"</i></p>
11.50 - 12.30	<p><b>Prof. John O'Leary</b> Chair of Pathology, TCD &amp; Lead in Cancer Research <i>"Evolution and Revolution in Gastrointestinal Diagnostics"</i></p>
12.45	Lunch

**The Northern Ireland Practice and Education Council for Nursing and midwifery (NIPEC)** was established by the Northern Ireland Assembly in 2002 under the Health and Personal Social Services Act as an NDPB (Non Departmental Public Body) to support the development of nurses and midwives by promoting high standards of practice, education and professional development. NIPEC also provides advice and guidance on best practice and matters relating to nursing and midwifery.



**Irish Society of  
Gastroenterology**

**ISG Winter 2018  
meeting will be held  
22-23 November  
Fitzpatrick Castle Hotel  
Killiney, Co. Dublin**

## USG Executive Committee

**President:**

**Dr Peter Watson,**  
Consultant Gastroenterologist  
Royal Victoria Hospital, Belfast.

**Hon Sec:**

**Dr Shivaram Bhat,**  
Consultant Gastroenterologist  
Craigavon Area Hospital

**Hon Treas:**

**Dr Philip Hall,**  
Consultant Gastroenterologist  
Belfast Trust

**Member:**

**Mr Eamon Mackle,**  
Consultant Surgeon  
Craigavon Area Hospital.

**Member:**

**Dr Patrick Allen**  
Consultant Gastroenterologist  
South Eastern Trust

**Member:**

**Dr Jenny Addley**  
Consultant Gastroenterologist  
Ulster Hospital, Dundonald, Belfast

**Member:**

**Dr Helen Coleman**  
Senior Lecturer in Cancer Epidemiology  
Centre for Public Health  
Queens' University Belfast

**Member:**

**Mr Tim McAdam**  
Consultant Colorectal Surgeon  
Belfast Trust

### Organising Team



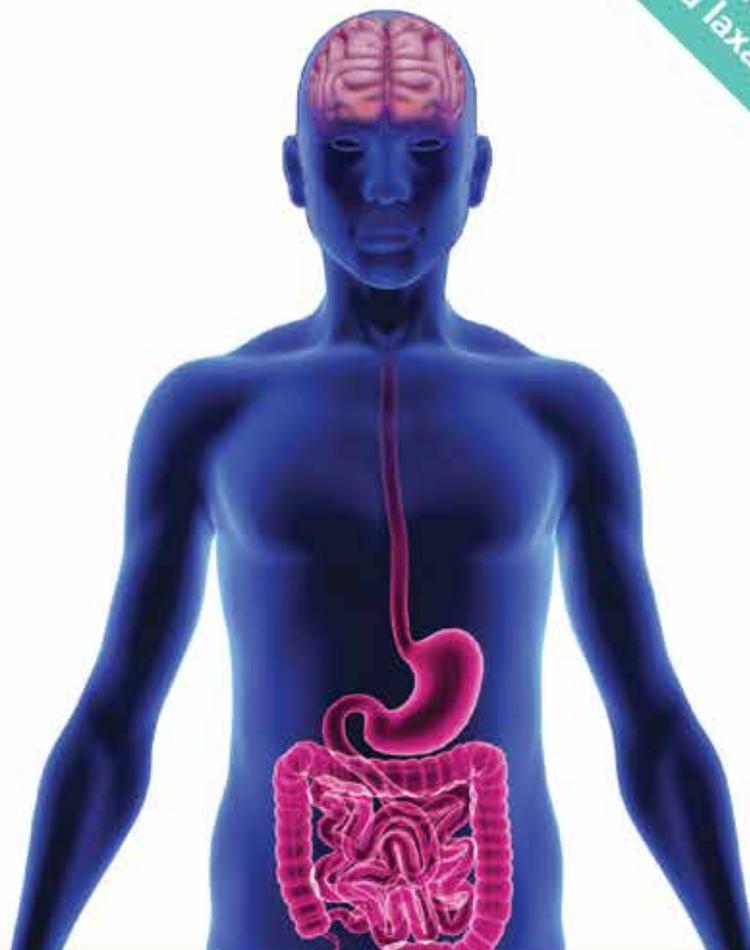
**Michael Dineen**  
Chief Exec ISG /  
Event Organiser USG



**Cora Gannon**  
Administrator ISG/USG

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

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



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

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

<sup>†</sup> PAMORA: Peripherally-Acting Mu-Opioid Receptor Antagonist.

**REFERENCES:** 1. MOVENTIG Summary of Product Characteristics.

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

**PRESCRIBING INFORMATION (prepared January 2018)**  
**Moventig 12.5mg and 25mg film-coated tablets**▼  
(naloxegol oxalate). Consult Summary of Product Characteristics (SmPC) before prescribing

**Indication:** Opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s) (concurrent OIC symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the previous 2 weeks). **Dosage and administration:** Recommended 25 mg once daily. Take on empty stomach at least 30 minutes prior to first meal of day or 2 hours after first meal of day. Crushed tablets can be mixed with water (120ml) and drunk immediately or administered via a nasogastric tube (CH8 or greater). **Renal impairment:**

Moderate to severe renal impairment starting dose 12.5mg. Discontinue if side effects impact tolerability. Increase to 25mg if well tolerated. **Hepatic impairment:** Use in severe hepatic impairment not recommended. **Moderate CYP3A4 inhibitors:** Starting dose 12.5mg, can be increased to 25mg if well tolerated. **Paediatric population (<18 years):** Safety and efficacy not yet established. **Adverse effects:** Consult SmPC for full list of side effects. **Very Common:** Abdominal pain, diarrhoea. **Common:** Nasopharyngitis, headache, flatulence, nausea, vomiting, hyperhidrosis. **Uncommon:** Opioid withdrawal syndrome. **Not known:** Hypersensitivity. **Contraindications:** Hypersensitivity to active substance or any of the excipients or any other opioid antagonist. Patients with known or suspected gastrointestinal (GI) obstruction or patients at increased risk of recurrent obstruction. Patients with underlying cancer who are at heightened risk of GI perforation, such as those with underlying malignancies of gastrointestinal tract or peritoneum, recurrent or advanced ovarian cancer or vascular endothelial growth factor (VEGF) inhibitor treatment. Concomitant use with strong CYP3A4 inhibitors. **Warnings and precautions:** Use with caution in patients with any condition which might result in impaired integrity of the gastrointestinal tract wall. Advise patients to discontinue therapy and promptly report if unusually severe or persistent abdominal pain develops. Use with caution in patients with clinically important disruptions to the blood brain barrier and observe for potential CNS effects. Discontinue if interference with opioid-mediated analgesia or opioid withdrawal syndrome occurs. Use with caution in patients taking methadone. If opioid withdrawal syndrome is suspected the patient should discontinue Moventig

and contact their physician. Use with caution in patients with a recent history of myocardial infarction, symptomatic congestive heart failure, overt cardiovascular (CV) disease or with a QT interval of  $\geq 500$ msec. Use with caution in OIC patients with cancer-related pain. **Use in pregnancy and lactation:** Not recommended. **Legal category:** POM. **Marketing Authorisation numbers:** Moventig 12.5mg x 30 tablets EU/1/14/962/001; Moventig 12.5mg x 30 x 1 film-coated tablets EU/1/14/962/008; Moventig 25mg x 30 tablets EU/1/14/962/005; Moventig 25mg x 30 x 1 film-coated tablets EU/1/14/962/010. **Further information available on request from the Marketing Authorisation holder:** Kyowa Kirin Ltd, Galabank Business Park, Galashiels, Scotland TD1 1QH, UK.

**For the United Kingdom:**

NHS cost: Moventig 12.5mg, 30 tablets, £55.20; Moventig 25mg, 30 tablets, £55.20.

**ADVERSE EVENT REPORTING:** Adverse Events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email [medinfo@kyowakirin.com](mailto:medinfo@kyowakirin.com)

**For the Republic of Ireland:**

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

## Biographical Sketches

### Dr Nigel Trudgill

Consultant Gastroenterologist,  
Sandwell and West Birmingham Hospitals



Consultant Gastroenterologist, Deputy Medical Director and Responsible Officer at Sandwell and West Birmingham Hospitals NHS Trust, West Midlands, UK. Graduated Sheffield University in 1988. Chair of BSG oesophageal section committee and member BSG endoscopy committee.. Leads regional oesophageal manometry and reflux monitoring service. Screening Centre Director Sandwell and West Birmingham Bowel Cancer Screening Centre. Director of Royal College of Physicians Medical Workforce Unit. Current President of Midlands Gastroenterological Society. Current research interests in health informatics in gastroenterology and endoscopy quality.

### Dr John Anderson

Consultant Gastroenterologist,  
Cheltenham General Hospital



Dr John Anderson is a Consultant Gastroenterologist in Cheltenham, Gloucestershire and has a clinical practice mainly related to advanced therapeutic endoscopy, training and education. Dr Anderson provides a specialist tertiary therapeutic colonoscopy service for both symptomatic and screening patients in the Regional Bowel Cancer Screening Programme (BCSP). As National Endoscopy Training Lead, he was part of the National Endoscopy Team, formed to enhance UK endoscopy service provision and develop of training and educational programmes for nurses, doctors and trainees. He recently stepped down as Chairman of the BCSP accreditation committee. His current roles include Director of the Gloucestershire Endoscopy Training Centre, BCSP and BSG Endoscopy committee members, JAG and BCSP assessor. In 2017 he was appointed as Lead for National Quality Improvement in Colonoscopy (EQIP) in the UK.

### Dr Myrtle van der Wel

Academic Medical Centre,  
Amsterdam, The Netherlands



Dr. Myrtle van der Wel became interested in 'all things small' when, as a child, she joined her mother (a medical microbiologist) in the laboratory during weekend shifts. She finished medical school in 2012. After working as an Internal Medicine resident for one year, she started her PhD in September 2013 at Gastroenterology and Pathology departments of the Academic Medical Center in Amsterdam (the Netherlands).

The focus of her research project was 'Observer agreement in Barrett's oesophagus', in 2015 leading to the set-up of the national digital review panel for dysplastic Barrett's oesophagus. This review panel now employs 15 gastrointestinal pathologists. As from January 2018, she started her residency in Pathology. She hopes to keep combining her clinical work with research.

### Dr John Morris

Consultant Gastroenterologist,  
Glasgow Royal Infirmary



Dr John Morris is a Consultant Gastroenterologist and Honorary Senior Lecturer at Glasgow Royal Infirmary. He is President of the Scottish Society of Gastroenterology, Director of the West of Scotland Regional Endoscopy Training Centre and Gastroenterology Specialty Advisor to Greater Glasgow and Clyde Health Board. Dr Morris was previously Clinical Director for Digestive Diseases at Glasgow Royal Infirmary and visiting Associate Professor of Medicine at the Medical University of South Carolina, USA.

Dr Morris has a strong clinical commitment in luminal Gastroenterology, and in particular, therapeutic endoscopy. He has been responsible for the introduction of several innovative techniques and procedures such as NOTES, Hemospray for nonvariceal upper GI bleeding and duodenal mucosal resurfacing for Diabetes Mellitus.

Dr Morris has demonstrated a strong commitment to Endoscopy Education and has been a member of the British Society of Gastroenterology and European Society of Gastrointestinal Endoscopy Committees. He has delivered several National and International Live Endoscopy Workshops on behalf of these organisations.

Dr Morris has published and has ongoing research interests in the field of Capsule Endoscopy and Small Bowel Enteroscopy, Barrett's Endotherapy, NOTES and metabolic endoscopy.

Currently he is leading a Multi-Society Acute Upper GI Bleeding Endoscopy Quality Improvement Project in the UK.

### Mr Mark Taylor

Consultant Surgeon,  
Mater Hospital, Belfast HSCT



Mr Mark A Taylor PhD FRCSI FRCS(Eng) FRCS(Gen Surg) is a Consultant HPB Surgeon at the Mater Hospital, Belfast Health and Social Care Trust. He is a Visiting Professor of Ulster University. He trained in Belfast and at the Regional HPB and Transplant Unit in Edinburgh. His Doctorate of Philosophy was in the pathophysiology of obstructive jaundice. He is the President Elect of GBI Hepato-pancreato-biliary Association (GBIHPBA), Director of Education and Training in AUGIS and board member of the Medical Advisory

Board of Bowel Cancer UK. In 2016, he was appointed by the Health Minister to an independent Expert panel tasked with Reconfiguration of Health and Social care in Northern Ireland. He is a member of the Transformation Implementation Group (TIG) in the Department of Health. In his spare time he is the District Surgeon and Trustee of St John Ambulance and a keen cyclist. He has published extensively in the field of Hepatobiliary Surgery.

#### **Dr Jill Somerville**

Consultant Gastroenterologist

I enjoyed training in gastroenterology in Northern Ireland and have been a consultant gastroenterologist for 4 years in Antrim hospital, including transitional IBD clinics and bowel cancer screening.

#### **Alan Wilson**

Gastroenterology Pharmacist Belfast trust, Clinical Pharmacist of the Year 2014.

As an experienced clinical pharmacist Alan provides expert pharmaceutical advice, supports new drug applications and the development of guidelines and protocols. He is also a pharmacist independent prescriber. Alan is well known for going that extra mile for his patients.

#### **Dr Conor Braniff**

Consultant Hepatologist  
Royal Victoria Hospital, Belfast.



#### **Professor John O'Leary**

Chair of Pathology, TCD & Lead in Cancer Research

Professor John O'Leary holds the positions of Professor/Chair of Pathology, Trinity College Dublin, Director of Pathology, The Coombe Women and Infants University Hospital, Dublin, and Consultant Histopathologist, St. James' Hospital, Dublin, Ireland. His consultant diagnostic experience includes Gynaecological pathology, Breast pathology, Gastrointestinal pathology, Molecular diagnostic pathology and Cytopathology. Prof. John O'Leary heads a multi-investigator group of 40 scientists at TCD focused on the molecular characterisation of several cancer systems including: Ovary, cervix, prostate, thyroid and head and neck cancer and cancer stem cell biology and the diagnosis of paediatric infections. In addition, the laboratory has a significant international reputation in the area of pregnancy proteomics and transcriptomics.



## **USG Committee Members**

#### **Dr Peter Watson,**

President USG



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

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

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

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

#### **Shivaram Bhat**

Consultant Gastroenterologist  
Hon Secretary USG



Dr Shivaram Bhat is a consultant Gastroenterologist at Craigavon Area Hospital in Northern Ireland. He graduated from Queens University Belfast medical school (2002) with subsequent postgraduate training in Northern Ireland and a clinical fellowship at the John Radcliffe Hospital in Oxford. During his postgraduate training he completed a PhD researching cancer progression in Barrett's oesophagus. His clinical and research interests include inflammatory bowel disease and early detection of GI cancer. He is a bowel cancer screening endoscopist and is the IBD lead for the Southern Health and Social Care Trust.

## Dr Philip Hall

Consultant Gastroenterologist  
Belfast Trust  
Hon Treasurer USG



Dr Philip Hall has recently been appointed consultant gastroenterologist within the Belfast Trust. He graduated from Queens University Belfast in 2008 and completed gastroenterology training in Northern Ireland. He has a Masters degree in Clinical Education. He completed an advanced therapeutic endoscopy fellowship in St Michael's Hospital, Toronto in 2017 and has interests in upper GI therapeutics, ERCP and quality improvement.

## Dr Patrick Allen

Consultant Gastroenterologist



Dr Patrick Allen is a Consultant Gastroenterologist working in the South East Trust. He graduated from Queen's University of Belfast in 2002. He completed his training in NI and completed a fellowship in St Vincent's Hospital, Melbourne in Endoscopy and IBD. He is a past Secretary for the Ulster Society of Gastroenterology and was on the organising committee for the BIG Meeting held in the Waterfront Hall in 2013. His main interests are IBD and Endoscopy.

## Dr Jenny Addley

Consultant Gastroenterologist



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

## Mr Eamon Mackle

Consultant Surgeon Southern Trust



Eamon Mackle admits to being a Surgeon, albeit with interests in GI Surgery and the pelvic floor. He has been a Consultant in Craigavon Area Hospital since 1992. He is a past president of the Ulster Society of Gastroenterology and also a past president of the Ulster Medical Society. He is a past member of council of AUGIS.

He is an Undergraduate examiner for QUB, RCSI and the Medical University of Bahrain. He is a member of the Intercollegiate Committee for Basic Surgical Examinations as well as a member of the OSCE Subgroup and ViceChair of the IMRCS Paper Panel.

## Dr Helen Coleman

Senior Lecturer Queen's University Belfast



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

## Mr Tim McAdam

Consultant Colorectal Surgeon  
Belfast Trust



I am a Consultant Colorectal Surgeon and clinical Lead in Belfast Trust having worked as a Consultant in Aberdeen for 6 years.

I was a medical student in QUB and trained in North of Scotland and England. My main interests are management of colorectal cancer, member of specialist endometriosis team and pelvic floor disorders. I am a faculty member for RCSEd surgical skills, NOTSS, RCSEng strategies in emergency surgery. I am a recognised national trainer for laparoscopic colorectal surgery.

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**Prescribing Information:** Pentasa® all formulations. **Please consult the full Summary of Product Characteristics before prescribing. Name of Product:** Pentasa® Sachet, prolonged release granules 1g, 2g and 4g. Pentasa® Slow Release Tablets 500mg and 1g. Pentasa® Mesalazine Enema 1g. Pentasa® Suppositories 1g. **Composition:** Sachets contain 1g, 2g or 4g mesalazine. Tablets contain 500mg or 1g mesalazine. Enema contains 1g mesalazine in 100ml of aqueous suspension. Suppositories contain 1g mesalazine. **Indications:** Sachets and Tablets: Mild to moderate ulcerative colitis. Enema: ulcerative colitis affecting the distal colon and rectum. Suppositories: ulcerative proctitis. **Dosage:** Sachets and Tablets: Adults: Active disease: up to 4g once daily or in 2-4 divided doses. Maintenance treatment: 2g once daily. Sachets and 500mg tablet: Children over 6 years old: Active disease: individual dosing starting with 30-50mg/kg/day in divided doses (total dose should not exceed 4g/day). Maintenance treatment: individual dosing starting with 15-30mg/kg/day in divided doses (total dose should not exceed 2g/day). Enema: Adults: one enema at bedtime. Suppositories: Adults: 1 suppository daily. **Contraindications:** patients with known hypersensitivity to salicylates or any of the excipients and patients with severe liver and/or renal impairment. **Special Warnings and Precautions:** Blood tests (differential blood count, liver function parameters such as ALT or AST, serum creatinine) and urinary status should be determined prior to and during treatment, at the discretion of the treating physician. Caution is recommended in patients with impaired hepatic function. PENTASA should not be used in patients with impaired renal function. Mesalazine-induced renal toxicity should be considered if renal function deteriorates during treatment. Patients with pulmonary disease, in

particular asthma, should be very carefully monitored during a course of treatment with PENTASA. Patients with a history of adverse drug reactions to preparations containing salicylates (such as aspirin) should be kept under close medical surveillance on commencement of a course of treatment with PENTASA. Should PENTASA cause acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever, severe headache and rash, the treatment should be discontinued immediately. Mesalazine-induced cardiac hypersensitivity reactions (brady- and parasydial) have been reported only. Treatment should be discontinued on suspicion or evidence of these reactions. In patients who are concomitantly treated with azathioprine or 6-mercaptopurine, or thiopurines, a possible increase in the myelosuppressive effects of azathioprine or 6-mercaptopurine, or thiopurines should be taken into account. There may be a decrease in the anticoagulant effect of warfarin. Do not use during pregnancy and lactation except when the potential benefit outweighs the possible risk. Sachets: Caution is recommended in patients with active peptic ulcer disease. The concurrent use of other known nephrotoxic agents, such as NSAIDs and aminoglycosides, may increase the risk of other renal reactions. Enema and Suppositories: If a patient develops dehydration while on treatment with mesalazine, normal electrolyte levels and fluid balance should be restored as soon as possible. **Side effects:** For the full list of side effects please consult the Summary of Product Characteristics. PENTASA 1g 2g 4g sachets, 1g enema and 1g suppository: Common: headache, dizziness, abdominal pain, nausea, vomiting, flatulence, rash. Rare: Dizziness, myocarditis, perianalitis, acute pancreatitis. Very rare: pericardial effusion, benign intracranial hypertension, quercetin's oedema, Erythema multiforme

and Steven-Johnson Syndrome. PENTASA 500mg and 1g tablets: Rare: headache, dizziness, myocarditis, pericarditis, abdominal pain, diarrhoea, nausea, vomiting, and flatulence. Very rare adverse events for all PENTASA formulations: altered blood counts (leucopenia, anaemia, agranulocytosis, pancytopenia, eosinophilia, leukopenia, thrombocytopenia, eosinophilic peripheral neuropathy, allergic and/or toxic lung reactions (including dyspnoea, cough, bronchospasm, asthma), pulmonary eosinophilia, lung infiltration, pneumonitis), acute pancreatitis, separation of renal function including acute and chronic interstitial nephritis, and renal insufficiency, alopecia, myalgia, arthralgia, hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, drug reaction with eosinophilia and systemic symptoms syndrome, pancreatitis, changes in liver function parameters, hepatitis, cholelithiasis, hepatitis, oligospermia. Enema and suppository: perianal, rectal discomfort, urge. **Nature and Contents of Container:** Sachets: Cartons contain 50 x 1g sachets, 60 x 2g sachets or 30 x 4g sachets. Tablets: Cartons contain 100 x 500mg and 60 x 1g tablets in blister strips. Enema: Cartons contain 7 x 100ml enemas. Suppositories: Cartons contain 26 x 1g suppositories in blister strips. **Marketing Authorisation Number:** Sachet 1g: 0394/0075. Sachet 2g: 0394/0082. Sachet 4g: 1g, 0394/0077. Tablets 500mg: 0394/0064. Tablets 1g: 0394/0068. Enema: 0394/0027. Suppositories: 0394/0045. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd, Drayton Hall, Church Road, West Drayton, UB7 7PS, United Kingdom. **Legal Category:** POM. **Basic NHS Price:** £30.74 for 50 x 1g sachets; £73.78 for 60 x 2g sachets; £73.78 for 30 x 4g sachets; £30.74 for 100 x 500mg tablets; £36.59 for 60 x 1g tablets; £77.73 for 7 x enemas; £40.00 for 26 x 1g suppositories. **Date of**

Preparation of Prescribing Information: November 2007. Pentasa® is a registered trademark. PA/439/2008/UK/02

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Ferring Pharmaceuticals Ltd. Tel: 0844 931 0850. Email: [medical@fering.com](mailto:medical@fering.com)

**References:** 1. Pentasa Slow Release Tablets 500 mg, SmPC. 2. Sulfasalazine 250mg/5ml Oral Suspension SmPC. 3. Octasa 400mg/HR Tablets, SmPC. 4. Asacol 400mg/HR Tablets, SmPC. 5. Mesalaxil XL 500mg, Gastro-resistant, Prolonged Release Tablets, SmPC. 6. Salixal 500mg Gastro-resistant Prolonged Release Granules, SmPC. 7. Colander 500mg Capsules, SmPC. 8. Olabazone Sodium 250mg Capsules, SmPC. 9. Salazopyrin (n-Tab), SmPC. 10. Salazopyrin Tablets, SmPC. 11. Probelo, CS, et al. *J Gastroenterol Hepatol* 2008;23(7):1052-9. 12. Bohmeyer B, et al. *J Gastroenterol Hepatol* 2008;23(7):1052-9. 13. Bohmeyer B, et al. *J Gastroenterol Hepatol* 2008;23(7):1052-9. 14. Bohmeyer B, et al. *J Gastroenterol Hepatol* 2008;23(7):1052-9. 15. Fiorino G, et al. *Aliment Pharmacol Ther* 2003;17(6):767-75. 16. Pentasa Slow Release Tablets 1g, SmPC. 17. Pentasa Sachet 1g, SmPC. 18. Pentasa Sachet 2g, SmPC. 19. Pentasa Sachet 4g, SmPC. 20. Pentasa Enema 1g, SmPC. 21. Pentasa Suppositories 1g, SmPC. Date of preparation: March 2008. Job code: PA/439/2008/UK/0



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## Oral Presentations - USG Meeting 2018

Ref. No.	Title of Paper:	Name	Time
101	Sex Hormone Receptor Expression In Oesophageal Adenocarcinoma And Recurrence And Survival: A Retrospective Cohort Study	Una McMenamin	10.30am
103	The Association Between Drinking Water Quality and Oesophageal Cancer Risk and Mortality: A Systematic Review	Ellen Creegan	10.40am
104	New strategies for offering hepatitis C treatment to 'difficult to reach' patient cohorts in Northern Ireland.	Rebecca O'Kane	10.50am
107	Vitamin D Receptor As A Marker of Prognosis In Oesophageal Adenocarcinoma: A Prospective Cohort Study	Stephen McCain	11.30am
109	A multicentre, retrospective cohort study into risk factors and outcomes for Clostridium Difficile in the Belfast Trust.	Gary Morrison	11.40am
110	The Association Between Smoking, Alcohol and Colon Cancer Survival By KRAS, BRAF, P53 and MSI status: A Molecular Pathology Epidemiology Cohort Study.	Nick Yeo	11.50am

## Poster Presentations - USG Meeting 2018

Ref. No.	Title of Paper:	Name
18A100	Laparoscopic Cholecystectomy is Safe and Feasible in Isolated Day-Case Units	Marian Seceleanu
18A102	Vedolizumab for Inflammatory Bowel Disease – Success or Failure?	Gary Dobson
18A105	Audit of Pre-assessment Care of Patients Undergoing Chemotherapy And Surgery for Early Stage Oesophageal and Gastro-Oesophageal Junction Adenocarcinoma	Rosalie Douglas
18A106	The Role of Nutritional Status in Oesophageal and Gastro-Oesophageal Junction Adenocarcinoma	Rosalie Douglas
18A108	Alcohol, Smoking, Related Biomarkers And Oesophageal Adenocarcinoma Survival: A Molecular Pathology Epidemiology Cohort Study In Northern Ireland	Stephen McCain

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## ORAL PRESENTATIONS

### Abstract No. USG A'2018 101

#### Sex Hormone Receptor Expression In Oesophageal Adenocarcinoma And Recurrence And Survival: A Retrospective Cohort Study

##### Authors:

ÚC McMenamin<sup>1</sup>, J Trainor<sup>2</sup>, HG Coleman<sup>1,4</sup>, DT McManus<sup>2</sup>, BT Johnston<sup>3</sup>, RC Turkington<sup>4</sup>

##### Institution:

<sup>1</sup> Cancer Epidemiology Research Group, Centre for Public Health, Queen's University Belfast, Belfast, Northern Ireland.

<sup>2</sup> Department of Pathology, Belfast Health and Social Care Trust, Belfast, Northern Ireland.

<sup>3</sup> Department of Gastroenterology, Royal Victoria Hospital, Belfast Health & Social Care Trust, Belfast, Northern Ireland.

<sup>4</sup> Centre for Cancer Research and Cell Biology, Queen's University Belfast, Belfast, Northern Ireland.

##### Introduction:

A striking epidemiological feature of oesophageal adenocarcinoma (OAC) is its unexplained male predominance, suggesting a protective effect for oestrogens, but few studies have investigated expression of sex hormone receptors in OAC.

##### Aim:

To evaluate Estrogen Receptor (ER)  $\alpha$  and  $\beta$  and Androgen Receptor (AR) tumour expression in OAC and investigate associations with recurrence and survival.

##### Methods:

We identified 148 OAC patients who underwent neo-adjuvant chemotherapy prior to surgical resection between 2004-2012 at the Northern Ireland Cancer Centre. Immunohistochemical expression of ER $\alpha$ , ER $\beta$  and AR was determined and Cox proportional hazards regression was used to calculate hazard ratios (HR) and 95% confidence intervals (CI) for associations between sex hormone receptor expression and overall survival, cancer-specific survival and recurrence-free survival. Sensitivity analysis was conducted restricting analysis to patients with gastro-oesophageal junctional (GOJ) cancer.

##### Results:

A low proportion of OAC tumours stained positive for ER $\alpha$  (4%) and AR (3%) while one third stained positive for ER $\beta$  (31%). After a mean follow-up of 3 years (max 9 years), no significant associations were seen for ER $\alpha$ , ER $\beta$  or AR expression and OAC recurrence or survival. A borderline significant reduction in mortality was observed for positive ER $\beta$  tumour expression, when restricting to patients with GOJ cancer (adjusted HR 0.58, 95% CI 0.33, 1.03,  $p=0.06$ ).

##### Conclusion:

In the largest study to date, we found little evidence of ER $\alpha$  or AR expression in OAC. We observed moderate expression of ER $\beta$  and there was suggestive evidence that its expression was associated with improved survival in GOJ cancer patients.

### Abstract No. USG A'2018 103

#### The Association Between Drinking Water Quality and Oesophageal Cancer Risk and Mortality: A Systematic Review

##### Authors:

Creegan E, Kunzmann AT, van den Brandt P, Coleman HG

##### Institution:

Centre for Public Health, Queen's University, Belfast, County Antrim, N. Ireland; School for Public Health and Primary Care, Maastricht University, The Netherlands

**Introduction:** Current knowledge of risk factors for oesophageal cancer do not fully account for disparate oesophageal cancer incidence worldwide. Numerous studies have reported conflicting results regarding the association between drinking water quality and oesophageal cancer development, or related mortality, but this evidence has yet to be summarised.

**Aim:** To conduct a systematic review of evidence investigating the association between the quality of drinking water and oesophageal cancer incidence/mortality risk.

**Methods:** A search strategy was applied to four databases from inception to June 2018. Observational studies evaluating drinking water quality and oesophageal cancer risk or mortality in adults were included. Studies were categorised according to the measure of drinking water quality investigated (source, nitrogenous compounds, Ca/Mg, heavy metals and other). A random effects meta-analysis was conducted for studies evaluating drinking water source.

**Results:** Thirty-four studies were included, consisting of 14 case-control, four cohort and 16 ecological studies, that examined a variety of exposures relating to drinking water quality. The pooled risk estimate from six case-control studies (five from China and one from Iran) showed a significant increased risk of oesophageal cancer in individuals drinking non-tap water, compared with tap or piped water (relative risk 2.41, 95% confidence interval 1.42-4.08). Too much heterogeneity existed among other studies to enable meta-analyses.

**Conclusions:** Consuming water from non-piped sources was associated with a 2.4-fold increased risk of oesophageal cancer, comparing with tap water consumption. Further studies are needed to examine the specific contaminants in drinking water that may be involved in oesophageal cancer aetiology.

### Abstract no. USG A'2018 104

#### New strategies for offering hepatitis C treatment to 'difficult to reach' patient cohorts in Northern Ireland.

##### Authors:

R O'Kane, O McCormick, K Patterson, G Wasson, A McCurley, N McDougall

##### Institution:

Regional Liver Unit, Royal Victoria Hospital, Belfast

##### Introduction:

Chronic hepatitis C virus (HCV) infection can lead to cirrhosis and associated complications. The advent of highly effective all-oral HCV treatments has revolutionised the management of HCV and led to discussions regarding the possibility of HCV eradication. In light of treatment advances, the focus of HCV treatment is moving towards identifying and treating 'difficult to reach' cohorts.

##### Method:

The Regional Liver Unit, RVH has modified its traditional outpatient service to target difficult to reach cohorts, namely prisoners and homeless patients.

For the prison cohort, outreach clinics were offered at a single prison site when the prison service identified sufficient patients for review. For the homeless cohort, the Liver Unit liaised with the social services Outreach team and offered rapid access to a "One Stop Shop" (Consultant, nurse specialist, pharmacist, blood tests and Fibroscan all at single visit) within 4 weeks of referral. This initiative began in 2017 due to public health concerns regarding a cluster of new HCV cases in a homeless cohort.

These two interventions were reviewed to determine whether or not they led to a successful outcome (commencing treatment) for 'difficult to reach' patients.

##### Results:

Since Autumn 2016, 20 prisoners have been booked in to a hepatology clinic in Maghaberry prison. Three refused to leave their cells, 3 were not able to stay in NI for treatment, and 14 (70%) agreed to treatment (8 already started). An additional 27 prisoners have been referred for treatment of HCV but were released from prison before a clinic appointment could be offered. Seventeen (63%) of the 27 were lost to follow-up, 6 commenced treatment and 4 remain on the waiting list.

For the homeless cohort, 20 patients were referred since the 'one-stop-shop' began in Sept 2017. Only 6 (30%) engaged with the rapid assessment program and commenced treatment. The remaining 14 (70%) either failed to attend first appointment (8) or became too unstable to start treatment after being assessed (6).

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**Presentation:** Modified Release tablets containing 400mg mesalazine or 800mg mesalazine. **Indications:** Ulcerative Colitis - Treatment of mild to moderate acute exacerbations. Maintenance of remission. Crohn's disease - Maintenance of remission. **Dosage and administration:** 400mg tablets - Adults: Mild acute disease: 6 tablets (2.4g) once daily or in divided doses, with concomitant steroid therapy where indicated. Moderate acute disease: 6 to 12 tablets (2.4g - 4.8g) daily. 2.4g may be taken once daily or in divided doses, higher doses should be taken in divided doses. Maintenance therapy: 5 to 6 tablets (1.2g - 2.4g) once daily or in divided doses. 800mg tablets - Adults: Mild acute disease: 3 tablets (2.4g) once daily or in divided doses with concomitant steroid therapy where indicated. Moderate acute disease: 3 to 6 tablets (2.4g - 4.8g) daily. 2.4g may be taken once daily, higher doses should be taken in divided doses. Maintenance therapy: 2 to 3 tablets (1.6g - 2.4g) once daily or in divided doses. 400mg and 800mg tablets - No more than 2.4g should be taken at one time. Tablets must be swallowed whole. **Elderly:** Normal adult dose may be used unless liver or renal function is severely impaired. **Children:** Limited documentation of efficacy in children >6 years old. Dose to be determined individually. Generally recommended that half the adult dose may be given to children up to a body weight of 40 kg, and the normal adult dose to those above 40 kg. **Contra-indications:** Hypersensitivity to colicytols, mesalazine or any of the excipients, severe impairment of hepatic or renal function (GFR less than 30 ml/min). **Warnings and Precautions:** Urinary stones (see above) should be determined prior to and during treatment, at discretion of treating physician. Caution in patients with raised serum creatinine or proteinuria. Stop treatment immediately if renal impairment is evident. Haematological investigations are recommended prior to and during treatment, at discretion of treating physician. Stop treatment immediately if blood dyscrasias are suspected or evident. Caution in patients with impaired hepatic function. Liver function should be determined prior to and during treatment, at the discretion of the treating physician. Do not use in patients with previous mesalazine-induced cardiac hypersensitivity and use caution in patients with previous myo- or pericarditis of allergic background. Monitor patients with pulmonary disease, in particular asthma, very carefully in patients with a history of adverse drug reactions to sulphasalazine. Discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Use with caution in patients with gastric or duodenal ulcers. Intact tablets in the stool may be largely empty shells. If this occurs repeatedly patients should consult their physician. Use with caution in the elderly subject to patients having normal or non-severely impaired renal and liver function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** No interaction studies have been performed. May decrease the anticoagulant activity of warfarin. May increase the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine. Monitoring of blood cell counts is recommended if these are used concomitantly. **Fertility, pregnancy and lactation:** Only to be used during pregnancy and lactation when the potential benefit outweighs the possible risk. No effects on fertility have been observed. **Adverse reactions:** Common: dyspepsia, rash (common: eosinophilia (as part of an allergic reaction), parosmia, urticaria, pruritus, pyrexia, chest pain). Rare: headache, dizziness, mycositis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, photosensitivity. Very rare: altered blood counts (aplastic anaemia, granulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia, hypersensitivity reactions (such as allergic exanthema, drug fever, lupus erythematosus syndrome, parosmia), peripheral neuropathy, allergic and toxic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), interstitial pneumonia, eosinophilic pneumonia, lung disorder, acute pancreatitis, changes in liver function, pruritus (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, alopecia, myalgia, arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure which may be reversible on withdrawal, nephrotic syndrome, oligospermia (reversible). Not known: pleurisy, lupus-like syndrome with pericarditis and pleuripneumonitis as prominent symptoms as well as rash and arthralgia, intolerance to mesalazine with C-reactive protein increased and/or exacerbation of symptoms of underlying disease, blood creatinine increased, weight decreased, creatinine clearance decreased, amylase increased, red blood cell sedimentation rate increased, lipase increased, BUN increased. Consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg - PL36633/0002; packs of 90 tablets (€16.58) and 120 tablets (€22.10); 800mg - PL36633/0001; packs of 90 tablets (€40.38) and 180 tablets (€80.77). **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire LN5 0HX, UK. Octasa is a trademark. ©2010 Tillotts Pharma UK Ltd. Further information is available from the Marketing Authorisation Holder. Date of preparation of APL: November 2017.

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

**References:**

1. MIMS. Accessed online. December 2017. 2. Octasa® 400mg Modified Release Tablets - Summary of Product Characteristics. PU-07103. Date of preparation: December 2017

**Conclusions:**

70% of prisoners who are offered assessment while still in prison proceed to receive HCV treatment. However, if the offer of assessment/treatment waits until after release from prison, nearly two thirds are lost to follow-up. Therefore, efforts should be made to offer all HCV positive prisoners treatment before they leave prison.

Similarly, 70% of the homeless cohort fail to engage with a hospital based assessment despite support from Outreach teams and being prioritised for urgent appointments. New strategies delivering assessment in the community will be required to reach this cohort.

**Abstract No. USG A'2018 107****Vitamin D Receptor As A Marker of Prognosis In Oesophageal Adenocarcinoma: A Prospective Cohort Study****Authors:**

S McCain, J Trainor, DT McManus, ÚC McMenamin, S McQuaid, V Bingham, JA James, M Salto-Tellez, RC Turkington, HG Coleman

**Institution**

Centre for public health ICS-B Building, RVH Site, Grosvenor Road, Belfast, BT12 6BJ,

**Background**

Oesophageal cancer causes 400,000 deaths worldwide each year and ranks as the sixth most common cause of cancer mortality. 5-year survival rates range between 10% and 18%. In addition to early detection initiatives, there is a need to identify actionable, prognostic biomarkers to help predict patient outcome and also to identify novel therapeutic targets.

**Aim**

Vitamin D receptor (VDR) expression has been associated with survival in several cancer sites. This study aims to evaluate the association between VDR expression and prognosis in oesophageal adenocarcinoma patients.

**Method**

Oesophageal adenocarcinoma specimens and clinical data were collected from 130 patients treated with neo-adjuvant chemotherapy prior to surgical resection at the Northern Ireland Cancer Centre between 2004 and 2012. Tissue microarrays were created and immunohistochemical staining for VDR was performed on triplicate tumour cores from each resection specimen. Cox proportional hazards models were applied to evaluate associations between VDR, according to tertiles of expression, and survival outcomes.

**Results**

During a median of 2.5 (maximum 9) years of follow-up, 75 patients died. In analysis adjusted for confounders, higher VDR expression was associated with an improved overall survival (HR 0.49 95% CI 0.25-0.96) and disease-specific survival (HR 0.50 95% CI 0.26-0.99), when comparing the highest with the lowest tertile of expression. These associations were strongest in sensitivity analysis restricted to junctional tumours

**Conclusions**

This study is the first to demonstrate that patients with higher VDR expression in oesophageal adenocarcinoma have a more favourable prognosis. Further work is needed to validate these findings, and to define the role of VDR in the aetiology, progression and management of oesophageal adenocarcinoma.

**Abstract No. USG A'2018 109****A multicentre, retrospective cohort study into risk factors and outcomes for Clostridium Difficile in the Belfast Trust.****Authors:**

Morrison G, Brown A

**Institution:**

Belfast Trust

**Background/Aim**

Studies show that the incidence of Clostridium Difficile Infection (CDI) is rising in our hospitals. This study was compiled to analyse risk factors and outcomes of CDI positive patients in the Belfast Trust over a period of 12 months (Nov 2016-Nov 2017).

**Method**

Data was collected from 5 centres within the Belfast Trust totaling 85 patients. Age greater than 65 was included as a risk factor. Previous hospital admission (within 90 days of positive culture), antibiotic usage, regular Proton Pump Inhibitor use and Inflammatory Bowel Disease were recorded risk factors.

**Results**

Age and recent anti-microbial use were identified as major risk factors, 71.8% and 87.1% respectively. 70.6% had a recent hospital admission. PPI usage was also found to have a positive correlation to testing positive for CDI, with 48.2% of patients having used a PPI at some point preceding or during admission.

One patient in this study required surgical intervention (1.8% of cases) despite 4.7% developing Toxic Megacolon. 23.5% of the patients included in the study died during the admission, assumed at least in part, to be due to CDI.

**Conclusions**

The analysis verifies the previously known risk factors: age, antibiotic use and hospital admissions. Interestingly PPI usage ranked higher than IBD and previous infection as a risk factor. This leads us to question the appropriateness of PPI use in patients with pre-existing risk factors. This would be of particular concern as the data suggests that there is nearly a 1 in 4 chance of death in the event of developing CDI in hospital.

**Abstract No. USG A'2018 110****The Association Between Smoking, Alcohol and Colon Cancer Survival By KRAS, BRAF, P53 and MSI status: A Molecular Pathology Epidemiology Cohort Study.****Authors:**

J Yeo,<sup>1</sup> MB Loughrey,<sup>2,3</sup> RT Gray,<sup>1</sup> S McQuaid,<sup>2,4</sup> JA James,<sup>2,3,4</sup> M Salto-Tellez,<sup>2,3</sup> DB Longley,<sup>2</sup> HG Coleman.<sup>1,2</sup>

**Institutions**

<sup>1</sup>Cancer Epidemiology Research Group, Centre for Public Health, Queen's University Belfast, <sup>2</sup>Centre for Cancer Research and Cell Biology, Queen's University Belfast <sup>3</sup> Department of Pathology, Belfast Health and Social Care Trust, <sup>4</sup> Northern Ireland Biobank.

**Introduction**

Previous studies have highlighted lifestyle factors in colon cancer survival. Smoking and alcohol may interact with features of tumour biology to influence patient outcomes.

**Aim**

To investigate the association between smoking status, alcohol intake and colon cancer survival by MSI, P53, KRAS and BRAF status, in a large population-based study.

**Methods**

Information from 661 patients who underwent surgery for their Stage II or III colon cancer between 2004 and 2008 in Northern Ireland were included. Follow-up and death information was retrieved via linkage to the Northern Ireland Registrar General's Office up to end 2013. Tissue blocks were retrieved via the Northern Ireland Biobank, and DNA extracted to determine mutations in BRAF, KRAS, P53 and MSI status. The association between lifestyle factors and survival was tested using Cox Proportional Hazard models, adjusting for key confounders.

**Results**

Smoking was associated with poorer outcomes in colon cancer patients, when investigating both all-cause mortality (HR 1.55, 95% CI 1.17-2.05) and colorectal cancer-specific mortality (HR 1.48, 95% CI 1.05-2.06). Stratified analyses by molecular features found this increased risk of colorectal cancer-specific death to be strongest in patients with MSI-high or P53 mutant tumours (HR 7.21 [95% CI 2.19 - 23.78]) and 1.69 [95% CI 1.10 - 2.56]), respectively. No associations were observed between alcohol intake and survival in colon cancer patients, which did not alter in analyses stratified by molecular subtypes.

**Conclusion**

Smoking was associated with poorer survival in Stage II and III colon cancer patients, particularly in those with MSI-high or P53 mutant tumours.

**POSTER PRESENTATIONS****Abstract No. USG A'2018 100****Laparoscopic Cholecystectomy is Safe and Feasible in Isolated Day-Case Units****Authors:**

M.J. Mullan, M.V. Seceleanu

Department of Surgery, South West Acute Hospital, Enniskillen, UK

**Introduction:**

Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis. To achieve NHS target plan to perform 60% of all elective cholecystectomies as day cases, laparoscopic

cholecystectomy was introduced into most day surgery units.

**Aims:**

The aim of this study was to assess the safety and acceptability of day-case laparoscopic cholecystectomy in an isolated day-case unit.

**Methods:**

This is a prospective study of the first twenty-one laparoscopic cholecystectomies performed in the unit between October 2017 and June 2018. Causes of failed discharges, postoperative complications and readmission rates were recorded. Patient recovery was monitored by telephone questionnaire and satisfaction was assessed at outpatient follow up.

**Results:**

Twenty-one patients underwent laparoscopic cholecystectomy as a day case procedure. Nineteen patients were discharged on the day of surgery. Two patients were unplanned admissions and transferred to the nearby district hospital: one patient required further analgesia and one patient was transferred in view of surgery- no progression policy applied. Mean operation time was 65 min. Two patients were readmitted with wound infection and postoperative choledocholithiasis. There was no conversion to open cholecystectomy or return to theatre for emergency laparotomy. Twenty patients were satisfied with the service when reviewed in the clinic.

**Conclusions:**

Day-case laparoscopic cholecystectomy in an isolated day surgery unit is safe and feasible with an acceptable discharge rate and level of patient satisfaction. Success depends on patient selection and education, consultant led and delivered surgery, appropriate transfer protocols in place and a policy of non-progression when encountering unexpected difficult cases.

**Abstract No. USG A'2018 102****Vedolizumab for Inflammatory Bowel Disease – Success or Failure?****Authors:**

Dobson G, McGuigan A, McIlmunn C, Tan CJ

**Institution:**

Belfast Health and Social Care Trust

**Background:**

Infliximab & Adalimumab have long been indicated for induction of remission of Crohn's Disease (CD) and Ulcerative Colitis (UC). More recently Vedolizumab has been considered as a "rescue" therapy for unresponsive disease. However, there are no data to demonstrate if the use of Vedolizumab helps to prevent surgical intervention.

**Aim:**

To assess how successful Vedolizumab is in preventing progression to surgery

**Method:**

We performed a retrospective review of CD & UC patients who were commenced on treatment with Vedolizumab. Success was determined by induction of remission. Failure was determined as either cessation of the treatment or progression to surgical procedure.

**Results:**

48 patients had CD. Age at induction ranged 15-66 years. 33 (69%) patients failed to achieve remission on Vedolizumab – 9 had surgery, 24 were switched to a further Biologic agent – 8 of which subsequently had a surgical procedure.

25 patients had UC. Age at induction ranged 16-69 years. 13 (52%) patients failed to achieve remission on Vedolizumab. 10 have undergone a surgical procedure, and 1 further has been recommended to have surgery but refused.

Significant differences in success of treatment was identified when patients were analysed by age at induction ( $p > 0.01$ ).

**Conclusions:**

Despite the success of Biologic therapies there remains some doubt as to their longer-term outcomes in regards to preventing surgical intervention. In particular this early data appears to show a low rate of success in patients treated with Vedolizumab. The rate of

surgery in this small group is higher than expected, and questions its purported benefits.

**Abstract No. USG A'2018 105**  
**Audit of Pre-assessment Care of Patients Undergoing Chemotherapy And Surgery for Early Stage Oesophageal and Gastro-Oesophageal Junction Adenocarcinoma**

**Authors:**

Douglas R, Singh U, Sutton E, Williams A, McGaughey S, Kennedy R, Turkington R.C

**Institution:**

Centre for Cancer Research and Cell Biology, Queens University Belfast, Northern Ireland.

Department of Surgery, Belfast City Hospital, Northern Ireland.

**Background**

Patients with early stage oesophageal (OAC) and gastro-oesophageal junction (GOJ) adenocarcinoma are offered platinum-based chemotherapy prior to radical surgery. Comprehensive physical and nutritional assessment is required to enable accurate patient selection

**Aim**

An audit of pre-assessment care of patients with early stage OAC and GOJ in the Northern Ireland Cancer Centre was undertaken to ensure that the care given to these patients is following current Association of Upper Gastrointestinal Surgeons (AUGIS) guidelines.

**Method**

Clinical notes were reviewed for patients diagnosed from the opening of the Upper GI Surgery unit in June 2015 until December 2017. Demographic, haematological, radiological, physiotherapy and dietetic factors were collected.

**Results**

94 patients were diagnosed between June 2015 and 2017 of whom 74 (79%) were male and the median age was 63.5 (31-82). All patients received staging CT and CT PET scans. Fifty eight patients (62%) had endoscopic ultrasound performed. All patients were seen by a physiotherapist and dietitian at pre-assessment. Physiotherapy assessments were available for 67 (71%) patients and all patients had shuttle walk test, BORG score, heart rate and oxygen saturations recorded. Dietetics assessments were available for 64 (68%) patients and all had dysphagia scores, hand grip strength, height and weight recorded. Fifty five (86%) of patients had weight change over time period recorded.

**Conclusions**

Appropriate pre-assessment care was given as per current guidelines for patients with early stage oesophageal cancer.

**Abstract No. USG A'2018 106**  
**The Role of Nutritional Status in Oesophageal and Gastro-Oesophageal Junction Adenocarcinoma**

**Authors:**

Douglas R, Singh U, Sutton E, Williams A, McGaughey S, Kennedy R, Turkington R.C

**Institution:**

Centre for Cancer Research and Cell Biology, Queens University Belfast, Northern Ireland.

Department of Surgery, Belfast City Hospital, Northern Ireland.

**Background**

The incidence of oesophageal cancer is rising. Despite improvement in treatment, the five year survival rate is 12%. Patients present with dysphagia and weight loss which affects their nutritional status and their ability to tolerate treatment.

**Aim**

We aim to assess how patients' nutritional status can affect their survival.

**Method**

Retrospective review of clinical notes of patients diagnosed with early stage oesophageal (OAC) and gastro-oesophageal adenocarcinoma (GOJ) in the Northern Ireland Cancer Centre between 2013 and 2017.

Patients' demographics and survival data were collected. The body mass index (BMI), Lorentz ideal body weight and the nutritional risk index (NRI) were calculated. Being underweight is defined as having a BMI of less than 18.5. Normal NRI is defined as a score of more than 100.

**Results**

164 patients were diagnosed with early stage OAC/GOJ between 2013 and 2017 of whom 134 (81.7%) were male and the median age was 63.9 (31-82). Seven patients (4.4%) were underweight and their recurrence free (RFS) and overall survival (OS) were significantly worse [HR 0.36 (CI 0.13-1); p=0.04 and HR 0.33 (CI 0.12-0.94); p=0.028] respectively). Twelve (7.6%) have NRI of less than 100. NRI<100 strongly predicted for poorer RFS [HR 2.6 (CI 1.1-6.2); p=0.023] and OS [HR 3.4 (CI 1.5-7.7); p=0.002].

**Conclusions**

Poor nutritional status is a poor prognostic factor in patients undergoing neo-adjuvant chemotherapy and surgery for oesophageal adenocarcinoma.

**Abstract No. USG A'2018 108**  
**Alcohol, Smoking, Related Biomarkers And Oesophageal Adenocarcinoma Survival: A Molecular Pathology Epidemiology Cohort Study In Northern Ireland**

**Author:**

S McCain, J Trainor, DT McManus, ÚC McMenamin, S McQuaid, V Bingham, JA James, M Salto-Tellez, RC Turkington, HG Coleman

Institution: Centre for public health ICS-B Building, RVH Site, Grosvenor Road, Belfast, BT12 6BJ,

**Background**

Cigarette smoking and alcohol consumption are associated with the development of multiple cancers, but evidence is lacking regarding their impact on cancer survival and in particular oesophageal adenocarcinoma survival.

**Aim**

To assess the impact of smoking and alcohol consumption on survival in oesophageal adenocarcinoma in a population-based study and assess the impact of these lifestyle factors on survival within biomarker groupings

**Method**

Oesophageal adenocarcinoma specimens and clinical data were collected from 130 patients treated with neo-adjuvant chemotherapy prior to surgical resection at the Northern Ireland Cancer Centre between 2004 and 2012. Tissue microarrays were created and immunohistochemical staining for p53, HER2, GLUT-1 and CD8 was performed on triplicate tumour cores from each resection specimen. Survival analysis was calculated using Cox proportional hazards regression models.

**Results**

During a median of 2.5 (maximum 9) years of follow-up, 75 patients died. In adjusted analysis comparing ever with never alcohol consumption there was a non-significant increased risk of mortality in overall (HR 1.70 95% CI 0.95-3.04) and disease specific survival (HR 1.70 95% CI 0.93-3.11). There was no difference in survival in current or former smokers compared to never smokers. In biomarker analysis, there was a statistically significant worsened survival in patients who were ever drinkers and had GLUT1 positive (HR 2.5 95% CI 1.37-4.57) and CD8 positive tumours (HR 2.78 95% CI 1.31-5.89).

**Conclusions**

Ever alcohol consumption may have an impact on survival in patients with oesophageal adenocarcinoma and in particular those patients with CD8 and GLUT1 positive tumours. More studies with larger numbers need to be performed to investigate these findings further.

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to next infusion, for patients with history of mild/moderate IRR to Entyvio. **Infections:** Not recommended in patients with active, severe infections until infections are controlled. Consider withholding in patients who develop severe infection while on treatment with Entyvio. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Entyvio treatment. **Progressive Multifocal Leukoencephalopathy (PML):** No cases were observed in Entyvio clinical trials, but John Cunningham (JC) virus infection resulting in PML and death has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs/symptoms. **Malignancy:** Underlying increased risk of malignancy in UC and CD. Immunomodulatory products may increase risk. **Prior and concurrent use of biological products:** No clinical data available for Entyvio use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should wait at least 12 weeks prior to initiating Entyvio therapy. Entyvio not recommended for concomitant use with biologic immunosuppressants as no clinical data available. **Live and oral vaccines:** Patients may continue to receive non-live vaccines. Patients recommended to be up-to-date with all appropriate immunisations prior to initiating Entyvio. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically meaningful effect on Entyvio pharmacokinetics. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use adequate contraception and continue for at least 18 weeks after last Entyvio treatment. Since maternal antibodies are excreted in breast milk, decision whether to discontinue breast-feeding or discontinue/abstain from Entyvio should be made according to relative benefit to child of breast-feeding or to mother of Entyvio. **Undesirable Effects: Very Common (≥1/10):** nasopharyngitis, headache, arthralgia. **Common (≥1/100, <1/10):** bronchitis, gastroenteritis, 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, anaphylactic reaction, anaphylactic shock. **Refer to the SmPC for details on full side effect profile and interactions. UK Basic NHS Price:** £2,050 for one vial (300mg powder for concentrate

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**References:** 1. Dulai P, Meserve J, Hartke J, et al. Poster presented at European Crohn's and Colitis Organisation (ECCO), 15-18 February 2017, Barcelona, Spain. Abstract DOPO23. 2. Dulai PS, Singh S, Jiang X, et al. Am J Gastroenterol. 2016;111(8):1147-1155. 3. Loftus EV, Colombel JF, Feagan B, et al. Poster presented at the European Crohn's and Colitis Organisation (ECCO), 15-18 February 2017, Barcelona, Spain. Poster P209. 4. Vermeire S, Loftus EV, Colombel JF, et al. Poster presented at Digestive Disease Week (DDW); 6-9 May 2017; Chicago, IL, USA. Poster Su1931. 5. Takeda UK Data on File UK/DF/1804/0008(1).

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