

abbvie



**Irish Society  
for Rheumatology**

**Autumn Meeting 2013**



**19 - 20 September, 2013  
Knightsbrook Hotel  
Trim, Co.Meath**

Brochure kindly sponsored by MSD

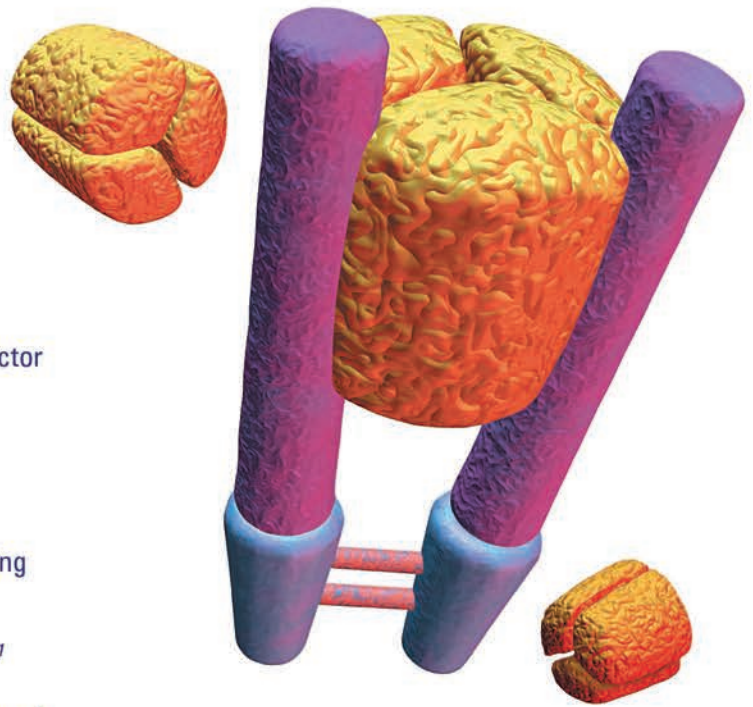


**Bristol-Myers Squibb**





# ENBREL is Different



## A unique mechanism of action

- Enbrel is the only fully human soluble tumour necrosis factor (TNF) receptor<sup>1,2,3,4,5,6</sup>
- It works differently than MAB's<sup>1</sup>

## No neutralising antibodies<sup>1</sup>

- Enbrel is not associated with the production of neutralising antibodies in humans

## Enbrel has a short half life (<3 days)<sup>1</sup>

- The half-life of anti-TNF agents should be taken into account if a treatment break is required

## Efficacy

- Registry data and Cochrane Review data support efficacy & safety of Enbrel<sup>7,8</sup>



**ABBREVIATED PRESCRIBING INFORMATION** Before prescribing Enbrel® please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC®): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporine, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthritides (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. **Children aged 6-17 years:** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. **Adults:** RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS and PsA – 25 mg twice weekly or 50 mg once weekly. **Children aged 2-17 years:** JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the

Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients identified as carriers of hepatitis B virus and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy < 18 years of age) in the postmarketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life threatening infections and sepsis.

Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) has also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. **Legal Category:** POM. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **S1B:** Product subject to a prescription which may be renewed. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. For full prescribing information see the Summary of Product Characteristics. 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. **API Reference Number:** EN 6\_1. **Date of Prescribing Information:** December 2012

**References:** 1. Enbrel SPC July 2010 2. Remicade SPC 3. Humira SPC 4. Orencia SPC 5. Mabthera SPC 6. Simponi SPC 7. Singh J et al. CMAJ: 2009;DOI:10.1503 8. Hetland ML et al. Arthritis & Rheumatism. Vol 62, no 1, January 2010.

Date of preparation: April, 2013  
ENB/2013/085/1

**Pfizer** Specialty Care





## WELCOME

### Dear Colleagues and Friends

It is once again my great pleasure as President of the Irish Society for Rheumatology to welcome you to our Autumn Conference in Trim. It promises to be a great occasion with a varied and interesting academic programme put together by our colleagues in St James Hospital. Gaye, Barry and Michelle you have really done us proud.



I look forward to welcoming our international guests, Prof John Stone from Harvard Medical School who will present on "New insights into the Immune System", and Prof Robert Inman from Toronto who will present on "Ankylosing Spondylitis".

From the University of Leeds we welcome Prof Philip Conaghan who will give us some "insights on imaging and therapeutic directions in Osteoarthritis". We also welcome Prof David Isenberg who will deal with "the rise of Biologics in SLE".

The home team will certainly not be let down. Prof Jim Lucey will emphasise the importance of anxiety and depression in our patients and patients and there is no need to introduce our multi-talented ex-president Ronan Kavanagh who will present a fascinating talk on life-long learning. I do hope that you will enjoy these presentations and that you will find them interesting and stimulating.

I would again like to thank our friends in Industry for their ongoing support and I would ask that you visit the stands to show your appreciation.

This year it is with great pleasure that we honour Dr Eoin Casey with a "Life Time Achievement award" for his contribution to Rheumatology.

We are again pleased to have our colleagues in the IRHPS present with us this year, we hope that their meeting will be fruitful and educational for them, we look forward to meeting with them during the two days.

During the past year the board of ISR has been very active in maintaining the status of ISR in difficult times. As most of you will know we have encountered problems in collecting membership subs. This has mainly been due to the restructuring within the banking system which has been responsible for the direct debit falling through. We are actively looking at this and will review the overall situation when the new SEPA guidelines come in Feb 2014.

Our 40th Anniversary Meeting was a huge success in Belfast last Autumn. The feedback from the meeting and dinner at the Titanic centre was extremely positive.

It has been my honour to serve you as President of our Society the past two years and I will hand over the chain to Prof David Kane next January. I would like to thank the Board, staff of ISR and members for your all support.

Enjoy the meeting and the opportunity of renewing old acquaintances and making some new ones.

**Dr Gary Wright,**  
ISR President

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### Dr Gary Wright

Dr Wright qualified from Queens University in 1987 and was appointed Consultant Rheumatologist at the Royal Victoria Hospital and Musgrave Park Hospitals in Belfast in 1998. He is an Honorary Clinical lecturer at Queen's University Belfast.

He trained in Rheumatology in Belfast and spent a further year as Honorary Senior Registrar in Nottingham with Professor Mike Doherty.

His Research interests include the genetics of osteoarthritis and crystal disease, early diagnosis and treatment of inflammatory arthritis and musculoskeletal ultrasound in rheumatic disorders. He is the Royal College of Physicians of London Northern Ireland Regional Advisor for Training.



# Help Protect Your Post-Menopausal Patients From Osteoporotic Fractures

With 5600 IU of Vitamin D

**FOSAVANCE**  
alendronate/colecalciferol **5600**

The Only Osteoporosis Therapy With 5600 IU of Vitamin D That Provides Demonstrated Fracture Prevention at the Hip and Spine,<sup>1,2</sup> in one tablet



Actual size

Updated NOF<sup>3</sup> guidelines recommend 800–1000 IU of vitamin D per day for adults ≥50 years<sup>3</sup>

**FOSAVANCE** 70 mg/2800 IU Tablets (70 mg alendronate acid as alendronate sodium trihydrate and 70 micrograms (2800 IU) colecalciferol (vitamin D<sub>3</sub>)). **FOSAVANCE** 70 mg/5600 IU Tablets (70 mg alendronate acid as alendronate sodium trihydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D<sub>3</sub>)). **ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing.** **PRESENTATION** FOSAVANCE 70 mg/2800 IU Tablets Capsule-shaped, white to off-white tablets marked with an outline of a bone image on one side, and '710' on the other, containing 70 mg alendronate acid as alendronate sodium trihydrate and 70 micrograms (2800 IU) colecalciferol (vitamin D<sub>3</sub>). FOSAVANCE 70 mg/5600 IU Tablets Modified rectangle-shaped, white to off-white tablets, marked with an outline of a bone image on one side, and '270' on the other, containing 70 mg alendronate acid as alendronate sodium trihydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D<sub>3</sub>). **USES** Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency and for 'Fosavance' 5600 for patients not receiving Vitamin D supplementation. 'Fosavance' reduces the risk of vertebral and hip fractures. **DOSAGE AND ADMINISTRATION** The recommended dose is one tablet **once weekly**. Patients should be instructed that if they miss a dose of FOSAVANCE they should take one tablet on the morning after they remember. They should not take two tablets on the same day but should return to taking one tablet once a week, as originally scheduled on their chosen day. Due to the nature of the disease process in osteoporosis, 'Fosavance' is intended for long-term use. The optimal duration of bisphosphonate treatment for osteoporosis has not been established. The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of FOSAVANCE on an individual patient basis, particularly after 5 or more years of use. Patients must be advised to follow the instructions below: *For adequate absorption of alendronate:* 'Fosavance' must be taken with water only (not mineral water) at least 30 minutes before the first food, beverage, or medicinal product (including antacids, calcium supplements and vitamins) of the day. Other beverages (including mineral water), food and some medicinal products are likely to reduce the absorption of alendronate. *The following instructions should be followed exactly in order to minimise the risk of oesophageal irritation and related reactions:* • Swallow 'Fosavance' only upon arising for the day with a full glass of water (not less than 200 ml or 7 fl.oz.). • Patients should only swallow FOSAVANCE whole. Patients should not crush or chew the tablet or allow the tablet to dissolve in their mouths because of a potential for oropharyngeal ulceration. • Do not lie down until after the first food of the day • Do not lie down for at least 30 minutes after taking 'Fosavance'. • Do not take at bedtime or before rising for the day. Patients should receive supplemental calcium if intake from diet is inadequate. Additional supplementation with vitamin D should be considered on an individual basis taking into account vitamin D intake from vitamins and dietary supplements. Equivalence of 2800 IU of vitamin D, weekly in 'Fosavance' to daily dosing of vitamin D 400 IU has not been studied. Equivalence of intake of 5600 IU of vitamin D, weekly in FOSAVANCE to daily dosing of vitamin D 800 IU has not been studied. *Use in the elderly:* No dosage adjustment is necessary. Use in renal impairment: No dose adjustment is necessary for patients where GFR is greater than 35 ml/min. Alendronate is not recommended for patients with renal impairment where GFR is <35 ml/min. *Use in children and adolescents:* Not recommended. **CONTRAINDICATIONS** Oesophageal abnormalities and other factors which delay oesophageal emptying, such as stricture or achalasia. Inability to stand or sit upright for at least 30 minutes. Hypersensitivity to alendronate or to any of the excipients. **Hypocalcaemia.** **PRECAUTIONS** Alendronate can cause local irritation of the upper gastro-intestinal mucosa and potentially worsen any underlying disease. Because there is a potential for worsening of the underlying disease, caution should be used when alendronate is given to patients with active upper gastro-intestinal problems, such as dysphagia, oesophageal disease, gastritis, duodenitis, or ulcers, or with a recent history (within the previous year) of gastro-intestinal disease such as peptic ulcer, or active gastro-intestinal bleeding, or surgery of the upper gastro-intestinal tract other than pyloroplasty. In patients with known Barrett's oesophagus, prescribers should consider the benefits and potential risks of alendronate on an individual patient basis. Oesophageal reactions (sometimes severe and requiring hospitalisation), such as oesophagitis, oesophageal ulcers and oesophageal erosions, rarely followed by oesophageal strictures, have been reported in patients receiving alendronate. Physicians should be alert to any signs or symptoms of a possible oesophageal reaction, and patients should be instructed to discontinue alendronate and seek medical attention if they develop symptoms of oesophageal irritation such as dysphagia, pain on swallowing, retrosternal pain, or new or worsening heartburn. The risk of severe oesophageal adverse reactions appear to be greater in patients who fail to take alendronate properly and/or continue to take alendronate after developing symptoms suggestive of oesophageal irritation. It is very important that the full dosing instructions are provided to, and understood by the patient. Patients should be informed that failure to follow these instructions may increase their risk of oesophageal problems. While no increased risk was observed in extensive clinical trials with alendronate, there have been rare (post-marketing) reports of gastric and duodenal ulcers, some severe and with complications. Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection (including osteomyelitis) has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. The following risk factors should be considered when evaluating an individual's risk of developing osteonecrosis of the jaw: potency of the bisphosphonate (highest for zoledronic acid), route of administration (see above) and cumulative dose, cancer, chemotherapy, radiotherapy, corticosteroids, smoking, a history of dental disease, poor oral hygiene, periodontal disease, invasive dental procedures and poorly fitting dentures. A dental examination with appropriate preventive dentistry should be considered prior to treatment with oral bisphosphonates in patients with poor dental status. While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. During bisphosphonate treatment, all patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain, or swelling. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment. Bone, joint and/or muscle pain has been reported in patients taking bisphosphonates. In post-marketing experience, these symptoms have rarely been severe and/or incapacitating. The time to onset of symptoms varied from one day to several months after starting treatment. Most patients had relief of symptoms after stopping treatment. A subset had recurrence of symptoms when rechallenged with the same medicinal product or another bisphosphonate. Atypical subtrochanteric and diaphyseal femoral fractures have been reported with bisphosphonate therapy, primarily in patients receiving long-term treatment for osteoporosis. These transverse or short oblique, fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. Fractures are often bilateral; therefore the contralateral femur should be examined in bisphosphonate-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit/risk assessment. During bisphosphonate treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete

femur fracture. Cause of osteoporosis other than oestrogen deficiency and ageing should be considered. Hypocalcaemia must be corrected before initiating therapy with 'Fosavance'. Other disorders affecting mineral metabolism (such as vitamin D deficiency and hypoparathyroidism) should also be effectively treated before starting 'Fosavance'. The content of vitamin D in 'Fosavance' is not suitable for correction of vitamin D deficiency. In patients with these conditions, serum calcium and symptoms of hypocalcaemia should be monitored during therapy with 'Fosavance'. Due to the positive effects of alendronate in increasing bone mineral, decreases in serum calcium and phosphate may occur especially in patients taking glucocorticoids in whom calcium absorption may be decreased. *Colecalciferol:* Vitamin D<sub>3</sub> may increase the magnitude of hypercalcaemia and/or hypercalcaemia when administered to patients with disease associated with unregulated overproduction of calcitriol (e.g. leukaemia, lymphoma, sarcoidosis). Urine and serum calcium should be monitored in these patients. Patients with malabsorption may not adequately absorb vitamin D<sub>3</sub>. *Excipients:* Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose isomaltase insufficiency should not take 'Fosavance'. *Drug interactions:* If taken at the same time, it is likely that food, beverages (including mineral water), calcium supplements, antacids, and some oral medicinal products will interfere with absorption of alendronate. Therefore, patients must wait at least 30 minutes after taking alendronate before taking any other oral medicinal product. Since NSAID use is associated with gastrointestinal irritation, caution should be used during concomitant use with alendronate. *Colecalciferol:* Olestra, mineral oils, orlistat, and bile acid sequestrants (e.g. cholestyramine, colestipol) may impair the absorption of vitamin D. Anticonvulsants, cimetidine and thiazides may increase the catabolism of vitamin D. Additional vitamin D supplements may be considered on an individual basis. *Use in pregnancy and lactation:* 'Fosavance' is only intended for use in postmenopausal women and therefore it should not be used during pregnancy or in breast-feeding women. There are no adequate data from the use of 'Fosavance' in pregnant women. It is not known whether alendronate is excreted into human breast milk. Colecalciferol and some of its active metabolites pass into breast milk. Fertility There are no data on fetal risk in humans. However, there is a theoretical risk of fetal harm, predominantly skeletal, if a woman becomes pregnant after completing a course of bisphosphonate therapy. **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES** Certain adverse reactions that have been reported with FOSAVANCE may affect some patients' ability to drive or operate machinery. Individual responses to FOSAVANCE may vary. **SIDE EFFECTS** Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/100), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (≥1/10,000).

<b>Immune system disorders:</b>	<i>Rare:</i> hypersensitivity reactions including urticaria and angioedema
<b>Metabolism and nutrition disorders:</b>	<i>Rare:</i> symptomatic hypocalcaemia, often in association with predisposing conditions
<b>Nervous system disorders:</b>	<i>Common:</i> headache, dizziness <sup>1</sup> <i>Uncommon:</i> dysgeusia <sup>1</sup>
<b>Eye disorders:</b>	<i>Uncommon:</i> eye inflammation (uveitis, scleritis, or episcleritis)
<b>Ear and labyrinth disorders:</b>	<i>Common:</i> vertigo <sup>1</sup>
<b>Gastrointestinal disorders:</b>	<i>Common:</i> abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distension, acid regurgitation <i>Uncommon:</i> nausea, vomiting, gastritis, oesophagitis, oesophageal erosions, melena <sup>1</sup> <i>Rare:</i> oesophageal stricture, oropharyngeal ulceration <sup>1</sup> , upper gastrointestinal PUBs (perforation, ulcers, bleeding)
<b>Skin and subcutaneous tissue disorders:</b>	<i>Common:</i> alopecia <sup>1</sup> , pruritus <sup>1</sup> <i>Uncommon:</i> rash, erythema <i>Rare:</i> rash with photosensitivity, severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis <sup>1</sup>
<b>Musculoskeletal and connective tissue disorders:</b>	<i>Very common:</i> musculoskeletal (bone, muscle or joint) pain which is sometimes severe <sup>1</sup> <i>Common:</i> joint swelling <sup>1</sup> <i>Rare:</i> osteonecrosis of the jaw <sup>1</sup> ; stress fractures of the proximal femoral shaft <sup>1</sup> atypical subtrochanteric and diaphyseal femoral fractures (bisphosphonate class adverse reaction) <sup>1</sup>
<b>General disorders and administration site conditions:</b>	<i>Common:</i> asthenia <sup>1</sup> , peripheral oedema <sup>1</sup> <i>Uncommon:</i> transient symptoms as in an acute-phase response (myalgia, malaise and rarely, fever), typically in association with initiation of treatment <sup>1</sup>

<sup>1</sup>Frequency in Clinical Trials was similar in the drug and placebo group. <sup>2</sup>This adverse reaction was identified through post-marketing surveillance. The frequency of rare was estimated based on relevant clinical trials. <sup>3</sup>Identified in postmarketing experience.

**OVERDOSE** Alendronate Hypocalcaemia, hypophosphataemia and upper gastrointestinal adverse reactions, such as upset stomach, heartburn, oesophagitis, gastritis, or ulcer, may result from oral overdose. No specific information is available on the treatment of overdose with alendronate. In case of overdose with FOSAVANCE, milk or antacids should be given to bind alendronate. Owing to the risk of oesophageal irritation, vomiting should not be induced and the patient should remain fully upright. *Colecalciferol:* Vitamin D toxicity has not been documented during chronic therapy in generally healthy adults at a dose less than 10,000 IU/day. In a clinical study of healthy adults a 4,000 IU daily dose of vitamin D<sub>3</sub> for up to five months was not associated with hypercalcaemia or hypercalcaemia.

**PACKAGE QUANTITIES** 'Fosavance' 70 mg/2800 IU Tablets 4 tablets. 'Fosavance' 70 mg/5600 IU Tablets 4 tablets. **POM Date of review:** June 2011 Marketing Authorisation numbers: 'Fosavance' 70 mg/2800 IU Tablets EU/1/05/310/002. 'Fosavance' 70 mg/5600 IU Tablets EU/1/05/310/007. **Marketing Authorisation Holder:** Merck Sharp & Dohme Limited, Hertford Road, Hoddeston, Hertfordshire EN11 9BU, UK. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. © Merck Sharp & Dohme Ireland (Human Health) Limited, 2012. All rights reserved. Date of preparation: September 2012.

**References:** 1. Data on file, MSD. 2. Schnitzer T, Bone HG, Crepaldi G, et al; Alendronate Once-Weekly Study Group. Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis. Aging Clin Exp Res. 2000;12(1):1–12. 3. NOF Scientific Statement. National Osteoporosis Foundation's Updated Recommendations for Calcium and Vitamin D<sub>3</sub> Intake, 13 March 2007. Available at: [www.nof.org/prevention/calcium\\_and\\_vitaminD.htm](http://www.nof.org/prevention/calcium_and_vitaminD.htm). Accessed March 2013. A NOF–National Osteoporosis Foundation



Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland







## PROGRAMME ISR Autumn Meeting

Knightsbrook Hotel, Trim, September 19th and 20th 2013

### Thursday September 19th

9.00a.m:	<b>Registration / coffee / poster viewing</b>
10.15a.m:	<b>Welcome</b> from the President of the ISR: Dr Gary Wright
10.30a.m:	<b>Plenary Session 1</b> Scientific Research Oral Presentations 1 - 4
11.30a.m:	<b>Talk 1: <i>New Insights into the Immune System from IgG-Related Disease</i></b> Speaker: Professor John Stone, MD, MPH, Harvard Medical School, Boston, USA
12.15p.m:	<b>Lunch / poster viewing</b>
1.30p.m:	<b>Plenary Session 2</b> Clinical Research Oral Presentations 5 - 8
2.30p.m:	<b>Talk 2: <i>Life-long learning using new technologies</i></b> Speaker: Dr Ronan Kavanagh, MD, MRCP, Consultant Rheumatologist, Galway Clinic, Galway.
3.15p.m:	<b>Coffee / poster viewing</b>
3.45p.m:	<b>Talk 3: <i>Importance of recognising depression and anxiety in patients with rheumatic disease</i></b> Speaker: Professor Jim Lucey, MD, PhD, FRCPI, FRCPsych, Clinical Professor of Psychiatry, TCD
4.30p.m:	<b>Talk 4: <i>The treatment of SLE – the rise of the new Biologicals</i></b> Speaker: Professor David Isenberg, MD, FRCP, FAMS Arthritis Research UK Diamond Jubilee Professor of Rheumatology, University College London Medical School, UK
5.30p.m:	<b>ISR AGM</b>
7.30p.m:	<b>Reception / Music</b>
8.00pm:	<b>Conference Dinner</b>

### Friday 20th September

9.00a.m:	<b>Plenary Session 3</b> Clinical Case Presentations (with Interactive audience participation)
10.00a.m:	<b>Talk 5: <i>Osteoarthritis: insights on imaging and therapeutic directions</i></b> Speaker: Professor Philip Conaghan, PhD FRACP FRCP, Professor of Musculoskeletal Medicine, University of Leeds, UK
10.45a.m.	<b>Coffee / poster viewing</b>
11.15a.m.	<b>Talk 6: <i>Current advances in Ankylosing spondylitis</i></b> Speaker: Professor Robert Inman, MD, Professor of Medicine and Immunology, University of Toronto, Canada
12.00p.m:	<b>Young Investigator Award Lecture</b>
12.15p.m:	<b>Prize giving / close of meeting</b>
12.45p.m:	<b>Lunch</b>





# RA treatment is changing

It's time to change your  
ideas about ORENCIA®



ORENCIA®  
(abatacept)

ORENCIA® is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) – alpha inhibitor.

**ORENCIA® (abatacept) PRESCRIBING INFORMATION.** See Summary of Product Characteristics before prescribing. **PRESENTATION:** 250 mg powder for concentrate for solution for IV infusion containing abatacept per vial. Each ml contains 25 mg of abatacept, after reconstitution; 125 mg pre-filled syringe for SC injection. Each pre-filled syringe contains 125 mg of abatacept in 1 ml. **INDICATION: Rheumatoid arthritis (IV infusion and SC pre-filled syringe):** Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) – alpha inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC. **Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only):** Orenzia 250 mg powder for concentrate for solution for IV infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSE AND ADMINISTRATION:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. **Orenzia 250 mg powder for concentrate for solution for IV infusion. Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg paediatric patients weighing or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orenzia should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended. **Orenzia 125 mg solution for injection (SC pre-filled syringe) Adults and elderly:** Treatment should be initiated with a loading dose using an intravenous infusion. Following this loading dose, the first 125 mg subcutaneous injection of Orenzia should be given within a day, then 125 mg subcutaneous injections once weekly. Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orenzia without an intravenous loading dose. Patients transitioning from Orenzia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** Administration in children below 18 years of age is not recommended. The continuation of treatment with abatacept should be re-assessed if patients do not respond within 6 months. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS: Allergic Reactions:** Caution in patients with a history of allergic reactions. Orenzia should be discontinued if a patient develops serious allergic or anaphylactic reaction. **Infections:** Caution should be exercised when considering the use in patients with a history of frequent infections, or underlying conditions which may prompt to infection. Treatment with Orenzia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orenzia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orenzia. Co-administration of Orenzia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orenzia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of Orenzia in the development of malignancies is unknown, see SmPC. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orenzia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orenzia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orenzia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In adult placebo-controlled trials the following adverse drug reactions were reported. **Very Common (≥ 1/10):** upper respiratory tract infection including tracheitis, nasopharyngitis. **Common (≥ 1/100 to < 1/10):** Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes simplex, rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthenia, injection site reactions. **Uncommon (≥ 1/1,000 to < 1/100):** Tooth infection, onychomycosis, herpes zoster, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder, migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, arthralgia, amenorrhea, menorrhagia, influenza like illness, weight increased. **Rare (≥ 1/10,000 to < 1/1,000):** Bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm malignant, throat tightness. See SmPC for further details. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBER** Orenzia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack Orenzia 125 mg solution for injection - EU/1/07/389/008, 4 pre-filled syringes with needle guard. **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH. **FURTHER INFORMATION FROM:** Bristol-Myers Squibb Pharmaceuticals, South County Business Park, Leopardstown, Dublin or [medicalinformation@bms.com](mailto:medicalinformation@bms.com) **Tel:** 1-800-749-749. **DATE OF PREPARATION:** December 2012.





**IRHPS PROGRAMME Autumn Meeting**  
**Knightsbrook Hotel, Trim, September 19th and 20th 2013**

**Thursday 19th September 2013**

09.00	<b>Registration Opens Coffee &amp; Poster Viewing</b>
10.15	<b>IRHPS Programme</b> Chairs: Derek Deely, Susan Somerville
10.15	<b>Welcome by</b> <i>IRHPS Chairperson; Rhona Galway</i>
	<b>Working with Arthritis: An Occupational Therapy led Vocational Rehabilitation service for people with arthritis in the Border, Western and Midland Region of Ireland.</b> <i>Dr. Katie Robinson, Course Director MSc Occupational Therapy, University of Limerick</i>
10.30	<b>Impact of Fatigue and Activity Management Education (FAME) on activity participation of individuals with Systemic Lupus Erythematosus.</b> <i>Dr Deirdre Connolly, Head of Discipline of Occupational Therapy, Trinity Centre for Health Sciences, Dublin</i>
11.00	<b>Fatigue in inflammatory arthritis: A symptom in its own right</b> <i>Dr. Patricia Minnock, Advanced Nurse Practitioner Rheumatology Rehabilitation, Our Lady's Hospice and Care services, Harold's Cross</i>
11.30	<b>ISR Programme</b>
12.15	<b>Lunch &amp; Poster viewing</b>

13.30	<b>IRHPS programme</b> Chairs: Rhona Galway, Bindu Irudayaraj
	<b>Oral Presentations:</b>
	<b>The effectiveness of education and aerobic exercise in 'high functioning' patients with fibromyalgia: evaluation of a new service.</b> <i>Catherine Cullinane, Physiotherapist, Waterford Regional Hospital</i>
	<b>Physiotherapy Awareness of Inflammatory Back Pain / Ankylosing Spondylitis</b> <i>Martina Fitzpatrick, Physiotherapist, St. Vincent's University Hospital, Dublin</i>
14.30	<b>ISR Programme</b>
17.30	<b>IRHPS AGM</b>
19.30	<b>Drinks Reception</b>
20.00	<b>Gala Dinner</b>

**Friday 20th September 2013**

08.30	<b>Registration</b>
09.00	<b>ISR Programme</b>
10.45	<b>Coffee &amp; Poster Viewing</b>
11.15	<b>ISR Programme</b>
12.15	<b>Prize Giving &amp; Close of Meeting</b>
12.45	<b>Lunch</b>





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## Life Time Achievement 2013



**Dr Eoin Casey**

Dr Eoin B Casey is a consultant rheumatologist with a vast experience in the field of musculoskeletal disorders. He received his medical degree from Cork University Hospital in 1962 and after spending his Intern year at St Finbarr's Hospital, Cork, he went to the UK to undertake his general and specialist education in Derby and Sheffield. He pursued higher training in Neurology in London and was subsequently awarded his MD for research in Clinical Electrophysiology. He then spent several years in Rheumatology / Rehabilitation in London, moving to Dublin as a Consultant in these dual specialties in 1974.

Dr Casey was a single-handed Rheumatologist in the Trinity-associated hospitals for nearly 30 years, cycling his bicycle between St James's Hospital, Dr Steevens's Hospital and the Adelaide and Meath hospitals, the latter two subsequently merging into Tallaght hospital in the 1990s. He retained close links with Trinity College, holding the honorary title of Senior Lecturer and pursuing collaborative research with his colleagues, particularly in the fields of Immunology, Dermatology and Gastroenterology.

Dr Casey has a life-long interest in teaching and has inspired several generations of young physicians. He continues to provide guidance at the weekly Medical Update meetings in St James's and was famous for the pre-MRCPI tutorials for Senior House Officers which took place in his own home several times a year.

Dr Casey was President of the Irish Society for Rheumatology from 1990 – 1992. The ISR is delighted to honour him with the 2013 Lifetime Achievement Award for services to teaching, research and clinical work in the field of Rheumatology.

## SpR Update

This year the Royal College of Physicians has been busy signing off five rheumatology specialist registrars from the training scheme. Congratulations to Drs Ausaf Mohammad, Bernadette Lynch, Grainne Murphy, Joanne Kitchen and Peter Browne on completing their rheumatology and GIM training this year. They have all recently either taken up a consultant post or will be doing so in the near future in Ireland and the UK.

Also, congratulations to this year's winners of the 3 rheumatology educational bursaries; Dr Lorraine O'Neill received the MSD fellowship to support her research project, Dr Richard Conway was awarded the Bresnihan Molloy fellowship sponsored by Abbvie and Dr Fahd Adeeb Ashraf received the Pfizer bursary for his research.

Finally, the SpRs would like to welcome Dr Carl Orr, who joined the rheumatology scheme this year. Carl has started his training in a research post in St Vincents University Hospital.

## ISR Young Investigator Award 2013

### Muhammad Haroon

MB, MMedSc, MRCPI



Muhammad Haroon graduated in Medicine from King Edward Medical College Lahore in 1999. He completed his basic specialist training in Ireland before embarking on higher specialist training in Rheumatology. He also received his Masters in Sports and Exercise Medicine from University College Cork. He undertook a period of research at St Vincent's University Hospital Dublin under the supervision of Prof Oliver FitzGerald, and developed a special interest in clinical and genetic research in Psoriatic Arthritis and Spondyloarthropathies. He has authored so far, 33 peer-reviewed articles as a first author, and has presented >50 abstracts as first author in different national and international rheumatology meetings. He has recently taken up the post of Consultant Rheumatologist at Kerry General Hospital and South Infirmity-Victoria University Hospital, Cork.





## Welcome from Academic Team at St. James's Hospital

Welcome to the 2013 AGM of the Irish Society for Rheumatology. We are thrilled to have an exciting and stimulating programme with key speakers from Ireland and around the world presenting the latest information on rheumatic diseases and related subjects. Professor John H Stone (Boston) has a special interest in vasculitis and has won several awards both for his work in this field and for excellence in teaching. Dr Ronan Kavanagh (Galway) will update us on the use of new technologies which can help to educate and improve communication with our patients and each other. Professor Jim Lucey (Dublin) will speak about the importance of mental well-being in those with chronic arthritis, while Professor Isenberg (London) will deliver his expertise on the treatment of SLE. The subject of new therapies for osteoarthritis will be discussed by Professor Philip Conaghan (Leeds) and we will hear about recent research into Ankylosing Spondylitis from Professor Robert Inman (Toronto). In addition, we are looking forward to the presentations by our young physicians, scientists and health professionals. We applaud all of the work that has gone into the production of abstracts on a wide variety of clinical and scientific subjects in the field of Rheumatology. We hope you enjoy our programme and look forward to seeing you in Trim.

**Professor Gaye Cunnane, Dr Michele Doran  
and Dr Barry O'Shea, Academic Organisers**

## Academic Organising Team Biographical Sketches

### Professor Gaye Cunnane

PhD, MB, FRCPI



Professor Gaye Cunnane is a Clinical Professor of Rheumatology and Consultant Rheumatologist at Trinity College / St James's Hospital, Dublin. She received her medical degree from Trinity College and her subsequent PhD from University College Dublin. Her Fellowship training took place at the University of California, San Francisco, USA, after which she joined the University of Leeds, UK as Senior Lecturer in Rheumatology before taking up her current post in Dublin.

In addition to her clinical duties, Professor Cunnane is the Intern Tutor and Director of Post-graduate Education at St James's Hospital/Trinity College where she also runs a research programme which focuses on cardiovascular risk factors in inflammatory arthritis. She has held a number of recent national roles in Irish Rheumatology, including National Specialty Director for Rheumatology Training (2005 – 2012). She is the immediate past President of the Irish Society for Rheumatology.

### Dr Michele Doran

MD, FRCPI



Dr. Michele Doran is a Consultant Rheumatologist/Trinity College Lecturer in Medicine since 2003. She graduated from University College Dublin and completed her initial training between St Vincent's and the Mater Misericordiae University Hospitals. She then commenced her specialist training in Rheumatology and General Medicine and completed this over subsequent years between Ireland, UK, and USA. She spent 2 years working as a Research Fellow at the Mayo Clinic, USA, from which she obtained a Doctor of Medicine Degree by thesis and a Masters Degree in Clinical Research. Her areas of interest include early inflammatory arthritis, teaching and the epidemiology of rheumatic diseases.

### Dr Barry O'Shea

MB, MRCPI



Dr Barry O'Shea is a Consultant Rheumatologist in St James's Hospital, Dublin. During his specialist training in Rheumatology he worked in St Vincent's Hospital, Waterford Regional Hospital, St James's Hospital and the Mater Hospital. He was the inaugural recipient of the Irish Society for Rheumatology / Wyeth Travelling Fellowship award. This facilitated the completion of his training in the University of Toronto and Toronto Western Hospital, Canada. He went on to undertake a Research Fellowship in Toronto with Dr Robert Inman. Specifically he was involved in coordinating and running the Spondylitis Clinic in Toronto Western Hospital. Particular areas of research included imaging of the sacroiliac joint and spine in back pain and ankylosing spondylitis (AS), as well as comparative studies between juvenile and adult onset AS. He has presented at the American College of Rheumatology Annual Meeting on this work. Since his return to St James's Hospital he has established a dedicated multi-disciplinary AS Clinic. He is an active member of ASAS (Assessment of SpondyloArthritis international Society), an international group of experts in the field of AS. He is a co-founder and principal investigator of ASRI – the recently created Ankylosing Spondylitis Registry of Ireland, a national database of patients with AS from across Ireland.





## Invited Speakers Biographical Sketches

### Professor John Stone

MD, MPH,



Professor John H Stone is Professor of Medicine at the prestigious Harvard Medical School and Director of Clinical Rheumatology at the Massachusetts General Hospital (MGH), Boston. He has had a career-long interest in teaching, research, and clinical care of patients with rheumatic diseases. His research has focused on the systemic vasculitides and, more recently, on IgG4-related disease (IgG4-RD).

Prof Stone graduated from Harvard Medical School, after which he completed his internal medicine training at Johns Hopkins University, Baltimore, and then moved to the University of California-San Francisco as a Rheumatology Fellow. He subsequently returned to Johns Hopkins as Faculty member where he co-founded and directed the Vasculitis Center at Johns Hopkins University, the first of its kind in the United States.

In 2008, he was recruited as Director of Clinical Rheumatology at the Massachusetts General Hospital (MGH), where he has continued his extensive research in vasculitis, publishing many highly-cited articles, including those as first author in the New England Journal of Medicine. He is the Section Editor for Vasculitis on Up-to-Date. He has written and edited a new book entitled A Clinician's Pearls & Myths in Rheumatology (Springer). His work has significantly changed clinical practice in relation to the management of vasculitis and facilitated the use of new drugs for the treatment of these diseases. He is the global Principal Investigator for a new clinical trial of interleukin-6 receptor blockade in giant cell arteritis that will enroll its first patients in 2013.

Professor Stone has won many awards for his work, including 2 Department of Medicine Teaching Awards. He has conducted "Meet the Professor" or "Curbside Consultation" sessions each year at the American College of Rheumatology meetings since 2002. He has lectured on this work in the United States, Europe, and Asia. He gave the Sir James Cameron Lecture at the Royal College of Physicians (Edinburgh) in 2003, the Dunlop-Dottridge Lecture at the Canadian Rheumatology Association (2007), the Woodbury Lecture at Dalhousie University (2010), the Cogen Lecture at Maine Medical Center (2011), and the Dworkin Memorial Lecture at McGill University in 2012.

### Professor Jim Lucey

MD (Dub), PhD (Lond), FRCPI, FRCPsych



Medical Director, St. Patrick's University Hospital, Dublin and Clinical Professor of Psychiatry, TCD

Clinical Expertise: Prof. Jim Lucey is Medical Director of St. Patrick's University Hospital since 2008. He has more than 25 years experience in psychiatry. In addition to medical management he maintains his clinical practice at St. Patrick's where he works on the assessment, diagnosis and management of obsessive compulsive (OCD) and other anxiety disorders.

Career: Prof. Lucey was educated at St. Michaels College and at the Royal College of Surgeons in Ireland (RCSI) where he qualified in medicine in 1977. He trained in psychiatry at St. Patrick's Hospital in Dublin and at the Maudsley Hospital in London, graduating with an MD from Trinity College, Dublin and a PhD from the University of London. He is a fellow of the Royal College of Physicians of Ireland and of the Royal College of Psychiatrists in London, as well as a member of the College of Psychiatry of Ireland.

In 1993 he was appointed Consultant Psychiatrist, and Director of Psychiatric Intensive Care in St. Bartholomew's Hospital in London. He returned to Ireland in 1997 to become a Consultant Psychiatrist with at Connolly Hospital. In 2002 he was appointed to St. Patrick's where he became the Director of the Anxiety Disorders Service and also Consultant Psychiatrist with responsibility for electro-convulsive therapy. He has been a Senior Lecturer in Psychiatry at the University of London (1993-1997) at St. Bartholomew's Hospital, London, and at The Royal College of Surgeons in Ireland (1998-2002) and is currently Clinical Professor of Psychiatry at Trinity College Dublin.

Other Activities: Dr. Lucey's research includes studies into the biology of OCD. Dr Lucey provides psychiatric assessment services to undergraduate students at The Royal College of Surgeons in Ireland (RCSI). He teaches medical undergraduates and post graduate students of psychiatry at TCD. He gives public lectures and is a regular broadcaster on mental health matters on RTE radio.



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Full prescribing information is available upon request from AbbVie Limited, Block B, Liffey Valley Office Campus, Quarryvale, Co Dublin, Ireland. **Legal category** POM. **Marketing Authorisation Numbers:** EU/1/03/256/001-005, EU/1/03/256/007-010. **Marketing Authorisation Holder:** AbbVie Ltd., Maidenhead, Berkshire SL6 4XE, UK.

**Reference: 1.** For more information on HUMIRA's licensed indications, please refer to Humira's Summary of Product Characteristics available on [www.medicines.ie](http://www.medicines.ie).

IREHUR130242

**Date of Preparation:** August 2013

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**Ronan Kavanagh**

MD, MRCPI

Dr Ronan Kavanagh is a Consultant Rheumatologist at the Galway Clinic. His special interests include the management of inflammatory arthritis and osteoporosis. In addition, he runs a clinic for musicians with musculoskeletal disorders.



He has expertise in the use of new technologies (including social media and blogging) to help keep himself (and his patients) up to date with current developments in rheumatology.

Dr Kavanagh also acts as a medical advisor to a number of medical technology companies (Clear.MD, Full Health and Healthsnap) and runs an annual medical innovation meeting (DotMed), the next one of is scheduled for 6th December 2013.

He is a former president and secretary of the Irish Society for Rheumatology and a founding member of Performing Arts Medicine Ireland and a member of the British Association of Performing Arts Medicine, Performing Arts Medicine Association (USA) and the American College of Rheumatology.

**Professor David Isenberg**

MD, FRCP, FAMS

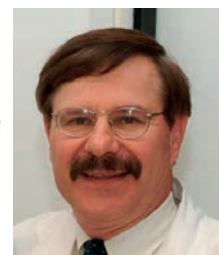
Professor Isenberg is the Arthritis Research UK Diamond Jubilee Professor of Rheumatology, University College London Medical School, UK. He graduated from the University of London in 1973, after which he pursued his clinical training at University College Hospital (UCH), London. He undertook the Jules Thorn Scholarship in Rheumatology & Haematology in UCH, after which he became a Research Fellow in Haematology / Oncology at Tufts University, Boston, USA. He returned to the UK in 1983 as a Senior Registrar in Rheumatology at UCH and shortly afterwards was offered a Consultant Rheumatologist post. He has been Professor of Rheumatology since 1992. He has an extensive publication record and has been honoured on multiple occasions for his research in SLE and other rheumatic diseases. He received the Evelyn Hess prize award in 2010 from The Lupus Foundation of America for 'outstanding contribution to research and treatment of Lupus'. He was awarded the Roger Demers award in 2012 from the Laurentian Conference of Rheumatology for 'Unique Contribution to International Rheumatology'.



**Professor Robert Inman**

MD

Dr. Inman completed his undergraduate degree at Yale University, USA and his medical degree at McMaster University, Canada. He did his training in Internal Medicine at Vanderbilt University and his fellowship in Rheumatology at Cornell University, based at the Hospital for Special Surgery, USA. He worked as a research fellow at the Hammersmith Hospital in London, UK and was then appointed Assistant Professor of Medicine at Cornell University, USA. He moved to the University of Toronto where he was appointed Professor in the Departments of Medicine and Immunology. He was Director of Rheumatology at the University of Toronto 1991-2002. He is currently Director of the Arthritis Center of Excellence at the University Health Network, Director of the Spondylitis Program at Toronto Western Hospital, and Deputy Physician in Chief, Research at University Health Network. He has held many national and international appointments including the member of the Board of Directors of the American College of Rheumatology, Chair of the Medical and Scientific Board of the Spondylitis Association of America, and member of the Advisory Board of the Assessment of Spondyloarthritis International Society (ASAS).



**Professor Philip Conaghan**

MBBS PhD FRACP FRCP

Professor Philip Conaghan holds the Chair of Musculoskeletal Medicine at the University of Leeds, and is a Consultant Rheumatologist for the Leeds Teaching Hospitals NHS Trust. He is a Senior Investigator for the UK NIHR and is Deputy Director of the NIHR Leeds Musculoskeletal Biomedical Research Unit. His research covers a spectrum from translational studies through to large clinical trials. His major research interests are in understanding pathogenesis and therapeutic response in arthritis, with a special focus on the role of imaging biomarkers. Nationally he is Chair of the NICE OA Guidelines Development Group and of the Arthritis Research UK Osteoarthritis Clinical Studies Group; internationally he is co-Chair of the international outcomes group OMERACT. He was President of the International Society for Musculoskeletal Imaging in Rheumatology and inaugural Chair of the EULAR Standing Committee on Musculoskeletal Imaging. He is co-editor of the Oxford Textbook of Rheumatology, is on a number of journal editorial boards and has authored over 300 publications.





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**ADENURIC 80 mg and 120 mg film-coated tablets: Abbreviated Prescribing Information** Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing 80 mg or 120 mg febuxostat. Also contains lactose monohydrate. **Use:** Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis) in adults. **Dosage and administration:** Oral use with or without food. Recommended dose is 80 mg once daily. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, 120 mg once daily may be considered. **Elderly:** No dose adjustment required. **Renal impairment:** No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. **Hepatic impairment:** Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. **Children and adolescents:** Safety and efficacy in children under 18 has not been established. **Organ transplant recipients:** No experience therefore not recommended. **Contra-indications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** **Cardio-vascular disorders:** **Not recommended in patients with ischaemic heart disease or congestive heart failure.** **Product allergy/hypersensitivity:** Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, and do not re-start febuxostat at any time. **Acute gouty attacks (gout flare):** Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares. **Xanthine deposition:** As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience, febuxostat is not recommended for use in these populations. **Mercaptopurine/azathioprine:** Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. **Theophylline:** Use with caution in patients concomitantly treated with theophylline. Monitor theophylline levels in patients starting febuxostat therapy. **Liver disorders:** Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. **Thyroid disorders:** Caution in patients with alteration of thyroid function. **Lactose:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** **Mercaptopurine/azathioprine:** On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. No data is available regarding the safety of febuxostat during cytotoxic chemotherapy. **Theophylline:** Inhibition of XO may cause an increase in the theophylline level. Caution advised if these substances are given concomitantly, monitor theophylline levels in patients starting febuxostat therapy. **Naproxen and other inhibitors of glucuronidation:** Can be co-administered with naproxen with no dose adjustments necessary. **Inducers of glucuronidation:** Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of febuxostat. **Colchicine/indomethacin/hydrochlorothiazide/warfarin:** Can be co-administered with

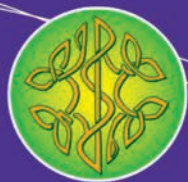
colchicine or indomethacin with no dose adjustments necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. **Desipramine/CYP2D6 substrates:** Co administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. **Antacids:** May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects:** **Clinical Studies and post-marketing experience:** **Common (1-10%):** Gout flares, headache, diarrhoea\*, nausea, liver function test abnormalities\*, rash, oedema. **Uncommon (0.1-1%):** Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hypoaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discolouration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, haematocrit decrease, blood lactate dehydrogenase increased, blood potassium increase. **Rare (0.1-0.01%):** Pancytopenia, thrombocytopenia, anaphylactic reaction\*\*, drug hypersensitivity\*\*, blurred vision, weight decrease, increase appetite, anorexia, nervousness, tinnitus, pancytopenia, mouth ulceration, hepatitis, jaundice\*\*, Stevens-Johnson Syndrome\*\*, angioedema\*\*, generalized rash (serious)\*\*, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic\*\*, rash erythematous, rash morbilliform, alopecia, hyperhidrosis, rhabdomyolysis\*\*, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis\*\*, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase. \*Treatment-emergent non-infective diarrhoea and abnormal liver function tests in combined Phase III studies more frequent in patients concomitantly treated with colchicine. \*\*Adverse reactions coming from post-marketing experience. Rare serious hypersensitivity reactions including Stevens-Johnson Syndrome and anaphylactic reaction/shock have occurred in post-marketing experience. Hypersensitivity reactions to febuxostat can be associated with the following symptoms: skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia, and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Gout flares commonly observed soon after treatment start and in first months. Frequency decreases after time. Gout flare prophylaxis is recommended. Please consult the SmPC for further information. **Pack sizes:** 80 mg and 120 mg tablets: 28 film-coated tablets. **Legal category:** POM. **Marketing authorization number:** EU/1/08/447/001 & 003. **Marketing authorization holder:** Menarini International Operations Luxembourg S.A., Avenue de la Gare, L-1611 Luxembourg, Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin or may be found in the SmPC. **Last updated:** January 2013. **References:** 1. Adenuric SmPC. December 2012. 2. McQueen, F.M., et al. *Nat Rev Rheumatol*, 2012. 8(3): p. 173-81.

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Date of item: January 2013  
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## Oral Presentations – Autumn Meeting 2013 September 19th and 20th 2013

	Abstract No	Abstract Title	Author(s)	Day	Time
<b>PLENARY SESSION 1: SCIENTIFIC ORAL PRESENTATIONS</b>					
1	13A121	Interleukin-34 regulates angiogenesis in Inflammatory Arthritis	Emese Balogh	Thurs	10.30
2	13A136	Hypoxia and STAT3 signalling interactions regulate pro-inflammatory pathways in Rheumatoid Arthritis	Wei Gao	Thurs	10.45
3	13A161	TLR-2 induces pro-inflammatory/angiogenic mechanisms in GCA Temporal artery explant cultures ex vivo	Aoife Maher	Thurs	11.00
4	13A171	Characterising monocyte activation in Caucasian SLE Patients	Eoghan M. McCarthy	Thurs	11.15
<b>PLENARY SESSION 2: CLINICAL ORAL PRESENTATIONS</b>					
5	13A105	Defining hand arthritis in SLE, from an Ultrasound, MRI & antibody status perspective	Elisabeth Ball	Thurs	1.30
6	13A151	Declining incidence of co-morbidities in rheumatoid arthritis inpatients: 6yr analysis of nationwide data	Len Harty	Thurs	1.45
7	13A158	Does rheumatoid arthritis disease activity correlate with weather conditions?	Eimear Savage	Thurs	2.00
8	13A179	Major cost savings associated with reduced biologic dosing frequency in Inflammatory Arthritis-2 year data	Claire-Louise Murphy	Thurs	2.15
<b>PLENARY SESSION 3: CLINICAL CASE ORAL PRESENTATIONS</b>					
9	13A133	Case 1 (Abstract 9)	Claire Benson	Friday	9.00
10	13A138	Case 2 (Abstract 10)	Ali Taha	Friday	9.15
11	13A160	Case 3 (Abstract 11)	Kieran Murray	Friday	9.30
12	13A168	Case 4 (Abstract 12)	Surabhi Waghmare	Friday	9.45
<b>PLENARY SESSION 3: YOUNG INVESTIGATOR AWARD</b>					
13	13A132	A novel evidence-based detection of undiagnosed Spondyloarthritis in patients presenting with Acute Anterior Uveitis: the DUET (Dublin Uveitis Evaluation Tool)	Muhammad Haroon	Friday	12.00





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The IV anti-TNF for patients that:<sup>1</sup>

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- are unable to self inject
- need medical supervision

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**Indications:** Rheumatoid Arthritis (RA): Remicade, in combination with methotrexate (MTX), is indicated for the reduction of signs and symptoms, as well as the improvement in physical function, in adult patients with active RA when the response to disease-modifying anti-rheumatic drugs (DMARDs), including MTX, has been inadequate; and in adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X-ray, has been demonstrated. **Adult Crohn's Disease (CD):** Remicade is indicated for the treatment of moderately to severely active CD in adult patients who have not responded to, or are intolerant of, a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; and fistulising active CD in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). **Paediatric Crohn's Disease (CD):** Remicade is indicated for the treatment of severe, active CD in children and adolescents aged 6 to 17 years who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy, or who are intolerant to or have contraindications for such therapies. **Ulcerative Colitis (UC):** Remicade is indicated for the 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. **Paediatric Ulcerative Colitis (UC):** Remicade is indicated for treatment of severely active UC, in children and adolescents aged 6 to 17 years, 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. **Ankylosing Spondylitis (AS):** Remicade is indicated for the treatment of severe, active AS, in adult patients who have responded inadequately to conventional therapy. **Psoriasis (PsO):** Remicade is indicated for the treatment of active and progressive PsA, in adult patients when the response to previous DMARD drug therapy has been inadequate. Administration should be in combination with MTX or alone in patients who show intolerance to MTX or for whom MTX is contraindicated. A reduction in the rate of progression of peripheral joint damage in patients with polyarticular symmetrical subtypes of PsA has been measured by X-ray. **Psoriasis (PsO):** Remicade is indicated for the treatment of moderate to severe plaque PsO in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, MTX or PUVA. **Dosage and administration:** To improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded in the patient file. Remicade should be administered intravenously, initiated and supervised by physicians experienced in the diagnosis and treatment of RA, CD, UC, AS, PsA and PsO. Remicade should be administered intravenously over a 2-hour period. All patients administered Remicade should be observed for at least 1 to 2 hours post infusion for acute infusion-related reactions by appropriately trained healthcare professionals. **Shortened infusions across adult indications:** In carefully selected adult patients who have tolerated at least 3 initial 2-hour infusions of Remicade (induction phase) and are receiving maintenance therapy, consideration may be given to administering subsequent infusions over a period of not less than 1 hour. If an infusion reaction occurs in association with a shortened infusion, a slower infusion rate may be considered for future infusions if treatment is to be continued. Shortened infusions at doses >6 mg/kg have not been studied. RA: 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. **Adult moderately to severely active CD:** 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment should be given. **Adult, fistulising, active CD:** 5 mg/kg intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after first infusion. If a patient does not respond after 3 doses, no additional treatment should be given. **UC:** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. Clinical response is usually achieved within 14 weeks of treatment (3 doses). AS: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 6 to 8 weeks. If a patient does not respond after 2 doses, no additional treatment should be given. PsA: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. If a patient shows no response after 4 doses, no additional treatment should be given. **Readministration:** Remicade can be readministered within 16 weeks following the last infusion. The safety and efficacy of readministration after a Remicade-free interval of more than 16 weeks has not been established in either CD or RA. The safety and efficacy of readministration in AS, other than every 6 to 8 weeks and in PsA and UC, other than every 8 weeks, has not been established. Readministration with one single Remicade dose in PsO after an interval of 20 weeks suggests reduced efficacy and a higher incidence of mild to moderate infusion reactions when compared to the initial induction regimen. Limited experience from retreatment, using a reinduction regimen suggests a higher incidence of infusion reactions, some serious, when compared to 8 weekly maintenance treatment. In case maintenance therapy is interrupted in any indication, and there is a need to restart treatment, Remicade should be reinitiated as a single dose followed by the maintenance dose recommendations. **Paediatric population:** CD (6 to 17 years): 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond by 10 weeks, no additional treatment should be given. **UC (6 to 17 years):** 5 mg/kg given as an intravenous infusion over a 2-hour period followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data do not support further infliximab treatment in paediatric patients not responding within the first 8 weeks of treatment. **Contra-indications:** Tuberculosis or other severe infections such as sepsis, abscesses and opportunistic infections; patients with a history of hypersensitivity to infliximab, other murine proteins or any of the excipients; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** **Infection reactions:** Acute infusion reactions including anaphylactic reactions may develop during (within seconds) or within a few hours following infusion. If acute infusion reactions occur, the infusion must be interrupted immediately. Emergency equipment, such as adrenaline, antihistamines, corticosteroids and an artificial airway must be available. Antibodies to infliximab may develop and have been associated with increased frequency of infection reactions. Symptomatic treatment should be given and further Remicade infusions must not be administered. In clinical studies, delayed hypersensitivity reactions have been reported. Available data suggest an increased risk for delayed hypersensitivity with increasing Remicade-free intervals. **Infections:** Patients must be monitored closely for infections, including tuberculosis, before, during and up to 6 months after treatment with Remicade. Exercise caution with use of Remicade in patients with chronic infection or a history of recurrent infection. Patients should be advised of potential risk factors for infections. Suppression of TNF $\alpha$  may mask symptoms of infection such as fever, tuberculosis, bacterial infections including sepsis and pneumonia, invasive fungal, viral and other opportunistic infections, have been observed, some of which have been fatal. Infections were reported more frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving Remicade. Patients should be evaluated for active or latent tuberculosis before Remicade treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active tuberculosis is diagnosed, Remicade therapy must not be initiated. If latent tuberculosis is diagnosed, treatment with anti-tuberculosis therapy must be initiated before initiation of Remicade. Patients on Remicade treatment should be advised to seek medical advice if symptoms of tuberculosis appear. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected in patients if a serious systemic illness is developed, a physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD and acute suppurative fistulas must not initiate Remicade therapy until possible source of infection is excluded. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Remicade who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Remicade. **Hepatobiliary events:** Very rare cases of jaundice and non-infectious hepatitis, some with features of autoimmune hepatitis have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. **Vaccinations:** It is recommended that live vaccines not be given concurrently. Prior to initiating Remicade therapy it is recommended that paediatric patients be brought up to date with all vaccinations. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Remicade and is positive for antibodies against double-stranded DNA, treatment must be discontinued. **Neurological events:** Anti-TNF $\alpha$  agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of Remicade therapy. Discontinuation of Remicade should be considered if these disorders develop. **Malignancies and lymphoproliferative disorders:** A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution is advised in patients with history of malignancy and in patients with increased risk for malignancy due to heavy smoking. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. All Remicade cases have occurred in patients with CD or UC treated concomitantly with AZA or 6-MP. Caution should be exercised in patients with PsO and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Patients with UC or UC treated concomitantly with AZA or 6-MP should be screened for dysplasia before therapy and at regular intervals throughout their disease course. Melanoma and Merkel cell carcinoma have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart failure:** Remicade should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in face of new or worsening symptoms of heart failure. **Others:** Patients requiring surgery whilst on Remicade therapy should be closely monitored for infections. **Haematologic reactions:** Discontinuation of Remicade therapy should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leucopenia, neutropenia and thrombocytopenia. **Special populations:** Particular attention should be paid when treating the elderly (>65 years) due to a greater incidence of serious infections seen in Remicade-treated patients. Some of these had a fatal outcome. **Interactions:** No interaction studies have been performed. Combination of Remicade with other biological therapeutics used to treat the same conditions as Remicade, including anakinra and abatacept is not recommended. It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently with Remicade. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Remicade treatment. Administration of Remicade is not recommended during pregnancy or breast-feeding. Administration of live vaccines to infants exposed to infliximab in utero is not recommended for 8 months following the mother's last infliximab infusion during pregnancy. Effects of infliximab on fertility and general reproductive function are unknown. **Side-effects:** Very Common >1/10: Viral infection, headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, infusion related reaction, pain. Common >1/100 to <1/10: Bacterial infections, neutropenia, leucopenia, anaemia, lymphadenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hypoaesthesia, paraesthesia, conjunctivitis, tachycardia, palpitation, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection, dyspnoea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm & soles), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, arthralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills and oedema. In phase 3 clinical studies, 18% of infliximab-treated patients compared with 5% of placebo-treated patients experienced an infusion related reaction. In post-marketing spontaneous reporting, infections are the most common serious adverse event. The most frequently reported opportunistic infections with a mortality rate of >5% include pneumocystosis, candidiasis, listeriosis and aspergillosis. **Other less common and rarely reported side effects are listed in the SPC. Overdose:** No case of overdose has been reported. Single doses up to 20 mg/kg have been administered without toxic effects. **Package Quantities:** Type I vials, with rubber stoppers and aluminium crimps protected by plastic caps, containing a lyophilised powder (infliximab 100mg). **Legal Category:** POM Marketing Authorisation Number: EU/199/116/001 Marketing Authorisation Holder: Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands © Merck Sharp & Dohme Ireland (Human Health) Limited, 2013. All rights reserved. **Date of Revision:** July 2013 Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. Date of preparation: August 2013.

**Reference:** 1: Remicade (Remicade/SPC/EU/07-13/053) Summary of Product Characteristics June 2013. For full text see www.medicines.ie.







## PLENARY SESSION 1

### SCIENTIFIC RESEARCH ORAL PRESENTATIONS

#### Abstract 1 (13A121)

#### Oral Presentation

##### Interleukin-34 regulates angiogenesis in Inflammatory Arthritis

Emese Balogh, Monika Biniecka, Mary Connolly, Jennifer McCormick, Douglas J. Veale, U. Fearon

Rheumatology, Translational Research Group, Dublin Academic Medical Center, St. Vincent's University Hospital, Dublin, Ireland

**Introduction:Aims/Background:** IL-34 is a cytokine implicated in angiogenesis and osteoclastogenesis in inflammatory arthritis(IA), we investigated its role in the regulation of angiogenesis and hypoxia in IA.

**Method:** IA patients (n=23) were recruited with a subgroup of (n=6) pre-post TNFi therapy. Knee synovial tissue (ST) was collected and in vivo ST tpO<sub>2</sub> was measured. Synovial IL-34, VEGF, Ang-2, Tie-2 and Ki67 expressions were measured by immunohistology, colocalisation by immunofluorescence. IA fibroblasts(IASFC) and human endothelial cells (HMVECs) were examined by proliferation/tube formation assays. VEGF expression was measured by ELISA, IAFSC and osteoarthritic (OASFCs) mRNA levels were compared by RT-PCR. MMP expression was examined by zymography, PBMC adhesion by adhesion assay.

**Results:** Baseline mean tpO<sub>2</sub> level was hypoxic(25.94 mmHg). Highest IL-34 expression was observed in the vascular region. IA synovial IL-34 expression was higher compared to control(p<0.05), and correlated with VEGF(r=0.60, p=0.011), Tie2(r=0.50, p=0.021), Ang2(r=0.70, p=0.013) and Ki67(r=0.56, p=0.025) and macroscopic vascularity(r=0.47, p=0.043). IL-34 expression decreased in the sublining/vascular layers(p=0.039, p=0.026) posttherapy, tpO<sub>2</sub> increased(20.9->23.2 mmHg). IL-34 colocalised with actin/vimentin at baseline. Basal IL-34 mRNA expression was higher in IASFCs than in OASFCs(p<0.05), the previous was potentiated by TNF? stimulation(p<0.05). IL-34 induced proliferation and tube formation(all p<0.05), that was potentiated by hypoxia(p<0.05). IL-34 induced VEGF expression in IASFCs and stimulated PBMC adhesion to HMVECs, also facilitated MMP-2/MMP-9 expression.

**Conclusions:** IL-34 is strongly associated with synovial inflammation and promotes synovial angiogenesis and cell proliferation, an effect that is potentiated by hypoxia.

#### References:

Interleukin 34 expression is associated with synovitis severity in rheumatoid arthritis patients. Chemel M, Le Goff B, Brion R, Cozic C, Berreur M, Amiaud J, Bougras G, Touchais S, Blanchard F, Heymann MF, Berthelot JM, Verrecchia F, Heymann D. Ann Rheum Dis. 2012 Jan;71(1):150-4.

Redox balance dynamically regulates vascular growth and remodeling. Shyamal C. Bir, Gopi K Kolluru, Kai Fang, Christopher G. Kevil. Semin Cell Dev Biol. 2012 Sep; 23(7):745-57.

#### Abstract 2 (13A136)

#### Oral Presentation

##### Hypoxia and STAT3 signalling interactions regulate pro-inflammatory pathways in Rheumatoid Arthritis

Wei Gao, Jennifer McCormick, Mary Connolly, Emese Balogh, Douglas J. Veale, Ursula Fearon

Rheumatology Department, St. Vincent's University Hospital, Dublin

**Introduction:** Signal Transducer and Activator of Transcription 3 (STAT3), plays a crucial role in the pathogenesis of Rheumatoid Arthritis.

**Aims/Background:** This study was to examine the effect of hypoxia on STAT3-induced pro-inflammatory pathways in RA.

**Method:** Expression of pSTAT3 was assessed by IH/IF. Primary RASFC and synoviocyte cell lines (K4IM) were cultured under 3% hypoxia and normoxia conditions +/-Stat3-siRNA, HIF-siRNA or WP1066. HIF1 $\alpha$ , p-STAT3 and Notch-1IC protein expression were analyzed by Western blot. Functional mechanisms were quantified by invasion chamber, matrigel and wound repair assays. IL-6, IL-8, IL-10 and MMP-3 were quantified by ELISA. Notch-1 receptor, its DLL-4 ligand and downstream target genes were quantified by Real-time PCR. Finally the effect of WP1066 on spontaneous secretion of pro/anti-inflammatory cytokines was examined in RA synovial explants ex-vivo.

**Results:** Increased p-STAT3 expression was demonstrated in RA synovium compared to healthy control and 3% hypoxia induced nuclear translocation of p-STAT3 in RASFC. Hypoxia induced p-STAT3 and HIF1 $\alpha$  expression, an effect blocked by Stat3-siRNA and WP1066. Hypoxia-induced cell invasion, migration and cytokine production were inhibited by Stat3-siRNA and WP1066. While HIF1 $\alpha$  siRNA inhibited hypoxia-induced p-STAT3 expression, Stat3-siRNA also inhibited hypoxia-induced HIF1 $\alpha$ . Furthermore hypoxia-induced Notch-1IC, DLL4, hrt-1 and -2 expression were significantly inhibited by STAT3 blockade. Finally, in RA synovial explant cultures ex-vivo, STAT3 blockade decreased spontaneous secretion of IL-6, IL-8 and MMP3, and induced IL-10.

**Conclusions:** This is the first study to provide evidence of a functional link between HIF1 $\alpha$ , STAT3 and Notch-1 signalling in the regulation of pro-inflammatory mechanisms in RA.

#### Abstract 3 (13A161)

#### Oral Presentation

##### TLR-2 induces pro-inflammatory/angiogenic mechanisms in GCA Temporal artery explant cultures ex vivo

A. Maher, D. Molloy, J. McCormick, L. O'Neill, D. Veale, C. Murphy, U. Fearon, E. Molloy

Dublin Academic Medical Centre, St. Vincent's University Hospital and Royal Victoria Eye and Ear Hospital, Dublin

**Introduction:** Giant cell arteritis (GCA) is a common form of primary vasculitis characterised by dysfunctional vessels and inflammatory infiltration leading to luminal occlusion. Toll-Like receptor 2(TLR2) has been implicated in the pathogenesis of GCA.



**Aims/Background:** This study examines the mechanistic role of TLR2 activation in regulating the pro-inflammatory mechanisms in GCA.

**Method:** Temporal artery (TA) sections from patients with GCA were assessed for TLR2 expression by immunohistology. Ex-vivo TA explant cultures were stimulated with Pam3CSK4 (TLR2 agonist)(1ug/ml) for 24 hrs. VEGF, Ang2, IL-6, IL-8 and MMP2/9 expression were quantified in cultured supernatants by ELISA and gelatin zymography. The effect of Pam3CSK4-induced GCA TA-explant conditioned media (CM) on endothelial cell (dHMEC) function was assessed by angiogenic assays. GCA TA-explant myofibroblast outgrowth was assessed using matrigel assays<sup>1</sup>. The effect of GCA TA-explant CM on HEK-TLR2 cells was quantified by NF- $\kappa$ B-luciferase reporter assays.

**Results:** TLR2 expression was higher in positive TA-sections. Pam3CSK4 significantly increased VEGF, IL-6 and IL-8 expression, with differential effects observed for Ang2 and MMP2/9 in TA explant cultures. Pam3CSK4-induced GCA TA CM promoted dHMEC tube formation. Pam3CSK4-induced myofibroblast outgrowths from GCA TA-explants. GCA TA CM induced TLR2 activation through induction of NF- $\kappa$ B activation in HEK-TLR2 cells( $p < 0.05$ ), confirming the presence of endogenous ligands for TLR2 at the site of inflammation.

**Conclusions:** Using ex-vivo TA-explant cultures, TLR2 activation induced angiogenic and invasive functional mechanisms. Furthermore activation of TLR2 by GCA TA CM, suggests that TLR2 may represent a potential therapeutic target for GCA.

**References:** 1. Lozano E, Segarra M, García-Matínez A, Hernández-Rodríguez J, Cid MC. (2008) Imatinib mesylate inhibits in vitro and ex vivo biological responses related to vascular occlusion in giant cell arteritis. *Ann Rheum Dis.*, 67(11): 1581-8.

#### Abstract 4 (13A171)

#### Oral Presentation

#### Characterising monocyte activation in Caucasian SLE Patients

Eoghan M. McCarthy<sup>1,2</sup>, Joan Ní Gabhann<sup>2</sup>, Siobhán Smith<sup>2</sup>, Suzanne Donnelly<sup>3</sup>, Eamonn Molloy<sup>4</sup>, Ann-Barbara Mongey<sup>4</sup>, Donough Howard<sup>1</sup>, Paul O'Connell<sup>1</sup>, Caroline A. Jefferies<sup>2</sup>, Grainne Kearns<sup>1</sup>

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<sup>4</sup>St. Vincent's University Hospital, Dublin

**Introduction:** Monocytes play a significant role in the dysregulated immune response seen in SLE, with members of the Toll like receptor (TLR) family also identified as key players.

**Aims/Background:** To characterise the activation state of SLE monocytes in an Irish population.

**Method:** CD14+ SLE monocytes was characterised in the resting state and following TLR stimulation by flow cytometry using the following markers: CD80, CD86, HLA-DR. Samples were stimulated with TLR 3, 4, 7 and 9.

**Results:** 25 Patients were recruited. Resting state lupus patient monocytes have higher expression of surface CD86 and HLA-DR

compared to controls [(CD86 85.32% v 64.42 %,  $p = 0.018$ )(HLA-DR(68.5% v 46.5%,  $p = .03$ )). Both inactive and active patients expressed more CD86 in their resting state than controls.

Following stimulation with each of the TLR ligands a significant increase in monocyte CD80 expression from the resting state was observed in healthy controls. No significant increase was observed in SLE patient monocytes.

SLE patient monocytes failed to upregulate HLA-DR expression following TLR3 stimulation in comparison to healthy control monocytes, the reverse effect being observed following TLR9 stimulation, with SLE monocytes upregulating HLA-DR expression whereas no increase was observed in healthy control monocytes in response to TLR9.

A significant relationship being observed between %CD80 and %HLA-DR cell surface expression and IFN- $\gamma$  production [(CD 80  $r = 0.69$ ,  $p = 0.016$ )(HLA-DR  $r = 0.623$ ,  $p = 0.03$ )). Monocyte HLA-DR levels also demonstrated significant correlation with serum IL-6 levels ( $r = 0.837$ ,  $p = .001$ ).

**Conclusions:** SLE patient monocytes are hyperactivated in their resting state and appear less responsive to TLR stimulation than controls in part due to this baseline hyperactivated state.

#### PLENARY SESSION 2

#### CLINICAL RESEARCH ORAL PRESENTATIONS

#### Abstract 5 (13A105)

#### Oral Presentation

#### Defining hand arthritis in Systemic Lupus Erythematosus, from an Ultrasound, MRI and antibody status perspective

Elisabeth MA Ball, Arthur Grey, Gunter Steiner, Ai Lyn Tan, Eiji Fukuba, Dennis McGonagle, Aubrey L Bell, Madeleine M Rooney

Queen's University Belfast/Musgrave Park Hospital, Belfast/Chapel Allerton Hospital, Leeds/Medical University Hospital, Vienna

**Introduction:** Musculoskeletal involvement in systemic lupus erythematosus is common but poorly characterised.

**Aims/Background:** Erosive disease in SLE associated with rheumatoid factor (RF) or anti-CCP antibody (ACPA) is often referred to as 'rhupus'<sup>[1]</sup>.

**Method:** 50 SLE patients with joint symptoms and 40 RA patients had a detailed US scan (Grey-scale (GS) and Power Doppler (PD)) of dominant hand/wrist [2,3]. 34 of these SLE patients had a contrast enhanced MRI of their hand which was scored according to the OMERACT RAMRIS system. Extended antibody analysis (including anti-RA33 antibody and ACPA) was performed.

**Results:** 61.8% of SLE patients had MRI determined MCP joint erosion compared to 100% of RA patients. 93.3% had at least one erosion at the wrist with erosions in 45% of the total number ( $n = 240$ ) of SLE carpal bones. There was a strong negative correlation with anti-RA33 and total MRI MCP and PIP bone oedema ( $p = 0.013$  and  $p = 0.019$ ). Five SLE patients fulfilled criteria for 'rhupus' (a positive ACPA or RF in the presence of erosive disease).

There was good correlation of MRI synovitis scores at the MCP joints with MCP ultrasound GS and PD ( $p = 0.003$  and  $p < 0.001$ ).





**Conclusions:** This is the largest study to date using MRI in lupus and the first to combine US and MRI in SLE arthritis. We have shown that erosive lupus arthritis is independent of RF or ACPA status, challenging the use of the term 'Rheupus' as the only manifestation of erosive arthritis in SLE. The association of anti-RA33 with a more favourable outcome has been reported before in RA but not in relation to lupus arthritis.

#### References:

1. Fernández, G. Quintana, F. Rondón et al., "Lupus arthropathy: a case series of patients with rheupus," *Clinical Rheumatology* 2006;25 (2); 164-167.
2. Wakefield RJ et al. Musculoskeletal ultrasound including definitions for ultrasonographic pathology. *J Rheum* 2005; 32(12):2485-87.
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#### Abstract 6 (13A151)

#### Oral Presentation

#### Declining incidence of co-morbidities in rheumatoid arthritis inpatients: 6yr analysis of nationwide data

Harty L, FitzGerald O

Department of Rheumatology, St. Vincent's University Hospital, Dublin 4

**Introduction:** 83% TNFi treated RA patients now reach LDA reducing the systemic burden of RA<sup>(1)</sup>. It is unclear how effective suppression of synovitis has impacted upon RA comorbidities.

**Aims/Background:** To evaluate comorbidities in RA inpt's from 2005-2010.

**Method:** HIPE was evaluated from 57 hospitals from 2005-10. Annual national TNFi prescription was discovered. Values are given as total annual numbers in 2005 and 2010 and the average percentage reduction from 2005-10. Linear regression was employed to assess correlation of TNFi prescription with outcomes.  $p < 0.05$  was significant.

**Results:** 13,902 inpt records were reviewed; F:M 2:1, mean age 66 (Std.Dev 15). 851 RA pts were admitted for non-traumatic rheumatic complaints in 2005, decreasing by 12%pa to 492 in 2010 ( $r^2=0.97$ ,  $p < 0.01$ ). Pts admitted for anaemia decreased by 12%pa from 40 to 20 ( $r^2=0.95$ ,  $p < 0.01$ ) and GORD decreased by 9%pa from 27 to 22. The number of OGD's decreased by 3%pa along with a 6%pa reduction in blood transfusions from 40 to 35. Fractures increased by 4%pa from 55 to 69 whereas the relative incidence of RA inpt events for DM, CVA, MI, Cancer and infection remained stable compared to the general population.

**Conclusions:** TNFi's effects on RA may be both direct and indirect. TNFi prescription negatively correlates with admissions for arthritis and anaemia in RA pts possibly due to reduced NSAID and steroid usage. Despite wider TNFi use, cancer and infection rates remain stable as do DM, cardio & cerebrovascular incidents. Fractures in RA pts continue to increase possibly related to greater longevity or enhanced locomotion.

**References:** 1. Smolen JS, et al. Maintenance, reduction, or withdrawal of etanercept after treatment with etanercept and methotrexate in patients with moderate rheumatoid arthritis (PRESERVE): a randomised controlled trial. *Lancet*. 2013 Mar 16;381(9870):918-29.

**Table 1. Principal reason for admission and procedures in RA inpts 2005-10**

	Joint Related	Fracture's	Anaemia	GORD	Transfusion	OGD's
2005	851	55	40	27	28	64
2006	831	63	35	20	36	58
2007	717	54	34	20	32	57
2008	594	61	31	16	19	50
2009	570	63	27	11	26	36
2010	492	69	20	22	25	60

#### Abstract 7 (13A158)

#### Oral Presentation

#### Does rheumatoid arthritis disease activity correlate with weather conditions?

Savage EM, McCormick D, McDonald S, Moore O, Stevenson M, Cairns A

Department of Rheumatology, Musgrave Park Hospital, Belfast Health and Social Care Trust, Belfast

**Aims/Background:** Patients with Rheumatoid Arthritis (RA) often report increasing joint pain with changing weather conditions. Previous studies examining weather impact on pain severity have yielded contradictory results<sup>(1,2)</sup>. The relationship between disease activity in RA patients on Anti-TNF and weather variance has not previously been examined.

**Method:** A retrospective analysis of 133 patients attending Musgrave Park Hospital, with a diagnosis of RA on anti-TNF was performed. Data collected at 5 time points included TJC, SJC, VAS, ESR, CRP, and DAS-28. This was correlated with maximum/minimum temperature, hours of sunshine, rainfall, relative humidity, pressure and wind-speed from a local weather station on day of attendance. A linear regression analysis was used to determine relationship between weather components, disease activity and pain.

**Results:** The weather-based components were extracted after a global factor analysis using data from all time-points revealed three components from the seven quantitative variables. These were; temperature component, sunny/dry component, wet/windy component. All components were calculated from z-scores. Using DAS-28 as an outcome variable, increased hours of sunshine and low humidity resulted in a lower das-28 score ( $p=0.001$ ). Sunny and dry conditions resulted in a DAS-28 reduction of 0.143 (95% CI -0.230, -0.057)  $p=0.001$ . Temperature component resulted in a DAS-28 reduction of 0.048 (95% CI -0.129, 0.032),  $p = 0.23$ . Wet and windy conditions led to a DAS-28 increase (0.013 (95%CI -0.098, 0.123)  $p=0.82$ ).

**Conclusions:** While DAS-28 scores tended to be higher in times of low temperature, dull, wet and windy weather, our study highlights statistically significant lower DAS-28 scores in sunny and dry conditions.

**References:** 1. Drane D, Berry G, Bieri D, McFarlane AC, Brooks P. The association between external weather conditions and pain



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## Irish Rheumatology Health Professionals Society

### **Welcome to Trim for the Annual Scientific Meeting of the Irish Rheumatology Society and the Irish Rheumatology Health Professionals Society.**

2013 has again been a busy year for the IRHPS!!

At EULAR in Madrid we were ratified to EULAR membership. EULAR Health Professionals Standing Committee is very keen to work collaboratively with us. At congress there are study groups and you can meet and discuss areas of common interest. There are also benefits IRHPS members in the opportunity to apply for educational travel bursaries, research grant funding and travel bursaries when abstracts have been accepted for congress. They have a twice a year newsletter which will be displayed on [www.irhps.ie](http://www.irhps.ie).

Thanks again to the Pharma companies for their continued support, without which a valuable educational opportunity would be lost. Thanks must go to MSD and Roche. New this year is the Abbvie bursary which goes to the two top abstract submissions chosen for oral presentation – this is financial support for an educational visit and also the "Professor Barry Bresnihan gold medal to the top abstract and the IRHPS silver medal to the second place abstract. Please take the opportunity to have a look at the large number of posters we have received again this year and remember to vote for the "Peoples' choice" poster!

The IRHPS committee's support and dedication over the year has been invaluable. Many Thanks to all!

Finally remember if you come across an interesting speaker or any developments in your area please let us know on [EdOfficer@irhps.ie](mailto:EdOfficer@irhps.ie).

Best Wishes

**Rhona Galway**  
IRHPS Chairperson



and stiffness in women with rheumatoid arthritis. *J Rheumatology* 1997; 24:1309–16.  
2. Aikman H. The association between arthritis and the weather. *Int J Biometeorol* 1997; 40:192–9.

#### Abstract 8 (13A179)

#### Oral Presentation

### Major cost savings associated with reduced biologic dosing frequency in Inflammatory Arthritis-2 year data

Claire-Louise Murphy, Miriam O'Sullivan, Sohail Awan, Clara Bannon, Linzi Martin, Chavrimootoo Shawn, Trevor Duffy, Eithne Murphy, Maurice Barry

Department of Rheumatology, Connolly hospital, Blanchardstown, Dublin 15

**Introduction:** Biologic agents are highly effective in Inflammatory Arthritis but are extremely expensive. A sustained reduction in biologic dosing frequency would lead to major cost savings.

**Aims/Background:** The purpose of this study was to explore whether patients with Inflammatory Arthritis would remain in remission following a reduction in biologic dosing frequency and therefore lead to cost savings.

**Method:** This prospective non-blinded non-randomised study commenced in 2010.

Patients with Inflammatory Arthritis (RA, PsA or AS) being treated with a biologic agent were screened for disease activity. A cohort of those (DAS28<2.6, BASDAI<4) was offered a reduction in the dosing frequency of two biologic therapies (etanercept 50mg once per fortnight instead of weekly, adalimumab 40mg once per month instead of fortnightly). Patients were assessed for disease activity at 3, 6, 12, 18 and 24 months following reduction in dosing frequency. Cost saving was calculated over two years.

**Results:** 79 patients with inflammatory arthritis in remission were recruited. 57% had RA (n=45), 13% PsA (n=10) and 30% AS (n=24). 57% (n=45) were taking etanercept and 43% (n=34) adalimumab. The percentage of patients in remission at 24 months was 56% (n=44). Using paired sample t-tests in SPSSv20, no significant difference in measures of DAS28, HAQ or BASDAI scores was identified from baseline to 24 months in those who remained in remission. This resulted in an actual saving to the state of approximately 600,000 euro over 2 years.

**Conclusions:** This study suggests reduction in biologic dosing frequency is feasible and results in considerable cost savings at 2 years. The potential for major cost savings in biologic usage should be pursued further.

#### References:

1. Raffeiner B, Botsios C et al. The effects of low dose etanercept on disease control and radiographic progression in moderate to severe rheumatoid arthritis. *Arthritis Rheum* 2010;62:S120.
2. Van der Maas A, Kievit W, Van den Bemt B, Van den Hoogen F, Van Riel P, den Broeder A. Down-titration and discontinuation of infliximab in rheumatoid arthritis patients with stable low disease activity and stable treatment: an observational cohort study. *Ann Rheum Dis* 2012;71:1849-1854.
3. Cantini F, Niccoli L, Cassara E et al. Sustained maintenance of

clinical remission after adalimumab dose reduction in patients with early psoriatic arthritis: a long term follow-up study. *Biologics* 2012;6:201-6.

4. Taniguchi T, Noda S, Takahasi N et al. An observational, prospective study of monthly adalimumab therapy for disease maintenance in psoriasis patients: a possible new therapeutic option for good responders to the initial induction treatment. *J Eur Acad Dermatol Verereol*. 2012 Jun 15. doi: 10.1111/j.1468-3083.2012.04610.x.

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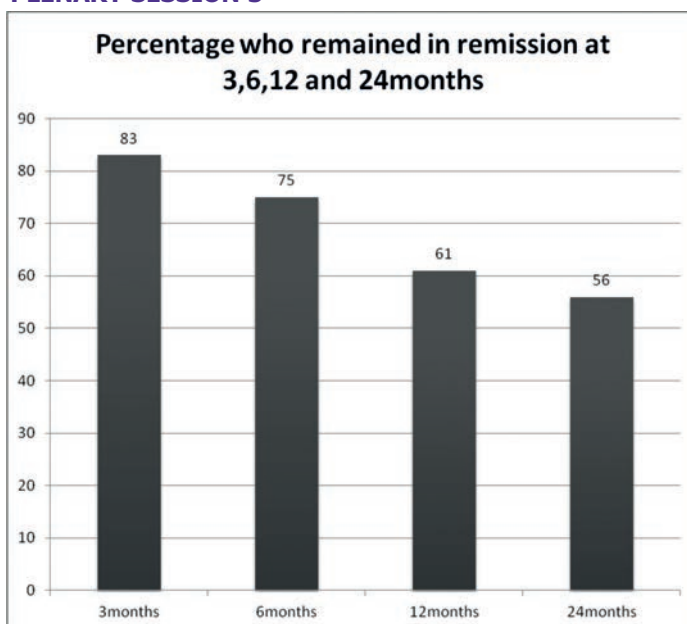
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#### PLENARY SESSION 3







YOUNG INVESTIGATOR AWARD: 2013

Abstract 13 (13A132)

Oral Presentation

**A novel evidence-based detection of undiagnosed Spondyloarthritis in patients presenting with Acute Anterior Uveitis: the DUET (Dublin Uveitis Evaluation Tool)**

Muhammad Haroon, Michael O'Rourke, Pathma Ramasamy, Conor Murphy, Oliver Fitzgerald

Department of Rheumatology, St Vincent's University Hospital, Dublin, and Department of Ophthalmology, Royal Victoria Eye and Ear hospital, Dublin

**Introduction:** To date, there are no formal guidelines or referral pathways for AAU patients developed or endorsed by any international or national societies.

**Aims/Background:** The objectives of our study were: (1) to investigate the prevalence of undiagnosed SpA in patients presenting with idiopathic AAU; (2) to develop and validate an assessment algorithm for referral from Ophthalmologists of appropriate AAU patients to Rheumatology that will aid the early diagnosis of the SpA.

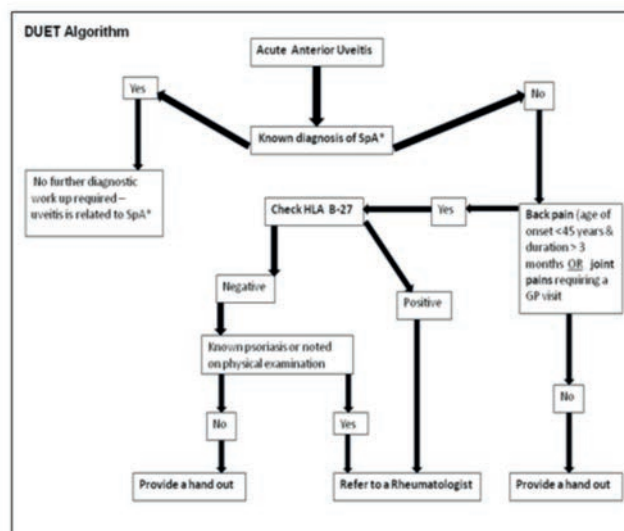
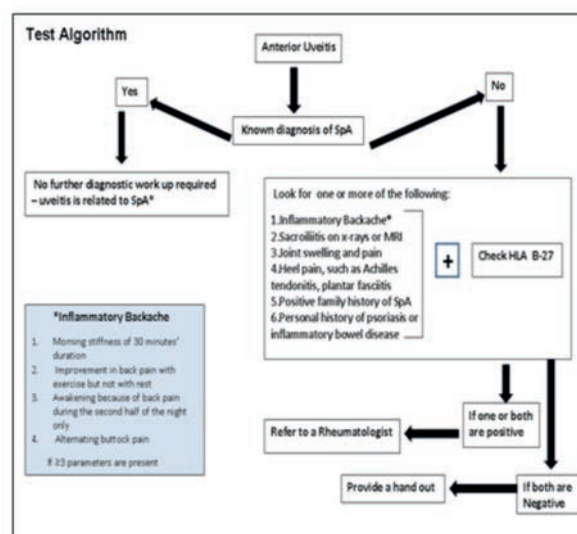
**Method:** All consecutive patients attending emergency department of local ophthalmology hospital with AAU, but who did not have a known diagnosis of SpA, were eligible to partake in this study. Patients with any other known cause of AAU were excluded. Two independent cohorts were enrolled. Test algorithm and DUET algorithm (revised form of test algorithm) were used in these cohorts to identify patients as SpA suspects and non-SpA controls, respectively.

**Results:** ALGORITHM DEVELOPMENT COHORT: After rheumatologic evaluation of the entire cohort, 41.6% (n=42) had undiagnosed SpA. Our test algorithm was noted to have: sensitivity 100% and specificity 53.5%. Further regression analysis resulted in the development of the DUET algorithm which made the following improvements: sensitivity 95%, specificity 98%, positive LR 56.19, and negative LR 0.04.

DUE ALGORITHM VALIDATION COHORT: After rheumatologic evaluation of the cohort, 40% (n=29) were diagnosed with SpA, with the following performance of DUET algorithm - sensitivity 96%, specificity 97%, positive LR 41.5 and negative LR 0.03.

**Conclusions:** Approximately 40% of patients presenting with idiopathic AAU have undiagnosed SpA. A simple to apply algorithm is described with excellent sensitivity and specificity.

Figure-1



POSTERS

Abstract 14 (13A102)

Poster

**Previous exposure to Varicella (Chickenpox) infection in patients starting biologic therapy for inflammatory arthritis**

Dr Ali Taha, Dr S A Ramakrishnan

Department of Rheumatology, Or Lady's Hospital, Navan, Ireland

**Aims/Background:** There is increased risk of serious morbidity and mortality of Varicella (Chickenpox) infection in adults which is compounded in those treated with biologic drugs. Self-reported history of previous exposure is unreliable. One of our patients on biologic in the past contacted us post exposure to Varicella virus with no history of previous exposure. He received Varicella Zoster immunoglobulin as per guidelines, subsequent testing showed that he was immune.

We audited the prevalence of exposure to varicella in our population of inflammatory arthritis prior to initiating biologic



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Prescribing Information [Refer to full SPC text before prescribing Simponi (golimumab)] **Indications:** Rheumatoid Arthritis (RA): Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; **Psoriatic Arthritis (PsA):** Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. **Ankylosing Spondylitis (AS):** Simponi is indicated for treatment of severe, active AS in adults who have responded inadequately to conventional therapy. **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 or AS. 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:** 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. 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. **Elderly patients (> 65 years):** no dose adjustment required. **Paediatric patients (<18 years) and patients with renal and hepatic impairment:** Simponi is not recommended in these populations. **Contraindications:** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. 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. Melanoma (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-

blocking agents) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart Failure:** Simponi should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in the event of worsening symptoms of heart failure. **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. In patients with a history of demyelinating disorders, the benefits and risks of Simponi treatment should be carefully considered before initiation of therapy. **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 must be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leucopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations:** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. 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:** Very Common (> 1/10): upper respiratory tract infection; Common (> 1/100): bacterial infections, viral infections, bronchitis, sinusitis, superficial fungal infections, anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, paraesthesia, headache, hypertension, constipation, dyspepsia, gastrointestinal and abdominal pain, nausea, alanine aminotransferase increased, aspartate aminotransferase increased, alopecia, dermatitis, pruritus, rash, pyrexia, asthenia, injection site reaction, impaired healing and chest discomfort were reported. Other less common and rarely reported side effects are listed in the SPC. **Overdose:** Single doses up to 10mg/kg intravenously have been administered without toxic effect. **Package quantities:** 0.5 ml solution in a pre-filled syringe (1.0 ml Type 1 glass) with a fixed needle (stainless steel) and a needle cover (rubber containing latex) in a pre-filled pen or pre-filled syringe. Simponi is available in packs containing 1 pre-filled pen or 1 pre-filled syringe. **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number:** Pre-filled Pen EU/1/09/546/001; Pre-filled Syringe EU/1/09/546/003 **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands © Merck Sharp & Dohme Ireland (Human Health) Limited, 2013. All rights reserved. **Date of Revision of Text:** July 2013 Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). Date of preparation: August 2013.

Ref 1: Simponi (SIMPON/EN/SPC/07-13/15) Summary of Product Characteristics June 2013. For full text see [www.medicines.ie](http://www.medicines.ie).



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golimumab





therapy.

**Method:** To ascertain serological immunity to Varicella in consecutive patients starting biologics for various inflammatory arthritides from June 2011 to March 2012, samples were sent for varicella titres along with usual other screening. Previous history of varicella exposure was recorded.

**Results:** 52 consecutive patients were tested. Patients were aged between 18 and 82 years. 31 females, 21 males. All tested positive with Varicella Zoster IgG > 100 mIU/ML. 29 had Rheumatoid Arthritis, 15 Spondyloarthropathy, 4 Psoriatic arthropathy and 4 undifferentiated arthritis. 40 patients reported exposure to Varicella (Chickenpox) and 12 patients were not aware. Of our patients 4 were eastern Europeans, 3 non Caucasians (two African decent and one Asian) and 45 were Irish.

**Conclusions:** Previous Varicella zoster infection is the norm in our patients starting biologic drugs. Given that the history of previous exposure is unavailable in many cases, documented immunity is very valuable for post exposure advice. We continued testing for varicella immunity for all patients starting Biologic therapy.

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#### Abstract 15 (13A108)

#### Poster

##### **Patient characteristics and reason for referral for Bone Mineral Densitometry in a community based hospital**

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The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim

**Introduction:** Dual-energy X-ray absorptiometry (DXA) is the most accurate and widely used method to identify patients with low bone mineral density (BMD), however it is expensive and has limited availability across the country.

**Aims/Background:** To identify the reasons for referral to DXA in patients presenting to the Bone Densitometry Service, Our

Lady's Hospital, Manorhamilton, Co. Leitrim.

**Method:** Reasons for referral for DXA were examined in 283 patients aged > 40 years, referred in 2012 to the The North Western Rheumatology Unit. Age, sex, clinical risk factors, fracture history and bone mineral density (BMD) T scores were recorded.

**Results:** Mean age of the study population was 63.2 yrs (Std + 11.9), females 87%, males 13%. In total 36.5% of the patients had normal BMD levels, a further 33% were in the osteopenic group and 30% were either osteoporotic or severely osteoporotic. Seventy percent of the patients referred (N=192) had a clinical risk factor documented and the most common reason for referral was advanced age (35%) and history of a fracture (27%). In total 75 patients (64%) with a history of fracture did not have osteoporosis (27% normal BMD, 37% osteopenic). There was a statistically significant correlation between the presence of a clinical risk factor and BMD level  $p < .05$  and also with the number of clinical risk factors and BMD level  $p < .05$ . BMD levels were found to decrease with age.

**Conclusions:** BMD levels alone cannot accurately predict fracture probability and the challenge for health care professionals in primary and secondary care continues to be screening and accurately identifying and treating patients who are at increased risk of sustaining a fragility fracture.

#### Abstract 16 (13A110)

#### Poster

##### **Major and minor discordance in the diagnosis of osteoporosis among Irish men and women using hip and spine dual-energy X-ray absorptiometry**

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The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim

**Introduction:** Diagnostic discordance for osteoporosis is the presence of different categories of T-scores in 2 different skeletal sites, falling into 2 different diagnostic categories as identified by the World Health Organization classification system (1). Discordances between hip and spine areal density T-score values are common and incompletely understood.

**Aims/Background:** To determine discordance in the diagnosis of osteoporosis among patients referred for DXA scan at The North Western Rheumatology Unit using hip and spine Dual-energy X-ray Absorptiometry.

**Method:** The study included men and women who underwent bone mineral densitometry (BMD) for suspected osteoporosis at The North Western Rheumatology Unit. The BMD measures at the hip and spine were used to derive T-scores and to determine the prevalence of discordance. Factors potentially associated with discordance were explored in univariate and a multivariate regression model.

**Results:** The mean age of the 276 patients in the study was  $63.2 \pm 11.92$  years (males 35 (13%), females 241 (87%).



Results of T-Score Concordance was identified in 128 patients (51.2%), minor discordance in 101 patients (36.5%) and major discordance was seen in 21 patients (7.6%). Independent t-test of age, BMI, presence of co-morbidities, fracture history, identified age as the only risk factor ( $P < .05$ ) which had a significant effect on T-score discordance.

**Conclusions:** At least 40% of patients tested by DXA will demonstrate T-score discordance between spine and total hip measurement sites. T-score discordance has been shown to occur for a variety of reasons related to physiologic and pathologic patient factors as well as the performance or analysis of DXA itself <sup>(2)</sup>.

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#### Abstract 17 (13A111)

#### Poster

##### A discrete-choice experiment to elicit the preferences of Irish patients for osteoporosis drug treatment

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1 The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim

**Aims/Background:** To evaluate the preferences of patients with osteoporosis for medication attributes and to establish how they trade between these attributes.

**Method:** A discrete-choice experiment was designed in which patients were asked to choose, from a series of hypothetical scenarios, between two drug alternatives which vary in five attributes: efficacy in fracture risk reduction, type of side-effects, mode and frequency of administration and costs. An efficient experimental design was used to construct the sets of treatment options and a mixed logit panel data model was employed to estimate patients' preferences and their trade-offs between attributes.

**Results:** 200 patients with osteoporosis completed the experiment. Patients preferred a drug treatment with a higher effectiveness and a lower cost. They also preferred 6-month subcutaneous injection and yearly intravenous above weekly oral tablets and favoured weekly oral tablet over 3-months intravenous injections. No significant difference in preference was observed between weekly oral tablets, monthly oral tablets and 3 monthly subcutaneous injections. Patients disliked being at risk of gastro-intestinal disorders more than being at risk of skin reactions and flu-like symptoms. Significant heterogeneity for the preferences was present among nearly all attributes.

**Conclusions:** This study revealed that, at the group level, osteoporotic Irish patients preferred 6-monthly subcutaneous

injections and yearly intravenous injection and compared to other potential side-effects, gastro-intestinal effects were the least favoured. Moreover, they are willing to pay a personal contribution or to trade efficacy for such outcomes. Preference heterogeneity suggests the need to incorporate individual preferences into clinical decision-making to improve osteoporosis care.

#### Abstract 18 (13A112)

#### Poster

##### Plasma IL-6 levels correlate with clinical and ultrasound measures of disease activity in Lupus Arthritis

Elisabeth Ball, David Gibson, Aubrey Bell, Madeleine Rooney

Queen's University, Belfast

**Introduction:** The role of specific cytokines in lupus arthritis has not been elucidated <sup>(1)</sup>.

**Aims/Background:** To analyse the cytokine profile in SLE patients with erosive, non-erosive arthritis and arthralgia.

**Method:** 50 SLE patients, and 40 RA patients had an US scan of their hand <sup>(2,3)</sup>. US scores were expressed per joint and as a total 'ultrasound activity' score (sum of Power Doppler (PD) and Grey Scale Synovial Hypertrophy scores in all joints) and a total erosion score. SLE disease activity was assessed. Plasma levels of IL-6, TNF-alpha and BLYS were measured (Quantikine® ELISA kits, R & D).

**Results:** On the basis of the ultrasound results the SLE patients were divided into erosive arthritis ( $n = 24$ ), non-erosive arthritis ( $n = 14$ ) and those with a normal ultrasound scan ( $n = 12$ ). CRP and IL-6 levels between the erosive lupus group and the RA group were not significantly different ( $p = 0.3$  and  $p = 0.2$ ). Across the SLE groups plasma IL-6 levels correlated with CRP ( $p < 0.001$ ), hand deformity scores ( $p = 0.005$ ), swollen joint count ( $p = 0.002$ ) and BILAG musculoskeletal score ( $p = 0.009$ ); also with wrist PD score ( $p = 0.01$ ), extensor tenosynovitis ( $p = 0.008$ ) and total ultrasound activity score ( $p < 0.001$ ) (which remained constant when corrected for total BILAG score ( $p < 0.01$ )).

**Conclusions:** The most significant finding is that IL-6 levels correlated with both clinical and ultrasound measures of arthritis disease activity. There is preliminary evidence that IL-6 blockade may be a potential treatment for SLE<sup>(4)</sup> and if arthritis specific outcome measures were included in future clinical trials more robust evidence could be generated.

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## Abstract 19 (13A113)

## Poster

### An audit of the vaccination status of patients with autoimmune anti-inflammatory rheumatic disease attending The North Western Rheumatology Unit

Dr Sarah Nicholson<sup>1</sup>, Dr Carmel Silke<sup>1</sup>, Dr Bryan Whelan<sup>1</sup>, Dr Cathriona Walsh<sup>2</sup>, Mary McGovern<sup>1</sup>, Bernie McGowan<sup>1</sup>

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<sup>2</sup>HSE Community Services West (Sligo/Leitrim), Sligo

**Introduction:** Patients with immune modulated illnesses and those undergoing treatment with immunosuppressant therapies are more likely to develop vaccine-preventable disease than the general population<sup>(1)</sup>. EULAR guidelines state that vaccination status should be assessed in the initial workup of those with autoimmune inflammatory rheumatic disease (AIIRD)<sup>(2)</sup>. The National Immunisation Advisory Committee (NIAC) in Ireland recommends influenza and pneumococcal vaccine in those persons with chronic illness and immunosuppression<sup>(3)</sup>.

**Aims/Background:** To assess the vaccination status of patients with AIIRD attending The North Western Rheumatology Unit (NWRU).

**Method:** This was a cross sectional retrospective study in which an anonymised questionnaire was distributed to patients (N=66) with AIIRD over a 3 week period. The data was analysed using excel and JMP® 8.0.2 data analysis software. The study focused on the influenza and pneumococcal vaccines.

**Results:** In total, 67% of respondents had received the flu vaccine, 24% were unsure and 8% had not received the vaccine. A further 11% of respondents had received the pneumococcal vaccine, 53% were unsure and 35% had not received it. 53% (n=35) had a diagnosis of rheumatoid arthritis. In total, 86% of the patients were taking immunosuppressant medications.

**Conclusions:** The results of this study show that even though uptake of the flu vaccine (67%) is better than pneumococcal (11%), both vaccinations have a poor uptake in this group compared to the WHO target of 75% uptake in at risk groups<sup>(5)</sup>. The poor uptake of vaccines may be due to a lack of education about the risks and benefits of the flu and pneumococcal vaccines. It is imperative that patients are educated about the risks of vaccine-preventable disease

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## Abstract 20 (13A114)

## Poster

### Muscle Function in Patients with Stable Rheumatoid Arthritis

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<sup>2</sup>The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim

**Introduction:** Rheumatoid arthritis patients are less physically active than the general population<sup>(1)</sup>. Patients with rheumatoid arthritis show lower cardiorespiratory fitness than normal subjects<sup>(2)</sup>. The American College of Rheumatology recommends strengthening and aerobic conditioning regimens in its guidelines for the management of rheumatoid arthritis<sup>(3)</sup>.

**Aims/Background:** The aim of the study was to assess baseline muscle function in patients with stable rheumatoid arthritis.

**Method:** Functional assessments were conducted on 30 stable rheumatoid arthritis patients and compared to normative values of a healthy population. Assessments consisted of hand grip dynamometer, 2 minute step test, sit and reach flexibility test and single leg balance test.

**Results:** In total 30 stable rheumatoid arthritis patients (mean age 61.2, 10.6 SD) were tested and the results were compared to the age/gender specific norms of a healthy population. For the 2 minute step test, there was a statistically significant difference ( $p < 0.001$ , 95% CI -28.96 to -10.71) between the results of the patient study group and the normative values. The results of the sit and reach test identified that in total (78.6%) of males and all females (100%) rated in the poor category. In the single leg balance test, only 20% reached the maximum score. In total 43.7% of females and 50% of males reached the age/gender specific norms of the hand grip dynamometer.

**Conclusions:** The results show that the rheumatoid arthritis patients show lower levels of muscle function than the normal population. Efforts should be made to include physical training in the treatment of rheumatoid arthritis.

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## Abstract 21 (13A115)

## Poster



**To identify adherence to EULAR guidelines for anti TNF treatment in patients with a diagnosis of psoriatic arthritis**

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**Introduction:** The course of Psoriatic arthritis (PsA) is variable and unpredictable ranging from a non-destructive disease to a severe debilitating erosive arthropathy. Erosive and deforming arthritis occurs in 40–60% of PsA patients and is progressive from within the first year of diagnosis<sup>(1,2)</sup>. The classification of PsA is an area of ongoing international discussion. The five subgroups proposed by Moll and Wright<sup>(3)</sup> are still frequently used, although considerable overlap between these groups is now recognized.

**Aims/Background:** To check adherence to EULAR guidelines for anti TNF treatment in psoriatic arthritis.

**Method:** 78 patients' medical records were reviewed, and retrospectively audited against EULAR guidelines. Patients were subgrouped as RA pattern, oligoarthritis, enthesopathy, axial disease and arthritis mutilans PsA. Diagnosis was made according to the CASPAR criteria (5). Information recorded included assessment for subtype of arthritis, duration of disease & pharmacological treatment used.

**Results:** Rheumatoid arthritis pattern was the most commonly occurring sub-type in 56% (n=44), followed by oligoarthritic variant in 40% (n=31). Enthesitis and axial disease accounted for 8% and 4%, respectively. Methotrexate was the first line DMARD in 59 patients (77%) of the patients, followed by Sulphasalazine in 17 patients (22%) and Leflunomide in one patient (1.2%). In total 29 patients (37%) were changed from DMARD1 to DMARD2, the majority of whom were changed to methotrexate (55%, n=17). 97.4% of the patients were commenced on an anti TNF.

**Conclusions:** All patients in the study received biologic DMARDs appropriately. Subclassification of psoriatic arthritis & PsARC need to be recorded at baseline so the escalation of treatment and choice of pharmacological approach will be instituted in a timely manner and response to same would accurately be monitored.

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**Abstract 22 (13A116)**

**Poster**

**Audit of intra-articular steroid injection approach in Irish Society of Rheumatology members**

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**Introduction:** Intra-articular steroid injections are a key aspect in the management of rheumatology patients. There are, however, recognised potential risks that patients should be informed of.

A recently updated patient information leaflet produced by the Arthritis Research Council (ARC) for intra-articular steroid injections suggested checking (i) blood pressure and (ii) blood glucose prior to injection due to potential derangement. A literature review did not reveal any evidence to warrant this statement. This could result in a delay which lengthens patient suffering and clinic waiting times. This was not routine practice in Belfast so an audit sought to establish the practices of members of the Irish Society of Rheumatology.

**Results:** A questionnaire was completed by 22 ISR members and results showed that 32% used the ARC leaflet. Only 9% consented for effect on blood pressure but 73% discussed raised blood glucose in diabetics.

14% checked blood pressure prior to injection and none recommended follow up after injection. None checked blood glucose prior to injection, however, 14% recommended monitoring of blood glucose levels for 48 hours after injection. Information was also gained on aseptic technique and injection approach which showed a wide variation in results.

**Conclusions:** Audit results confirmed that it was not common national practice to check blood glucose and blood pressure prior to steroid injection. Findings were communicated with the authors of the ARC leaflets who have agreed with our suggestion and future versions will have this statement removed thereby hopefully reducing any unnecessary delay and any further potential joint destruction.

**References:** Note- data on aseptic technique and injection approach etc. would be available as well as data on blood pressure/blood glucose.

**Abstract 23 (13A117)**

**Poster**

**Does Fibrinogen have a role in the assessment of patients with Giant Cell Arteritis?**

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**Introduction:** Considerable difficulties exist in the evaluation of patients with suspected GCA. Temporal artery biopsy is negative in a substantial minority of patients. The traditional biomarkers ESR and CRP are non-specific and can also be negative. Therefore development of better disease biomarkers is needed





for diagnosis in GCA.

**Aims/Background:** The aim of this study was to evaluate the utility of plasma Fibrinogen in the assessment of patients with GCA.

**Method:** Patients presenting with suspected new-onset GCA were prospectively enrolled. Plasma Fibrinogen, ESR and CRP were assayed at baseline and 3 months following initiation of steroid therapy.

Biomarkers were also assayed in 25 age and sex matched controls attending with osteoarthritis (OA).

**Results:** Plasma Fibrinogen levels were significantly elevated in patients with GCA when compared with OA controls. (Mean 4.9 g/L vs. 3.05 g/L,  $p = 0.0017$ ).

Fibrinogen levels demonstrated a response to therapy. (Mean of 4.9 g/L at baseline vs. 3.5 g/L at 3 months,  $p = 0.04$ ).

Baseline Fibrinogen levels correlated with baseline ESR ( $r = 0.6946$ ,  $p < 0.0001$ ) and CRP ( $r = 0.6951$ ,  $p < 0.0001$ ). ROC analysis revealed Fibrinogen to be a less sensitive but more specific marker of GCA than CRP (Sensitivity of 67% vs. 82% and Specificity of 100% vs. 80% respectively) with comparable specificity to ESR above a cut off for ESR  $>30$  mm/hr.

Values above the upper limit of normal for Fibrinogen (4 g/L) were associated with a positive likelihood ratio of 15.18 for GCA.

**Conclusions:** Plasma fibrinogen levels are elevated in patients with GCA, respond to glucocorticoid therapy and correlate with serum ESR and CRP levels.

#### Abstract 24 (13A118) Poster

##### Lower Tissue Expression Of IL 6 In Patients With Giant Cell Arteritis Presenting With Cranial Ischaemic Complications

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**Introduction:** The majority of the morbidity associated with Giant Cell Arteritis is related to its ischaemic complications of acute visual loss and stroke. It has previously been suggested that patients with cranial ischaemic complications (CICs) due to GCA have lower tissue expression of IL 6.

**Aims/Background:** 1. To compare the spontaneous release of IL 6 from cultured temporal artery explants of patients with GCA and CICs to those without.

2. To investigate the association between spontaneous release of IL 6 from the explant cultures and findings on histopathology.

**Method:** Patients presenting with suspected GCA were prospectively enrolled.

Patients underwent a temporal artery biopsy and had serum biomarkers assayed at baseline.

TAB sections were sent to histopathology for diagnostic purposes. Additional sections were cultured and IL 6 expression in the supernatants quantified.

**Results:** 11 of the 55 (20%) patients included in the analysis presented with an ischaemic complication attributable to GCA.

Patients with CICs had significantly lower levels of IL 6 in explant supernatants when compared to those without CICs (Mean 8.66 ng/ml/mg biopsy weight vs 18.92 ng/ml/mg biopsy weight,  $p < 0.01$ ).

This lower tissue IL 6 production was significantly associated with both intimal hyperplasia ( $p < 0.03$ ) and luminal occlusion ( $p < 0.01$ ) on histopathology.

**Conclusions:** The study confirms the association between lower levels of IL 6 expression in patients with CICs than those without.

#### References:

Cid et al, Circulation 2003

#### Abstract 25 (13A119) Poster

##### Treatment with the GLP-1 Analogue Liraglutide is associated with Inflammatory Arthritis DAS28 Reduction in patients with concomitant T2DM

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**Introduction:** Recent evidence suggests that Glucagon-like peptide-1 (GLP-1) analogues, used for the treatment of type 2 diabetes (T2DM), possess novel anti-inflammatory effects including the amelioration of TNF inflammatory responses.

**Aims/Background:** To investigate the amelioration of inflammatory arthritis disease activity in a cohort of patients undergoing liraglutide therapy for T2DM.

**Method:** Patients with T2DM and either RA ( $n=11$ ) or PsA ( $n=4$ ) were commenced on liraglutide 1.2mg s/c od. DAS28 scores, weight, HbA1C, were recorded at baseline and weeks 6, 12 and 24. DAS28 outcomes were defined by EULAR good, or moderate vs non-responders.

**Results:** Patients had active arthritis (DAS28  $4.38 \pm 0.4$ ) and inadequate glycaemic control HbA1C ( $55 \pm 5.1$ ) at baseline. Nine patients achieved DAS28 response (DAS28 =  $4.2 \pm 0.8$  pre,  $2.7 \pm 0.5$  post) vs (DAS28 =  $4.7 \pm 0.8$  pre,  $5.0 \pm 2.7$  post,  $n=6$ ). Significant weight loss was seen in DAS28 responders ( $94 \pm 5$  pre,  $90.6 \pm 5.2$ kg,  $p=0.008$ ) but not non-responders ( $93.8 \pm 3.3$ kg pre,  $95 \pm 2.8$ kg post,  $p=0.79$ ). A significant fall in HbA1C was seen in DAS28 responders ( $60.5 \pm 6.3$  pre,  $45.5 \pm 2.1$  post,  $p=0.012$ ) but not non-responders ( $47.1 \pm 9.5$  pre vs  $39.4 \pm 13$ ,  $p=0.144$ ). A significant fall in SJC28 was seen in DAS28 responders ( $3.3 \pm 0.9$  pre,  $1.2 \pm 0.6$ ,  $p=0.027$ ) but not non-responders ( $4.2 \pm 2.8$  pre,  $4.8 \pm 3.2$  post,  $p=0.66$ ). Weight loss following liraglutide significantly associated with achieving a DAS28 response by Chi Square ( $p=0.044$ ). No differences were observed in baseline DAS28, weight, HbA1C, SJC, ESR or CRP according to subsequent DAS28 response grouping.

**Conclusions:** Liraglutide lowering effects for HbA1C and BMI, significantly associated with a DAS28 reduction. Further studies



may lead to novel therapeutic strategies in the treatment of inflammatory arthritis.

## Abstract 26 (13A122)

## Poster

### The Ankylosing Spondylitis Registry of Ireland (ASRI)

Martina Fitzpatrick<sup>1</sup>, Phil Gallagher<sup>1</sup>, Catherine Molloy<sup>2</sup>, Oliver FitzGerald<sup>1</sup>, Finbar O'Shea<sup>3</sup>

<sup>1</sup>St. Vincent's University Hospital, Dublin

<sup>2</sup>Cork University Hospital, Cork

<sup>3</sup>St. James' Hospital, Dublin

**Introduction:** In 2007, rheumatologists from Scotland and Northern Ireland created the Scotland and Ireland Registry for Ankylosing Spondylitis. As part of this collaboration, rheumatologists in the Republic of Ireland intend to create a similar registry of patients - The Ankylosing Spondylitis Registry of Ireland (ASRI).

**Aims/Background:** The primary objectives of ASRI are to provide basic descriptive epidemiological data on the AS population in Ireland, and to establish a registry for potential future studies of genetics, aetiology and therapeutics. Specifically, we will measure the burden of AS in the population and identify early predictors of a poor outcome. The secondary aim is to collect biological samples (serum and DNA) from participants. These samples will be used to investigate if genetic and serological factors predict poor outcomes.

**Method:** This is a prospective cohort study and will include adult patients who have been diagnosed with AS. A standardised clinical assessment of patients will be performed and entered in a web-based database. Results of relevant laboratory parameters and imaging studies will be documented. Specific measures of disease activity (BASDAI), function (BASFI and HAQ), and quality of life (ASQoL) will be obtained. Samples for serum and DNA will be stored for future use to correlate with clinical data and to facilitate genetic studies.

**Results:** Recruitment has recently commenced and is open to any centre in Ireland.

**Conclusions:** This is a unique opportunity for the Irish Rheumatology community to generate a valuable resource that will ultimately improve the delivery of care to Irish AS patients.

## Abstract 27 (13A123)

## Poster

### Ultrasound is as sensitive as nerve conduction studies but more cost effective and patient acceptable in the diagnosis of carpal tunnel syndrome

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**Introduction:** Carpal tunnel syndrome (CTS) is the commonest entrapment neuropathy affecting 9% of women<sup>(1, 2)</sup>. Sensitivity

of ultrasound to diagnose carpal tunnel syndrome has been reported to be as high as 97.9%<sup>(3)</sup>, while nerve conduction studies (NCS) have a sensitivity of >85%<sup>(4)</sup>.

**Aims/Background:** To document the sensitivity of ultrasound to diagnose CTS and to establish a new pathway for diagnosis of CTS using ultrasound.

**Method:** Patients with clinically confirmed idiopathic CTS were recruited from the rheumatology, orthopaedic and neurology outpatient clinics and the neurophysiology department in a tertiary referral teaching hospital. They were assessed clinically, by ultrasound and nerve conduction studies. Clinical diagnosis was the reference standard<sup>(5)</sup>.

**Results:** 29 patients (40 symptomatic wrists) have been recruited into the study. Of the 40 wrists at baseline 32 had ultrasound confirmation of CTS and 34 had positive NCS. The sensitivity of ultrasound to diagnose CTS when compared to clinical assessment was 80% and the sensitivity of NCS was 85%. The cost of ultrasound is £64 and EMG/NCS costs £256, potentially yielding a 75% saving if ultrasound is used as the first line test<sup>(6)</sup>. No patient reported pain during ultrasound examination and all subjects agreed to follow-up. Ultrasound additionally identified structural causes of CTS such as bifid median nerve, arterial anomaly and tenosynovitis, and ultrasound was used to guide injection avoiding nerve damage.

**Conclusions:** Ultrasound is a sensitive, more cost effective, highly patient acceptable modality for the diagnosis of CTS. A new paradigm is proposed where ultrasound is used as the initial test for CTS and NCS are reserved for those with a negative ultrasound or atypical symptoms.

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## Abstract 28 (13A124)

## Poster





**The prognosis of Scleroderma Renal Crisis in RNA-polymerase III antibody (ARA) positive compared to ARA negative patients**

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**Introduction:** Scleroderma renal crisis (SRC) usually presenting with accelerated hypertension and acute kidney injury (AKI) is one of the most severe complications of Systemic Sclerosis (SSc).

**Aims/Background:** The presence of RNA-polymerase III auto-antibodies (ARA) is recognized as a strong risk factor for SRC but studies have not explored long-term outcomes in ARA positive cases compared to ARA negative cases.

**Method:** Of more than 2000 SSc patients attending our institution between 1990-2013, 150 patients had a confirmed SRC. 80% patients had diffuse cutaneous SSc (dcSSc) and 20% patients had limited cutaneous SSc (lcSSc). ARA was measured by commercial ELISA or radio-immuno-precipitation. Patients were divided into two groups: ARA positive or ARA negative. Demographic and clinical parameters were compared between groups using Student's t-test or Chi-squared analyses where appropriate.

**Results:** 61/150 (41%) patients were ARA positive and significantly more likely to have dcSSc (88.3% vs 73.8%,  $p=0.032$ ) than lcSSc compared to ARA negative patients. There was no significant difference in age of onset of SRC (51.2 vs 51.9 years) or the number of females (73% vs 79%) between the two groups. 50.8% of ARA positive patients required dialysis compared to 29.2% of ARA negative patients ( $p=0.07$ ). The mean time to recovery of renal function was significantly longer in ARA positive patients (14.25 vs 8.27 months,  $p=0.032$ ). Significantly more ARA positive patients were able to discontinue dialysis compared to ARA negative patients (53.3% vs 25.5%,  $p=0.01$ ). ARA positive patients had a significantly better survival outcome.

**Conclusions:** In SRC, although more ARA positive patients required dialysis they had significantly greater capacity for long-term recovery and survival compared to ARA negative patients.

**Abstract 29 (13A125)**

**Poster**

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### Scleroderma Renal Crisis and Pulmonary Arterial Hypertension are rare in the same patient

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**Introduction:** Scleroderma renal crisis (SRC) and pulmonary arterial hypertension (PAH) have similar histological features and shared pathogenic mechanisms are plausible. Pulmonary hypertension (PH) after SRC is frequently observed but generally due to post capillary mechanisms.

**Aims/Background:** To explore the association of PAH with SRC.

**Method:** Of more than 2000 SSc patients attending our institution between 1990-2013, 150 patients had a confirmed diagnosis of SRC of which six (4%) patients had a diagnosis of PAH following right heart catheterisation. Demographic, clinical and haemodynamic parameters are expressed as mean  $\pm$  SD.

**Results:** Two patients had diffuse and 4 patients had limited cutaneous SSc. 5/6 had anti-RNA polymerase III (ARA) reactivity. All patients with SRC and PAH were female. PAH was diagnosed after SRC in all patients. 4/6 patients required dialysis. 2/6 who did not require dialysis had an eGFR of 26 and 44mls/min/1.73m<sup>2</sup>. 2 patients recovered renal function at 6 and 14 months after the diagnosis of SRC. The mean mPAP (mean pulmonary arterial pressure) was 42  $\pm$  12mmHg. 3/6 patients died with a mean survival from date of diagnosis of SRC of 112 months and a mean survival from date of diagnosis of PAH of 47 months.

**Conclusions:** The presence of SRC and PAH in the same patient is very rare and PAH occurred after SRC in all patients at a mean of 5 years later. Temporal separation of SRC and PAH suggests that these complications may occur independently, but the frequent association with ARA suggests common susceptibility factors may be relevant.

#### Abstract 30 (13A126)

#### Poster

### Reduced eGFR in Systemic Sclerosis associated Pulmonary Arterial Hypertension is a marker of severity

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<sup>3</sup>Department of Nephrology, The Royal Free Hospital, London

**Introduction:** The prognosis of Systemic Sclerosis associated Pulmonary Arterial Hypertension (SSc-PAH) is determined by the severity of PAH and other organ involvement.

**Aims/Background:** To examine the prevalence of reduced eGFR in SSc-PAH and its association with clinical demographics,

pulmonary function tests and haemodynamics.

**Method:** We included 865 SSc patients from our centre between 1996-2010. In 580 patients who underwent a right heart catheterisation (RHC) and eGFR prior to RHC, 290 patients had PAH. 209 patients had limited cutaneous SSc (lcSSc) and 81 patients had diffuse cutaneous SSc (dcSSc). Patients were divided into two groups: eGFR <60 or  $\geq$ 60ml/min/1.73m<sup>2</sup>. Demographic, clinical and haemodynamic parameters were compared between groups using Student's t-test, Mann-Whitney U test or Chi-Squared analyses where appropriate.

**Results:** 77/290 (27%) patients had an eGFR <60. There were more females (92% vs 77%,  $p < 0.01$ ) in this group who were older (63.5 vs 56.8 years,  $p < 0.01$ ), more likely to have lcSSc (91% vs 65%,  $p < 0.01$ ) than dcSSc compared to those with an eGFR  $\geq$ 60. DLCO was significantly lower (42% vs 38%,  $p < 0.05$ ) in the eGFR <60 group but there was no significant difference in forced vital capacity (FVC) (87% vs 73%,  $p = 0.37$ ). The mean pulmonary artery pressure (mPAP) (42 vs 36mmHg,  $p < 0.01$ ) and pulmonary vascular resistance (PVR) (730 vs 524dyn.s.cm<sup>-5</sup>,  $p < 0.01$ ) were significantly higher in the eGFR <60 group.

**Conclusions:** Reduced eGFR in SSc-PAH is more frequent in limited cutaneous SSc, female and older patients and is associated with a reduced DLCO and preserved FVC. A higher mPAP and PVR reflects more severe pulmonary vascular disease.

#### Abstract 31 (13A127)

#### Poster

### High prevalence of Metabolic syndrome is associated with the severity of underlying Psoriatic Arthritis

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**Aims/Background:** The objectives of our study were: 1) to investigate the prevalence of metabolic syndrome (MetSyn) in an ethnically homogenous cohort of established psoriatic arthritis (PsA), 2) to identify clinical associations of MetSyn in patients with PsA.

**Method:** A cohort of 283 PsA patients, fulfilling CASPAR criteria, attending rheumatology clinics was included. Following informed consent, patients underwent detailed skin and rheumatologic assessments, along with cardiovascular risk factor evaluation. Moreover, an extensive medical record review was performed. Severe PsA was defined as the presence of PsA-related radiographic damage - peripheral joint erosions, osteolysis and sacroiliitis - along with their PsA requiring TNFi therapy.

**Results:** The demographics and clinical characteristics of the cohort was as follows: mean age 54.6 $\pm$ 12 years; 52% female; mean PsA duration of 19 $\pm$ 9 years; 60% of patients requiring TNFi for PsA, mean maximum PASI of 5.7 $\pm$ 5.2. MetSyn was present in 44% of the entire studied cohort. On univariate analysis, MetSyn patients were less educated, had more type-2 psoriasis, later PsO and PsA age of onset, shorter time from psoriasis to arthritis development, worse EQ-5D scores and high smoking pack years. No significant association was noted with PsA





duration, inflammatory markers and units of alcohol consumed. However, on multiple regression analysis, a significant association of MetSyn was noted with more severe PsA (OR 4.47,  $p < 0.001$ ), higher smoking pack years (OR 1.03,  $p = 0.02$ ), and worse EQ5D scores (OR 1.28,  $p = 0.02$ ).

**Conclusions:** Among PsA patients, MetSyn is highly prevalent, and is associated with the severity of underlying PsA.

**Table-1 Univariate and multivariate (adjusted simultaneously for variables shown) associations of different clinical variables with the development of Metabolic syndrome in patients with Psoriatic arthritis (n=283)**

	(Univariate analysis)	Model-1 (adjusted* OR)	Model-2 (adjusted* OR)	Model-3 (adjusted* OR)
Age	1.04 (1.02-1.06), $<0.001$			
PsA Duration	0.99 (0.95-1.00), 0.20			
Smoking pack years	1.02 (0.99-1.04), 0.056	1.02 (1.00-1.05), 0.03	1.02 (1.00-1.05), 0.052	1.03 (1.00-1.06), 0.02
Low Education Status	1.94 (1.08-3.48), 0.02			
Type-2 Psoriasis	2.35 (1.25-4.42), 0.008			
PASI max	1.02 (0.98-1.07), 0.25			
PsO age of onset	1.03 (1.01-1.05), $<0.001$			
PsA age of onset	1.02 (1.00-1.04), 0.006			
Time from PsO to arthritis development	0.97 (0.95-1.00), 0.052			
Deformed joints	1.54 (0.93-2.54), 0.08			
HAQ	1.45 (0.96-2.20), 0.07			
EQ5D	1.16 (1.02-1.32), 0.19		1.22 (1.00-1.05), 0.050	1.28 (1.03-1.59), 0.025
<b>Definition-1 of severe PsA</b> (defined as PsA requiring TNFi)	1.20 (0.74-1.94), 0.45	2.36 (1.03-5.41), 0.04		

**Abstract 32 (13A128)**

**Poster**

### Diagnostic delay of even 6 months contributes to poor radiographic and functional outcome in Psoriatic Arthritis

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**Aims/Background:** The objectives of this study were: 1) to investigate the demographic and clinical characteristics

contributing to the delay from symptom onset to the first visit with a rheumatologist; 2) to compare clinical and radiographic features and patient-reported outcome measures in those who saw a rheumatologist early in their disease course compared to those who diagnosed later, in a long-term follow-up cohort of PsA patients.

**Method:** All PsA patients, fulfilling CASPAR criteria, with an average disease duration of  $>10$  years were invited for detailed clinical evaluation. Patients were classified as early consulters or late consulters depending on whether they were seen by a rheumatologist within or beyond 6 months of symptom onset. Following informed consent, patients underwent a detailed skin and rheumatologic assessment.

**Results:** A total of 283 PsA patients were studied. Thirty percent ( $n=86$ ) of the cohort was seen by a rheumatologist within 6 months of the disease onset. On univariate analysis, late consulters had significantly more erosions (OR 4.58,  $p < 0.001$ ), osteolysis (OR 3.6,  $p = 0.01$ ), sacroiliitis (OR 2.28,  $p = 0.01$ ), arthritis mutilans (OR 10.6,  $p = 0.02$ ), number of deformed joints (OR 1.06,  $p = 0.006$ ), more DMARDs/TNFi failures (OR 1.47,  $p = 0.007$ ), less patients achieving drug free remission (OR 0.42,  $p = 0.01$ ), and worse functional disability as reflected by the HAQ scores (OR 2.17,  $p = 0.003$ ). On multiple step-wise regression analysis, the model predicted significant association of late consulters with the development of peripheral joint erosions (OR 4.25,  $p = 0.001$ ) and worse HAQ scores (OR 2.2,  $p = 0.004$ ).

**Conclusions:** Even a 6 month delay from symptom onset to the first visit with a rheumatologist contributes to the development of peripheral joint erosions and worse long-term physical function.

**Abstract 33 (13A129)**

**Poster**

### Clinical phenotype of patients with Arthritis Mutilans has important differences compared to other patients with Psoriatic Arthritis

Muhammad Haroon, Phil Gallagher, Prof Oliver FitzGerald

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**Introduction:** Arthritis mutilans (AM), a severe form of psoriatic arthritis (PsA). It is still unclear whether AM is simply the end-stage of polyarticular PsA, or whether it is a unique entity with different pathogenic mechanisms.

**Aims/Background:** The objectives of our study were 1) to investigate the prevalence of AM in an ethnically homogenous consecutive cohort of established PsA, 2) to identify the clinical phenotype of AM and its effect on quality of life, functional impairment and fatigue scores compared to those PsA patients who do not have AM.

**Method:** A cohort of 283 consecutive PsA patients, fulfilling CASPAR criteria, was included. Following informed consent, patients underwent detailed skin and rheumatologic assessments including disease activity measures.

**Results:** Among this cohort, 8% ( $n=23$ ) of patients were found to have AM, with 65% female. On univariate analysis, longer PsA



duration (OR 1.06,  $p < 0.001$ ), longer diagnostic delay (OR 1.10,  $p = 0.01$ ), more tender joint counts (OR 1.07,  $p = 0.009$ ), more swollen joint counts (OR 1.09,  $p = 0.009$ ), PsA requiring TNFi (OR 3.37,  $p = 0.03$ ), oral corticosteroids usage (OR 9.2,  $p < 0.001$ ), lower CRP maximum (OR 0.98,  $p = 0.07$ ), lower ESR maximum (OR 0.98,  $p = 0.13$ ) and higher HAQ score (OR 1.07,  $p = 0.10$ ), MCS-SF36 (OR 1.02,  $p = 0.16$ ) and PCS-SF36 (OR 1.00,  $p = 0.80$ ). On multivariate regression analysis, it was noted that heavier alcohol intake (OR 1.08,  $p = 0.002$ ), lower CRP rise (OR 0.96,  $p = 0.007$ ), greater oral corticosteroids usage (OR 7.6,  $p = 0.003$ ) and longer duration of PsA (OR 1.08,  $p = 0.001$ ) all remained significantly associated with the diagnosis of AM.

**Conclusions:** The clinical profile of patients with AM when compared to other PsA patients suggests that non-inflammatory pathogenic mechanisms, possibly related to bone turnover, may explain this unique clinical phenotype.

#### Abstract 34 (13A130) Poster

##### **HLA-B\*0801 is strongly associated with asymmetrical sacroiliitis and HLA-B\*27 with symmetrical involvement in psoriatic arthritis: results of a long-term follow-up study examining clinical and genetic**

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<sup>2</sup>Columbia University Medical Centre, New York, NY, USA

**Aims/Background:** The objectives of our study were: 1) To investigate the prevalence of SI in an ethnically homogenous cohort of established PsA, 2) to identify clinical and genetic predictors of SI in patients with PsA, 3) to describe different radiographic patterns of SI and their potential associations with clinical and genetic characteristics.

**Method:** A cohort of 283 PsA patients, fulfilling CASPAR criteria, was included. Following informed consent, patients underwent a detailed skin and rheumatologic assessment. In addition, HLA-B\*27 and B\*080101 status was recorded, which we have recently shown are the key genetic markers of radiographic SI.

**Results:** 70 patients (25%) had radiographic SI; all either had present or past history of backache. Mean age of patients with SI was  $51.6 \pm 11$  years, and 53.5% were male. Unilateral SI was present in 14 patients (27%); bilateral SI in 38 patients (73%). Of those with bilateral involvement, SI was asymmetrical in 28 (73%) patients. HLA-B\*0801 was significantly associated with asymmetrical SI, which included those with unilateral SI or asymmetrical bilateral involvement ( $p = 0.001$ ), and in striking contrast, HLA-B\*2705 was significantly associated with bilateral symmetrical SI ( $p < 0.001$ ). On backward step-wise multiple regression analysis, model predicted significant association of peripheral joint erosions (OR 1.91,  $p = 0.03$ ), PASI maximum (OR 1.05,  $p = 0.03$ ), younger PsA age of onset (OR 0.93,  $p < 0.001$ ), presence of HLA-B\*0801 (OR 2.9,  $p = 0.001$ ) and HLA-B\*2705 (OR 2.39,  $p = 0.02$ ) with SI.

**Conclusions:** PsA developing at younger age, severe skin PsO, peripheral joint erosions, HLA-B\*0801 and HLA-B\*2705 are

clinical and genetic predictors for the development of SI. We report for the first time that there are two separate principal patterns of HLA antigens explaining 2 clinically distinct sub-types of radiographic SI.

#### Abstract 35 (13A131) Poster

##### **Clinical and patient-reported outcome measures as predictors of poor functional outcome in Psoriatic Arthritis**

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Department of Rheumatology, St Vincent's University Hospital, Dublin, Ireland

**Aims/Background:** To identify predictors of poorer physical function in established psoriatic arthritis (PsA).

**Method:** A consecutive cohort of 283 PsA patients attending rheumatology clinics at St. Vincent's University Hospital, Dublin was included. Following informed consent, patients underwent a detailed skin and rheumatologic assessment including disease activity measures [PASI, Body Surface Area (BSA) for Psoriasis (Ps); DAS 28 CRP], CRP and ESR, patient-reported outcome measures (HAQ, Dermatology Life Quality Index (DLQI), Bristol Rheumatoid Arthritis Fatigue Numeric Rating Scale (BRAFF-NRS), EuroQol questionnaire (EQ5D), and radiographs were taken for involved joints along with hands, feet and sacroiliac joints.

**Results:** A total of 283 PsA patients were studied. The mean  $\pm$  SD HAQ score of the cohort was  $0.57 \pm 0.57$  (median 0.50). On univariate analysis, significant association of HAQ score was noted with female gender ( $p < 0.001$ ), older age ( $p < 0.001$ ), longer disease duration ( $p = 0.003$ ), smoking ( $p = 0.02$ ), age of Ps onset ( $p = 0.01$ ), disease duration prior to diagnosis ( $p = 0.001$ ), radiographic osteolysis ( $p = 0.012$ ), number of deformed joints on examination ( $p = 0.001$ ), maximum tender and maximum swollen joint counts ( $p < 0.001$ ), DLQI ( $p < 0.001$ ), BRAFF ( $p < 0.001$ ), EQ5D ( $p < 0.001$ ). On multiple linear regression analysis, the model predicted significant increases in HAQ related to smoking ( $p = 0.009$ ), disease duration prior to diagnosis ( $p = 0.013$ ), female gender ( $p < 0.001$ ), number of deformed joints on examination ( $p < 0.001$ ), BRAFF ( $p = 0.001$ ), EQ5D ( $p < 0.001$ ), and later PsA age of onset ( $p = 0.007$ ).

**Conclusions:** Smoking, delay to diagnosis, older age at the diagnosis, female gender, clinically deformed joints, and worse fatigue and quality of health-related life scores are associated with poor functional outcome in a cohort of established patients with PsA.

#### Abstract 36 (13A134) Poster





**Performance and benefits of replacing Mantoux test with Quantiferon in screening for latent TB in patients prior to anti TNF therapy**

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**Introduction:** Evidence shows an increased infection risk, in particular reactivation of latent TB, in patients receiving TNF inhibitor treatment<sup>(1)</sup>. Our earlier study revealed Quantiferon testing may identify additional patients with latent TB in Mantoux negative patients, indicating a potential benefit for Quantiferon testing as part of TB screening. In our modified screening protocol Mantoux testing was replaced with Quantiferon; however, chest x-ray and risk history remain part of the protocol.

**Aims/Background:** In this study, we sought to evaluate performance and benefits of incorporating Quantiferon into a TB screening protocol.

**Method:** 109 patients with inflammatory arthropathies were screened for latent TB over a twelve month period. Risk history assessment was taken, chest x-ray and Quantiferon. C.T thorax was performed if indicated by the radiologist.

**Results:** Mean age was 50.5 years, 55% female. Diagnosis: 50.5%, 27% and 21% had RA, PsA and AS, respectively, 8% (9 patients) had positive Quantiferon, all received LTBI chemoprophylaxis. Chest x-ray was suggestive of latent TB in 2.8% (3), all subsequently had normal CT- thorax. Moreover, these 2.8% (3) had negative Quantiferon testing. 7% (8) had high TB risk history, only one patient tested Quantiferon positive. To date, no patient from this cohort has developed active TB after a mean follow-up of one year.

**Conclusions:** Mantoux testing requires two patient visits, Quantiferon just one, with substantial benefits for the patient and the rheumatology nurse specialist identified in terms of time and indirect cost.

Replacing Mantoux testing with Quantiferon has to date proven a safe and effective strategy for latent TB screening.

**References:**

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**Abstract 37 (13A135)**

**Poster**

**Interleukin 10 negatively correlates with Glycoprotein VI-related platelet activation in rheumatoid arthritis (RA): a novel potential target of cardiovascular morbidity in RA**

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**Introduction:** Patients with rheumatoid arthritis (RA) die prematurely of cardiovascular disease (CVD). Platelet mediated thrombosis is a major cause of CVD. Platelets amplify inflammation in RA via the collagen receptor, glycoprotein (GP) VI. When platelets are activated, the GPVI receptor is shed and present in plasma as soluble GPVI (sGPVI).

**Aims/Background:** We investigated whether sGPVI differs in patients with active or stable RA. Since cytokines associated with disease activity in RA may effect platelet activation, we also assessed the relationship between sGPVI and plasma cytokine levels in this cohort.

**Method:** We assayed blood samples from healthy donors (n=5), patients with active RA (n=13), and controlled RA (n=10). Disease activity was assessed using the DAS-28 score. Platelet activation was assessed by measuring sGPVI. Plasma was centrifuged and sGPVI, tumour necrosis factor (TNF) $\alpha$ , interleukin (IL)1 $\alpha$ , IL6, IL8, IL10, IL12p70 and interferon (IFN) $\gamma$  were measured by ELISA.

**Results:** Mean plasma sGPVI was significantly higher in patients with active RA ( $14 \pm 7$  ng/ml; (mean $\pm$ SEM)  $p < 0.005$ ) compared to stable RA ( $5 \pm 1$  ng/ml) and controls ( $5 \pm 2$  ng/ml). Mean plasma IL-10 was significantly higher in stable RA patients ( $39 \pm 31$  pg/ml;  $p < 0.005$ ) compared to both active RA and controls ( $15 \pm 8$  and  $2.24 \pm 0.33$  pg/ml respectively). There was no association with measured cytokine and sGPVI levels apart from IL-10, which was negatively correlated with sGPVI in these 28, matched plasma samples ( $-0.432$ ;  $p = 0.045$ ).

**Conclusions:** sGPVI is a marker for platelet activation in active RA. The anti-inflammatory cytokine IL10 may negatively regulate platelet activation in active RA and could potentially be exploited in the management of RA.

**Abstract 38 (13A139)**

**Poster**



### Incident Vertebral Fractures on Routine Chest X-ray – A Missed Opportunity!

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**Introduction:** Vertebral fractures are the most common osteoporotic fracture. Women with vertebral fractures have a five-fold increased risk of developing a new vertebral fracture compared to a two-fold increased risk of developing a hip fracture.

**Aims/Background:** To determine the utility of chest radiographs in detecting vertebral fractures, establish their rates of documentation and evaluate osteoporosis management.

**Method:** We conducted a retrospective study in a random sample of 206 patients older than 60 years who presented to our emergency department over a 3 month period and underwent chest radiography for any indication. These lateral chest x-rays were independently reviewed by two clinicians to grade vertebral fractures and discrepant interpretations were subsequently resolved by consensus. Official radiology reports were then reviewed to determine the prevalence of reported fractures. In these patients, we compared their clinical notes to establish the frequency with which fractures were documented and appropriate, osteoporosis-preventing medications prescribed.

**Results:** Mean age was 73.2 years and 48.5% were women. The prevalence of moderate-to-severe vertebral fractures according to clinician interpretation was 9.2%. Of these 19 patients, 57.9% had a vertebral fracture mentioned in the official radiology report and even amongst these 11 patients, only 4 had fractures documented in their clinical notes while 3 were on treatment for osteoporosis.

**Conclusions:** Relatively few patients with evidence of clinically important vertebral fractures on chest x-ray had these recognised and documented. As up to two-thirds of these fractures are asymptomatic, this represents a missed opportunity to offer patients at high risk of future fracture appropriate treatment for osteoporosis.

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Abstract 39 (13A140)

Poster

### Hydrotherapy results in reduced pain and fatigue in patients with arthritis

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**Introduction:** Hydrotherapy, involving physiotherapy in a heated pool with the temperature ranging from 32°-36° C, is thought to give rise to decreased pain, sensation, decreased stiffness of the musculoskeletal system, and causes muscle relaxation.

**Aims/Background:** To establish the effectiveness of hydrotherapy in rheumatology patients with chronic pain.

**Method:** Short-term effects of hydrotherapy on fatigue and pain were studied, using the FACIT Fatigue Scale (version 4) and a Quadruple Visual Analogue Scale (current/typical/best/worst pain). Surveys were given to 24 rheumatology inpatients before and after 3 days of hydrotherapy. Patients' diagnoses included osteoarthritis, rheumatoid arthritis, degenerative disc disease, psoriatic arthritis and lupus. A literary review of existing randomised controlled trials or quasi-randomised clinical trials using the Cochrane Library was also carried out.

**Results:** Of the 24 patients a 17% (p.004) reduction in fatigue and a 9% (p 0.13) reduction in pain was obtained. Randomised control studies showed that a statistically significant improvement in physical function, pain, mental health and quality of life, when compared to a control group but in a six month follow-up randomized control trial reporting on this lasting effectiveness, benefits were not shown to last more than 6 months, suggesting that hydrotherapy may be better used on more of a continuum than a once off treatment<sup>(1)</sup>.

**Conclusions:** In conclusion, hydrotherapy is an excellent base on which to start physiotherapy before commencing land-based programmes and may be continued to preserve improvements seen at the end of initial hydrotherapy. Further studies looking at the longer term impact of hydrotherapy intervention are planned.

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Abstract 40 (13A143)

Poster

The Prevalence and Pattern Of Self Reported Joint





### Symptoms In Cystic Fibrosis

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**Introduction:** Arthritis in cystic fibrosis (CF) can be incapacitating, and is mainly of three types: CF arthritis, hypertrophic osteoarthropathy, and arthritis due to co-existent conditions and drug reactions<sup>[1]</sup>. Episodic arthritis occurring in patients with CF has been recognised<sup>[2]</sup>. However, although joint manifestations are common in children with cystic fibrosis (CF), they have received little attention in adults<sup>[3]</sup>.

**Aims/Background:** The prevalence of joint pain in the CF patients has been reported variously as: 12.9% [4], 2-8.5% of patients [3] and 4.5% in patients aged over 10 [5].

**Method:** 55 adult patients with CF (age 18 to 63 years) were assessed by questionnaire and phone interview designed to elicit the pattern of joint problems, and to determine features of definite inflammatory problems.

**Results:** 63.6% (35/55) reported having experienced joint pain, but only 37.1% of those who reported pain at any point said that it had affected important activities in their lives. 16.4% (9/55) reported more than one hour of morning stiffness in their joints. 30.9% (17/55) reported joint swelling or difficulty making a fist. In those that reported pain, 60% (21/35) reported wrist pain, with 42.9% (9/21) of these patients reporting wrist swelling. 16.4% (9/55) of the total cohort had experienced both wrist pain and swelling. In those that reported pain, 57.1% (20/35) reported hand pain, with 60% (12/20) reporting swelling and 65% (13/20) having difficulty making a fist. Knee 80% (28/35), ankle 60% (21/35) and foot 31.4% (11/35) pain were cited by those reporting pain. Symmetrical disease in time was reported in 48.6% (17/35) patients.

**Conclusions:** The prevalence of joint symptoms by self-report in our CF cohort far exceed that reported in previous studies, with up to 30% having inflammatory symptoms/signs. No definite pattern of involvement could be identified in this study.

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### Abstract 41 (13A144)

### Poster

#### An examination of the potential to change the NSAID prescription to paracetamol in primary care

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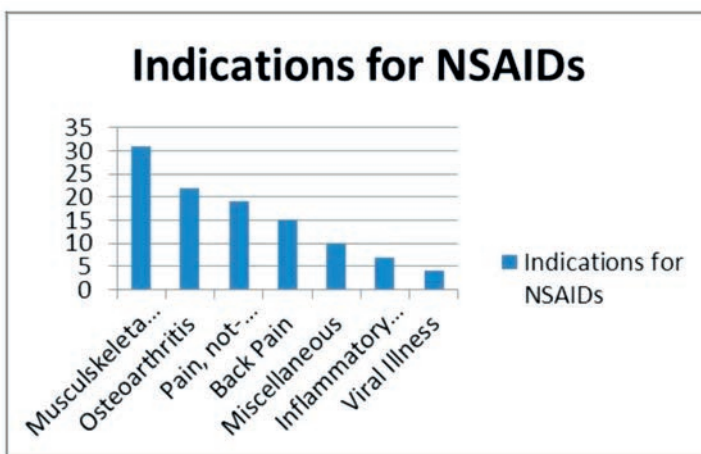
**Introduction:** The NSAID prescription is prevalent in primary care<sup>(1)</sup>, but new evidence suggests that there is a significant increase in the risk of death or myocardial infarction (MI), in patients with previous MI when given even short term treatment with NSAIDs<sup>(2)</sup>. Although NSAIDs have been shown to be superior to paracetamol in their analgesic effect, this difference is small<sup>(3)</sup>.

**Aims/Background:** We studied the prescribing of NSAIDs by duration of use, indication and the concomitant prescribing of paracetamol in a large primary care facility. The principal aim was to determine if patients could have been given a trial prescription for regular paracetamol instead of an NSAID.

**Method:** The clinics active patient list (n=10,000) was studied by interrogating the practice management software, to identify patients over 50 years who had been prescribed NSAIDs for any duration, over a two month period in 2012. A record was kept of the indication for treatment and the duration of prescription, as well as whether the patient was also prescribed or known to be taking paracetamol.

**Results:** 108 (45 male) patients were prescribed NSAIDs during the period of the study, whose ages ranged from 50-87 years. 29/108 (26.9%) were concomitantly prescribed paracetamol. This number increased for those prescribed NSAIDs for longer than one month to 17/108 (29%).

**Figure 1** displays the indications for NSAID





# TRUST in HUMIRA

10

YEARS OF EFFICACY DATA FOR RA IN LABEL<sup>1</sup>

9

INDICATIONS -  
THE MOST OF ANY SELF-  
ADMINISTERED BIOLOGIC<sup>1</sup>

MORE THAN

85

COUNTRIES<sup>2</sup>

15

YEARS OF CLINICAL TRIAL  
EXPERIENCE, BEGINNING WITH  
RHEUMATOID ARTHRITIS (RA)<sup>2</sup>

71

CLINICAL TRIALS IN THE LARGEST PUBLISHED  
ANTI-TUMOR NECROSIS FACTOR (TNF)  
CROSS-INDICATION SAFETY DATABASE<sup>3</sup>

**Humira (adalimumab) 40mg solution for injection in pre-filled pen or pre-filled syringe and Humira 40mg/0.8ml solution for injection for paediatric use** Refer to Summary of Product Characteristics for full information. **Presentation:** Each 0.8ml single dose pre-filled pen, pre-filled syringe or vial contains 40mg of adalimumab. **Indications:** Rheumatoid arthritis (RA): Humira in combination with methotrexate is indicated for the treatment of moderate to severe, active RA in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate has been inadequate. Humira is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with methotrexate. Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Humira has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. **Polyarticular juvenile idiopathic arthritis (JIA):** Humira in combination with methotrexate is indicated for the treatment of active JIA, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more DMARDs. Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **Psoriatic arthritis (PsA):** Humira is indicated for the treatment of active and progressive PsA in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Humira 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):** Humira is indicated for the treatment of adults with severe active AS who have had an inadequate response to conventional therapy. **Axial spondyloarthritis (SpA) non-radiographic:** Humira is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and / or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Crohn's disease (CD):** Humira is indicated for treatment of moderate to severe, active CD, in patients 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. **Paediatric Crohn's disease:** Humira is indicated for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. **Psoriasis (Ps):** Humira is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA. **Ulcerative colitis (UC):** Humira is indicated for treatment of moderate to severe active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Dosage and administration:** Humira treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Humira is indicated. Patients treated with Humira should be given the special alert card. After proper training in injection technique, patients may self-inject with Humira if their physician determines that it is appropriate and with medical follow-up as necessary. During treatment with Humira, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised. RA, PsA, AS or SpA non-radiographic: 40mg administered every other week as a single dose via subcutaneous injection. RA: In monotherapy some patients who experience a decrease in their response to Humira may benefit from an increase in dose intensity to 40mg every week. There may be a need for dose interruption, for instance before surgery or if a serious infection occurs. Available data suggest that re-introduction of Humira after discontinuation for 70 days or longer resulted in the same magnitudes of clinical response and similar safety profile as before dose interruption. For RA, JIA, PsA and AS, available data suggest that the clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in a patient not responding within this time period. JIA: Age 2 to 12 years: 24mg/m<sup>2</sup> body surface area to a maximum single dose of 40mg administered every other week via subcutaneous injection. The volume for injection is based on the patient's height and weight (see SmPC for height and weight dosing chart). A 40mg paediatric vial is available for patients who need to administer less than the full 40mg dose. Age 13 to 17 years: 40mg administered every other week via subcutaneous injection regardless of body surface area. CD: The recommended Humira induction dose regimen for adult patients with moderate to severe CD is 80mg at Week 0 followed by 40mg at Week 2. In case there is a need for a more rapid response to therapy, the regimen 160mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80mg at Week 2, can be used with the awareness that the risk for adverse events is higher during induction. After induction treatment, the recommended dose is 40mg every other week via subcutaneous injection. Alternatively, if a patient has stopped Humira and signs and symptoms of disease recur, Humira may be re-administered. There is little experience from re-administration after more than 8 weeks since the previous dose. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Some patients who experience decrease in their response may benefit from an increase in dosing frequency to 40mg Humira every week. Some patients who have not responded by Week 4 may benefit from continued maintenance therapy through Week 12. Continued therapy should be carefully reconsidered in a patient not responding within this time period. Paediatric CD: patients <40kg: recommended induction dose regimen of 40mg at Week 0 followed by 20mg at Week 2 via SC injection. In case of need for a more rapid response to therapy, the regimen 80mg at Week 0 (dose can be administered as two injections in one day), 40mg at Week 2, can be used with the awareness that the risk for adverse events is higher during induction. After induction treatment, the recommended dose is 20mg every other week via SC injection. Some patients who experience insufficient response may benefit from 20mg every week patients >40kg: double the dose regimen for those patients <40kg. Continued therapy should be carefully reconsidered in a patient not responding by week 12. Psoriasis: The recommended dose of Humira for adult patients is an initial dose of 80mg administered subcutaneously, followed by 40mg subcutaneously given every other week starting one week after the initial dose. Continued therapy beyond 16 weeks should be carefully reconsidered in a patient not responding within this time period. UC: The recommended Humira induction dose regimen for adult patients with moderate to severe UC is 160mg at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80mg at week 2. After induction treatment, the recommended dose is 40mg every other week via subcutaneous injection. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Some patients who experience decrease in their response may benefit from an increase in dosing frequency to 40mg Humira every week. Available data suggest that clinical response is usually achieved within 2-8 weeks of treatment. Continued therapy is not recommended in patients not responding within this time period. **Contraindications:** Active tuberculosis or other severe infections such as sepsis, and opportunistic infections; moderate to severe heart failure (NYHA class III/IV) and hypersensitivity to adalimumab or any of the excipients. **Precautions and Warnings:** Infections: Patients taking TNF-antagonists are more susceptible to serious infections. Impaired lung function may increase the risk for developing infections. Patients must therefore be monitored closely for infections, including tuberculosis, before, during and for 4 months after treatment with Humira. Treatment with Humira should not be initiated in patients with active, chronic or localised infections until infections are controlled. In patients who have been exposed to tuberculosis and patients who have travelled in areas of high risk of tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment with Humira should be considered prior to initiating therapy (see Opportunistic infections). Patients who develop a new infection while undergoing treatment with Humira should be monitored closely and undergo a complete diagnostic evaluation. Administration of Humira should be discontinued if a patient develops a new serious infection or sepsis, and appropriate antimicrobial or antifungal therapy should be initiated until the infection is controlled. Physicians should exercise caution when considering the use of Humira in patients with a history of recurring infection or with underlying conditions which may predispose to infections, including the use of concomitant immunosuppressive medications. **Serious infections:** Serious infections, including sepsis, due to bacterial, mycobacterial, invasive fungal, parasitic, viral, or other opportunistic infections such as listeriosis, legionellosis and pneumocystis have been reported in patients receiving Humira. Other serious infections seen in clinical trials include pneumonia, pyelonephritis, septic arthritis and septicaemia. Hospitalisation or fatal outcomes associated with infections have been reported. **Tuberculosis:** Tuberculosis, including reactivation and new onset of tuberculosis, has been reported in patients receiving Humira. Reports included cases of pulmonary and extra-pulmonary (i.e. disseminated). Before initiation of therapy with Humira, all patients must be evaluated for both active or inactive ("latent") tuberculosis infection. Appropriate screening tests, should be performed in all patients, local recommendations may apply. If active tuberculosis is diagnosed, Humira therapy must not be initiated. If latent tuberculosis is suspected, a physician with expertise in the treatment of tuberculosis should be consulted and the benefit/risk balance of therapy with Humira should be considered. If inactive ("latent") tuberculosis is diagnosed, appropriate treatment must be started with anti-tuberculosis prophylaxis treatment before the initiation of Humira, and in accordance with local recommendations. In patients who have several or significant risk factors for tuberculosis despite a negative test for tuberculosis, anti-tuberculosis prophylaxis treatment should also be considered before the initiation of Humira and in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Some patients who have previously received treatment for latent or active tuberculosis have redeveloped tuberculosis while being treated with Humira. **Other opportunistic infections:** Opportunistic infections, including invasive fungal infections have been observed in patients receiving Humira. These infections have not consistently been recognised in patients taking TNF-antagonists and this resulted in delays in appropriate treatment, sometimes resulting in fatal outcomes. For patients who develop the signs and symptoms such as fever, malaise, weight loss, sweats, cough, dyspnoea, and/or pulmonary infiltrates or other serious systemic illness with or without concomitant shock, an invasive fungal infection should be suspected and administration of Humira should be promptly discontinued. Diagnosis and administration of empiric antifungal therapy in these patients should be made in consultation with a physician with appropriate expertise. **Hepatitis B Reactivation:** Reactivation of hepatitis B (HBV) has occurred in patients receiving a TNF-antagonist including Humira, who are chronic carriers of this virus (i.e. surface antigen positive), with some fatal outcomes. Patients should be tested for HBV infection before initiating treatment. Patients that test positive should have a consultation with a physician. In patients who develop HBV reactivation, Humira should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated. Carriers of HBV should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of Humira. **Neurological events:** Humira has been associated, in rare cases, with



# - An unmatched legacy.

MORE THAN

670,000

PATIENTS CURRENTLY  
TREATED WORLDWIDE<sup>2</sup>

MORE THAN

23,000

PATIENTS IN GLOBAL STUDIES<sup>3</sup>

**HUMIRA** **10**  
adalimumab YEARS

new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease including multiple sclerosis and optic neuritis, and peripheral demyelinating disease, including Guillain-Barré syndrome. Caution should be exercised when considering Humira in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. **Allergic reactions:** Postmarketing serious allergic reactions including anaphylaxis have been received following Humira administration. If an anaphylactic reaction or other serious allergic reaction occurs, administration of Humira should be discontinued immediately and appropriate therapy initiated. **Malignancies and lymphoproliferative disorders:** In clinical trials, more cases of malignancies including lymphoma and leukaemia have been observed among patients receiving a TNF-antagonist compared with control patients. These data cannot exclude a possible risk of malignancy in patients including children and adolescents treated with TNF-antagonists. Furthermore, there is an increased background lymphoma risk in RA patients. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been identified in patients treated with adalimumab. Some of these cases have occurred in young adult patients on concomitant treatment with azathioprine or 6-mercaptopurine used for inflammatory bowel disease. The potential risk with the combination of azathioprine or 6-mercaptopurine and Humira should be carefully considered. A risk for the development of hepatosplenic T-cell lymphoma in patients treated with Humira cannot be excluded. Caution should be exercised in considering Humira treatment of patients with a history of malignancy. All patients, and in particular patients with a medical history of extensive immunosuppressive therapy or psoriasis patients with a history of PUVA treatment should be examined for the presence of non-melanoma skin cancer prior to and during treatment with Humira. Caution should also be exercised when using TNF-antagonists in COPD patients, as well as in patients with increased risk of malignancies due to heavy smoking. With current data it is not known if adalimumab treatment influences the risk for developing dysplasia or colon cancer. All patients with UC who are at increased risk for dysplasia or colon carcinoma (e.g. patients with long-standing UC or primary sclerosing cholangitis), or who had a prior history of dysplasia or colon carcinoma should be screened for dysplasia at regular intervals before therapy and throughout their disease course. This evaluation should include colonoscopy and biopsies per local recommendations. **Haematologic reactions:** Pancytopenia including aplastic anaemia has rarely been reported with TNF blocking agents. Adverse events of the haematologic system, including cytopenia (eg thrombocytopenia, leucopenia) have been reported with Humira. Patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias. **Vaccinations:** Patients on Humira may receive concurrent vaccinations, except for live vaccines. It is recommended that JJA patients, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Humira therapy. **Congestive heart failure:** Humira should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in patients who develop new or worsening symptoms of congestive heart failure. **Autoimmune process:** Humira may result in the formation of autoimmune antibodies. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Humira and is positive for antibodies against double-stranded DNA, further treatment with Humira should not be given. **Surgery:** There is limited safety experience of surgical procedures in patients treated with Humira. The long half life of Humira should be taken into consideration when a surgical procedure is planned, and the patient should be monitored for infections. **Small bowel obstruction:** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture that may require surgical treatment. Available data suggest that Humira does not worsen or cause strictures. **Elderly population:** The frequency of serious infections among Humira treated subjects over 65 years of age was higher than those under 65 years of age. Some of those had a fatal outcome. Particular attention regarding the risk for infection should be paid when treating the elderly. **Interactions:** Combination of adalimumab with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Pregnancy and lactation:** Administration of adalimumab is 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. Administration of live vaccines to infants exposed to adalimumab in utero is not recommended for 5 months following the mother's last adalimumab injection during pregnancy. Women must not breast-feed for at least five months after the last Humira treatment. **Driving and machinery:** Humira may have a minor influence on the ability to drive and use machines. **Side Effects:** From clinical trials unless marked '1' which indicates spontaneous reporting data. Very common  $\geq 1/10$ ; Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leucopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema). Common  $\geq 1/100$  to  $< 1/10$ ; Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections, benign neoplasm, skin cancer excluding melanoma (including basal cell carcinoma and squamous cell carcinoma), thrombocytopenia, leucocytosis, hypersensitivity, allergies (including seasonal allergy), hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphataemia, dehydration, mood alterations (including depression), anxiety, insomnia, paraesthesiae (including hypoesthesia), migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, cough, asthma, dyspnoea, GI haemorrhage, dyspepsia, gastroesophageal reflux disease, sicca syndrome, worsening and new onset of psoriasis (including palmoplantar pustular psoriasis), alopecia, pruritis, urticaria, bruising (including purpura), dermatitis (including eczema), onycholysis, hyperhidrosis, muscle spasms (including blood creatine phosphokinase increased), haematuria, renal impairment, chest pain, oedema, pyrexia, coagulation and bleeding disorders (including activated partial thromboplastin time prolonged), autoantibody test positive (including double stranded DNA antibody), blood lactate dehydrogenase increased, impaired healing. Uncommon  $\geq 1/1000$  to  $< 1/100$ ; Opportunistic infections and tuberculosis (including coccidioidomycosis, histoplasmosis and mycobacterium avium complex infection), neurological infections (including viral meningitis), eye infections, bacterial infections (including diverticulitis), lymphoma, solid organ neoplasm (including breast cancer, lung neoplasm and thyroid neoplasm), melanoma, idiopathic thrombocytopenic purpura, sarcoidosis, cerebrovascular accident, tremor, neuropathy, diplopia, deafness, tinnitus, myocardial infarction, arrhythmia, congestive heart failure, pulmonary embolism, chronic obstructive pulmonary disease, interstitial lung disease, pneumonitis, pleural effusion, pancreatitis, dysphagia, face oedema, cholecystitis and cholelithiasis, bilirubin increased, hepatic steatosis, night sweats, scar, rhabdomyolysis, systemic lupus erythematosus, nocturia, erectile dysfunction, inflammation, vascular arterial occlusion, aortic aneurysm, thrombophlebitis. Rare  $\geq 1/10,000$  to  $< 1/1,000$ ; Leukaemia, anaphylaxis, demyelinating disorders (e.g. optic neuritis, Guillain-Barré syndrome), pancytopenia, multiple sclerosis, cardiac arrest, pulmonary fibrosis, intestinal perforation, reactivation of hepatitis B, autoimmune hepatitis, erythema multiforme, cutaneous vasculitis, Stevens-Johnson syndrome, angioedema, lupus-like syndrome. Very rare  $< 1/10,000$ ; Liver failure. Not known: Hepatosplenic T-cell lymphoma, Merkel Cell Carcinoma. **Prescribers should consult the summary of product characteristics for further information on side effects. Overdose:** No dose-limiting toxicity was observed during clinical trials. The highest dose level evaluated has been multiple intravenous doses of 10 mg/kg (approximately 15 times the recommended dose). **Legal Category:** POM Marketing Authorisation Numbers/Presentations: Vial: EU/1/03/256/001; 1 pack contains 2 cartons each containing 1 single use vial and empty sterile injection syringe, needle and vial adapter. Pre-filled Syringe: EU/1/03/256/003; Each carton contains 2 single use pre-filled syringes in a blister, Pre-filled Pen: EU/1/03/256/008; Each carton contains 2 single use pre-filled pens in a blister. **Further information is available from AbbVie Limited, Block B, Liffey Valley Office Campus, Quarryvale, Co. Dublin. Date of revision of PI:** February 2013 PI/256/008. **References:** 1. HUMIRA [summary of product characteristics]. AbbVie Limited; Available on [www.medicines.ie](http://www.medicines.ie) 2. Data on file, AbbVie Inc. 2012. 3. Burmester GR, Panaccione R, Gordon KB, et al. Adalimumab: long-term safety in 23 458 patients from global clinical trials in rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis and Crohn's disease [published online ahead of print May 5, 2012]. *Ann Rheum Dis*. doi:10.1136/annrheumdis-2011-201244.

IREHUM130069(1) Date of Preparation: August 2013

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paracetamol to their NSAID prescription.

Recent recommendations in treating osteoarthritis do not advocate NSAIDs over paracetamol<sup>(4)</sup>.

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#### Abstract 42 (13A145)

#### Poster

### An assessment of the prevalence of NSAID prescriptions in primary care in those with ischaemic heart disease (IHD) or risk factors for IHD

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**Introduction:** Nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed in primary care<sup>(1)</sup>, but little is known about NSAID treatment duration and its implications for cardiovascular risk<sup>(2, 3)</sup>. New evidence suggests that there is a significant increase in the risk of death or myocardial infarction (MI), in patients with previous MI when given even short term treatment (<1 week) with NSAIDs<sup>(4)</sup>.

**Aims/Background:** We set out to address whether there is a need for prescribing guidelines on the use of NSAIDs in those with IHD.

**Method:** All patients over 50 years, who had been prescribed NSAIDs for any duration, over a two month period in 2012 were included. Those with documented IHD as well as those with diabetes mellitus and/or hypertension were identified.

**Results:** 108 patients were prescribed NSAIDs during the period of the study. 39/108 (36%) patients (17 male) had established ischaemic heart disease or risk factors for cardiovascular disease when they were prescribed NSAIDs. Diclofenac was the NSAID prescribed in 56% of cases. The mean duration of treatment in the 39 patients was 265 days. 22 of 39 (56%) were prescribed NSAIDs for longer than 1 month, and 6 of the 39 (15%) were prescribed NSAIDs for a year or longer.

**Conclusions:** It is disconcerting that diclofenac is the most commonly prescribed NSAID. The increased risk of death and MI becomes apparent immediately with it<sup>(4)</sup>. Diclofenac was

prescribed as the preferred agent in 53.9% of (NSAID) prescriptions filled in Ireland in 2010, making it the most commonly prescribed NSAID<sup>(5)</sup>.

A critical component of new guidelines should be a recommendation to switch from using diclofenac as the NSAID of choice, to safer alternatives.

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#### Abstract 43 (13A147)

#### Poster

### Adherence to Osteoporosis medications is better in patients who also have Rheumatoid Arthritis due to awareness of consequences of untreated disease & increased satisfaction with healthcare providers

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**Introduction:** Rheumatoid Arthritis (RA) and Osteoporosis (OP) are chronic diseases requiring long-term medication. Non-adherence is a well recognised problem in treating these conditions<sup>1,2</sup>. Patients' overall perception of their condition and its management could have an impact on their adherence<sup>3</sup>.

**Aims/Background:** To identify patients' perceptions of living with RA and/or OP and the overall management of their condition. There was a particular focus on medication adherence and factors that may influence it.

**Method:** 33 patients with RA and/or OP were identified through chart review and invited to participate in an interview. 15 individual interviews and 3 focus groups were conducted. Transcripts were analysed and the process of open data coding was used to identify themes emerging from conversations. Prevailing themes were agreed upon and statements were selected to illustrate each theme.

**Results:** Patients with RA reported better adherence for RA and OP medications than patients with OP alone. Reasons for this were regular follow up and confidence in healthcare





professionals. Patients with RA were confident that medication concerns would be dealt with. "I'm very pleased that they're trying different things, they don't make you feel that you're a nuisance when one drug doesn't work." Patients with OP alone reported less contact with health professionals in relation to their condition and were less concerned about their disease.

**Conclusions:** Regular contact with the healthcare provider improves patients' satisfaction with their disease management and in turn has a positive impact on medication adherence. Improved support and education may help to improve adherence in OP patients.

**References:** 1. Silverman S. Adherence to Medications for the Treatment of Osteoporosis. *Rheum Dis Clin N Am.* 2006; 32:721-731.  
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#### Abstract 44 (13A148)

#### Poster

##### Orthopaedic Surgeons' views of Physiotherapy Extended Scope Practitioners in Ireland

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**Introduction:** Physiotherapy Extended scope practitioners (ESPs) are defined as Clinical Specialists with an extended scope of practice<sup>(1)</sup>. ESP posts have resulted in reduced patient waiting times and costs in the United Kingdom<sup>(2)</sup>. The Health Service Executive has recently introduced ESP-led musculoskeletal clinics in Ireland. Research suggests that successful clinics depend on good relationships between Doctors and ESPs<sup>(3)</sup>.

**Aims/Background:** The primary aim of this survey was to determine Irish Orthopaedic Surgeons' views of ESPs and their level of support for this initiative.

**Method:** A cross-sectional, self-reported survey of 141 Consultant and Specialist Registrar members of the Irish Institute of Trauma and Orthopaedic Surgery (IITOS) was conducted using online and postal formats. Data were analysed using descriptive statistics and Spearman's rank correlation coefficients using SPSS v20.

**Results:** A response rate of 43% (60/141) was achieved (male 88%, Consultant level 70%). The majority (79.3%) supported the introduction of ESPs. Respondents agreed that benefits included waiting list reduction (66%), and freeing up Orthopaedic Surgeons' time for alternative tasks (73%). 71% agreed that ESPs are competent to formulate accurate diagnoses however

some disagreed that ESPs would be competent to interpret the results of MRIs (63%) and x-rays (45%). No significant correlations were found between the level of support for ESP introduction and respondents' demographic details.

**Conclusions:** In the first survey of its kind in Ireland, a high level of support was expressed by IITOS members for the ESP role. However members expressed concerns regarding aspects of competence and training. There is a need for further larger scale study as ESPs become established posts in Ireland.

**References:** 1. The Chartered Society of Physiotherapy. Information paper PA 29. Chartered physiotherapists working as extended scope practitioners. London: The Chartered Society of Physiotherapy; 2002.  
2. Stanhope J, Grimmer-Somers K, Milanese S, Kumar S, Morris J. Extended scope physiotherapy, roles for orthopaedic outpatients: an updated review of the literature. *J. Multidiscip. Healthc.* 2012; 5: p. 37-45.  
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#### Abstract 45 (13A152)

#### Poster

##### An Audit of concurrent Proton Pump Inhibitor (PPI) usage in Rheumatoid Arthritis patients who are on Non-Steroidal Anti-Inflammatory (NSAID) medications

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**Introduction:** There is a well established relationship between NSAID usage and gastrointestinal injury. The incidence of gastric and duodenal ulcer and their complications such as haemorrhage and perforation is much higher in patients taking NSAIDs, as compared to placebo, the risk is five times in patients above 60 yrs.

**Aims/Background:** To determine how many of our Rheumatoid Arthritis (RA) patient cohort are taking NSAIDs and if PPIs are prescribed correctly in particular high risk patient subgroups (ACG Guidelines) to protect against adverse events. ACG Guidelines: Patients prescribed NSAIDs, that are in a high risk subgroups should be co-prescribed a PPI. High Risk includes: 1) Age >60, 2) Prior history of a duodenal or gastric ulcer, 3) Concurrent use of steroids, Aspirin or anticoagulant, 4) Helicobacter Pylori infection.

**Method:** A retrospective study, in which the electronic outpatient health records of all RA patients attending the rheumatology outpatients in Tullamore Hospital were reviewed. Patients currently using an NSAID were noted. It was then determined if they were in a high risk category. Finally it was clarified if they were co-prescribed a PPI.

**Results:** 450 RA patients were analysed for data collection, with an age range from 21 to 90.

**Conclusions:** We have identified that there are RA patients who



are taking NSAIDs who fall into high risk group for developing adverse gastrointestinal events, that are currently not on a PPI. At outpatient review, RA patients that are on NSAIDs should be scrutinized to determine if they fall into a high risk group so that subsequent co-prescription of a PPI can be added to their drug regime.

**References:** 1. Cryer B, Feldman M. 2. Soll AH, Weinstein WM, Kurata J et al.

PATIENT SUBGROUP	NUMBER (%)
NSAIDS	196/450 (43.5%)
NSAIDS + PPI	90/196 (45.9%)
NSAIDS + age>60	85/196 (43.4%)
NSAIDS + age>60 + PPI	50/85 (58.8%)
NSAIDS + Aspirin	21/ 196 (10.7%)
NSAIDS + Aspirin + PPI	15/21 (71.4%)
NSAIDS + Steroids	34/196 (17.3%)
NSAIDS + Steroids + PPI	24/34 (70.6%)
NSAIDS + Anticoagulant	5/196 (2.6%)
NSAIDS + Anticoagulant + PPI	3/5 (60.1%)
NSAIDS + Helicobacter pylori	8/196 (4.1%)
NSAIDS + Helicobacter pylori + PPI	6/8 (75%)

#### adhering to the guidelines

Helbert L, Durcan L, Geraghty L, Kavanagh P, Donnelly S

Rheumatology Department, Mater University Hospital

**Introduction:** Hydroxychloroquine (HCQ) is a commonly prescribed medication in rheumatic conditions. HCQ is associated with retinal toxicity. The guidelines from The American Academy of Ophthalmology (AAO) in 2011 recommend annual screening for retinal toxicity after 5 years of exposure. The majority of cases of retinal toxicity have occurred after this timeframe. In our department at present there is no consensus on the best time for referral to ophthalmology.

**Method:** We screened the first fifty patients found to be prescribed HCQ. We recorded diagnosis, duration of therapy, maintenance dose and time of screening. Those who had not been screened accordingly were highlighted and a referral to ophthalmology was sent.

**Results:** Twenty seven (54%) had RA, 14 (28%) had SLE and 9 (18%) had other inflammatory conditions. Ten (20%) were taking 200mg per day and 40 (80%) were taking 400mg per day. The mean length of exposure was 5.34 years. Twenty four (48%)

individuals had in excess of 5 years exposure. Of these 6 (25%) had not been screened for retinal toxicity. In contrast to this 14 (53.8%) individuals with less than 5 years exposure have been screened. None of the screened patients were found to have any toxicity.

**Conclusions:** We found that a significant proportion of our patients taking long term HCQ therapy are not being appropriately screened, while in other cases patients are being referred prematurely. We have updated our patient information leaflet to reflect the AAO guidelines and have arranged a quarterly shared ophthalmology meeting as a best practice initiative. We now specifically educate patients on the need for an eye assessment after 5 years.

**References:** The American Academy of Ophthalmology (AAO) 2011, www.aao.org.

#### Abstract 47 (13A154)

#### Poster

#### Certain Class I HLA Alleles and Haplotypes Appear to Play a Role in Variations of the Psoriatic Arthritis Phenotype

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Department of Rheumatology, St Vincent's University Hospital, Dublin, Ireland and Columbia University medical Centre, New York, NY, USA

**Aims/Background:** Psoriatic arthritis (PsA) is associated with the inheritance of several different class-I alleles. This study was based on the hypothesis that this genetic heterogeneity contributes to the clinical heterogeneity of PsA.

**Method:** A cohort of 282 PsA patients was assessed for clinical risk factor and disease features. HLA-B and HLA-C genotypes were determined by sequence-based typing. We explored univariate associations of these alleles and haplotypes with specific clinical characteristics and with a propensity score that ranked patients according to the number of distinctive PsA features present (enthesitis, dactylitis, sacroiliitis, joint deformity, joint fusion, erosion, and osteolysis). To explore the potential genotypic effects of pairwise combinations of different HLA-B and C alleles/haplotypes on the propensity score, we created a series of allele/haplotype risk scores combining single alleles/haplotypes that were separately associated with the highest Propensity score.

**Results:** In univariate analysis enthesitis was strongly associated with the inheritance of HLA-B\*27:05-C\*01:01 and its constituent alleles. The more severe PsA phenotype characterized by the greatest propensity score was characterized by three haplotypes: B\*2705-C\*02:02 haplotype, or its constituent alleles, but not B\*27:05-C\*01:01; haplotype B\*08:01:01-C\*07:01:01 and the B\*37:01-C\*06:02 haplotype, but not B\*57:01-C\*06:02. In contrast, B\*44:02:01:01-C\*05:01:01:01 haplotype was associated with milder disease.

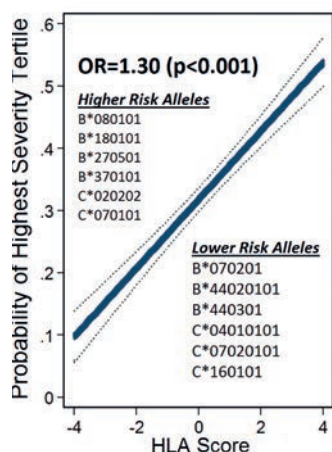
**Conclusions:** Multiple individual HLA alleles and haplotypes are separately associated with particular clinical features present in the overall phenotype of PsA such as enthesitis, osteolysis or dactylitis. Additionally, a more severe or a milder disease





phenotype is conferred in an apparent additive manner by different combinations of alleles.

## Figure



**Figure.** Each patient was assigned an HLA score based on their number of high and low risk alleles (from univariate modeling on the outcome of PsA Severity Propensity). A patient with 4 low risk alleles was assigned a score of -4, while one with 4 high risk alleles was assigned a score of +4. Each unit increase in the HLA score was associated with a 30% higher odds of being in the highest tertile of PsA Severity Propensity (p-value<0.001). The least squares estimator of the average probability (thick line) and 95% CI (dotted line) are depicted, with adjustment for age, current smoking, pack-years of smoking, duration of psoriasis and psoriatic arthritis, years between psoriasis and psoriatic arthritis, and TNF inhibitor use

## Detection of Pulmonary Hypertension in Patients with Connective Tissue Disease

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Department of Rheumatology, Cork University Hospital

**Introduction:** Pulmonary complications are a leading cause of morbidity and mortality in patients with systemic sclerosis and other connective tissue diseases.

**Aims/Background:** Right heart catheterization (RHC) is the investigation of choice for the diagnosis and evaluation of pulmonary hypertension. Accurate patient selection for this invasive test is important.

**Method:** We identified all patients with connective tissue disease who underwent RHC in the previous five years and gathered an extensive clinical dataset on these patients. We validated a recently published formula for non-invasive estimation of pulmonary pressures in patients with connective tissue disease.  $mPAP = 136 - SpO_2 - 0.25 \times DLCO\%$  predicted

**Results:** We identified 20 patients with connective tissue disease who underwent RHC due to clinical suspicion of pulmonary hypertension; the majority (n=16) had systemic sclerosis. 12 patients were diagnosed with pulmonary hypertension on the basis of RHC findings; 8 had normal pulmonary pressures.

When the formula for non-invasive detection of pulmonary hypertension was applied, those with a predicted mPAP of >30 mmHg (n=9) were at high risk of having RHC confirmed pulmonary hypertension.

**Conclusions:** We validated an easily applied formula that identifies a subgroup with a high prevalence of pulmonary hypertension. This information could improve the selection of patients for RHC.

**References:** Improving the Detection of Pulmonary Hypertension in Systemic Sclerosis Using Pulmonary Function Tests. Benjamin E. Schreiber, Christopher J. Valerio, Gregory J. Keir, Clive Handler, Athol U. Wells, Christopher P. Denton and John G. Coghlan. ARTHRITIS & RHEUMATISM. Vol. 63, No. 11, November 2011, pp 3531–3539.

## Abstract 49 (13A159)

## Poster

## The effect of exercise on sleep and fatigue in rheumatoid arthritis: a randomised controlled study

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**Introduction:** Sleep disturbance and chronic fatigue are common in rheumatoid arthritis (RA) and contribute to disability, symptomatology and healthcare utilization. It has long been recognised in other populations that exercise can improve sleep and diminish fatigue. The effect of exercise on sleep quality and fatigue in RA has not been evaluated.

**Aims/Background:** This is a randomised controlled study in RA to determine the effect on an exercise programme on sleep quality and fatigue.

**Method:** RA patients were randomised to either a 12 week home-based exercise intervention or usual care. The programme consisted of specific exercises to target deficiencies identified using the health assessment questionnaire (HAQ) with cardiovascular work as per the guidelines. Full evaluation was carried out at baseline and at 12 weeks. Fatigue was measured using the Fatigue Severity Index. Sleep quality was evaluated using the Pittsburgh Sleep Quality Index.

**Results:** Forty patients were randomised to the intervention with 38 controls. In the exercise intervention group there was a statistically significant improvement in HAQ, pain, stiffness, and perceptions regarding exercise benefits, sleep quality and fatigue. In our control group there was a statistically significant improvement demonstrated in their overall perceptions of the benefits of exercise but none of the other parameters (Table 1.).

**Conclusions:** This is the first study evaluating the effect of exercise on sleep quality and fatigue in RA. It demonstrates clinically important and statistically significant improvements in fatigue, sleep quality, symptomatology and functional disability. This gives further weight to the theory that in RA exercise should be encouraged, prescribed and could have disease modifying properties.

## Intervention Group



	Baseline (SD)	12 Weeks (SD)	Difference	Significance
HAQ	0.82 (0.38)	0.53 (0.54)	0.28	0.000*
Pain	29 (22)	21 (18)	7.8	0.000*
Stiffness	32 (23)	24 (24)	7.9	0.000*
EBBS	125.8 (5.5)	131.6 (9.4)	5.6	0.000*
Barriers	28.6 (3.2)	25.2 (3.4)	3.5	0.000*
PSQI	7.2 (4.4)	6.2 (3.6)	1.05	0.000*
FSS	29.5 (17.8)	21.4 (18.8)	11.2	0.000*

	Baseline (SD)	12 Weeks (SD)	Difference	Significance
HAQ	0.82 (0.38)	0.53 (0.54)	0.28	0.000*
Pain	29 (22)	21 (18)	7.8	0.000*
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EBBS	125.8 (5.5)	131.6 (9.4)	5.6	0.000*
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PSQI	7.2 (4.4)	6.2 (3.6)	1.05	0.000*
FSS	29.5 (17.8)	21.4 (18.8)	11.2	0.000*

HAQ= Health Assessment Questionnaire

EBBS= Exercise benefits and barriers scale

PSQI= Pittsburgh sleep quality index

FSS= Fatigue severity index

## Abstract 50 (13A162)

## Poster

### Role of Nox2 in Angiogenesis in the Hypoxic Joint of Inflammatory Arthritis

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<sup>2</sup>School of Veterinary Medicine, University College Dublin, Ireland

**Introduction:** Angiogenesis is an early and fundamental component of synovial inflammation and oxygen metabolism is recognized as important mediator of joint vascular remodeling.

**Aims/Background:** To investigate if in vivo synovial hypoxia (tpO<sub>2</sub>) and TNF blocking therapy alters synovial vascular expression of Nicotinamide Adenine Dinucleotide Phosphate Oxidase (Nox2), and how this regulates angiogenic mechanisms.

**Method:** Patients with active inflammatory arthritis were recruited pre/post-TNFi therapy and underwent arthroscopy and synovial tissue oxygen (tpO<sub>2</sub>) measurements. Mice were injected with collagen to induce arthritis. Human Microvascular Endothelial Cells (HMVECs) were stimulated with Nox2 activators (TNF- $\alpha$  and 4-HNE) and inhibitor (DPI) under normoxia or 3% hypoxia and pro-angiogenic effects were assessed.

**Results:** We demonstrated increased Nox2 expression in IA and CIA joints compared to controls. Nox2 expression was higher in patients with synovial tpO<sub>2</sub>3%, and correlated with in vivo macroscopic/microscopic scores of angiogenesis. Decrease in Nox2 expression paralleled by an increase in in vivo tpO<sub>2</sub> was found only in those patients who were defined as TNFi responders. In vitro Nox2 activators and 3% hypoxia promoted angiogenic tube-formation, cell migration and secretion of pro-

angiogenic mediators, effects that were blocked by Nox2 inhibitor.

**Conclusions:** Hypoxia activates expression of Nox2 protein and Nox2-induced oxidative stress may be an initiating factor in driving angiogenesis.

## Abstract 51 (13A165)

## Poster

### Periarticular Bone Gain in Early Psoriatic Arthritis but not in Rheumatoid Arthritis Following Anti-Rheumatic Treatment as Measured by Digital X-Ray Radiogrammetry

Agnes Szentpetery<sup>1</sup>, Muhammad Haroon<sup>1</sup>, Phil Gallagher<sup>1</sup>, Eric Heffernan<sup>2</sup>, Oliver FitzGerald<sup>1</sup>

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<sup>2</sup>Department of Radiology, St. Vincent's University Hospital, Dublin, Ireland

**Introduction:** Hand bone loss is an early feature in both RA and PsA, but there is less data available on bone gain following treatment. Digital-X-ray-radiogrammetry (DXR) is a sensitive method for quantifying early changes in periarticular bone mineral density (DXR-BMD).

**Aims/Background:** To investigate DXR-BMD changes in early PsA and RA prior to and 3, 12 months after introducing an anti-rheumatic-drug.

**Method:** Recent-onset, active, treatment-naïve PsA and RA patients were selected. Hand BMD was measured by DXR at 3 timepoints. Mean DXR-BMD (mg/cm<sup>2</sup>) values of both hands and delta-DXR-BMD (mg/cm<sup>2</sup>/month) were calculated.

**Results:** 64 patients were included. 95% were commenced on a DMARD, 11.7% on a TNFi.

DXR-BMD decreased in both diseases at 3 months and was significantly lower in RA at 12 months compared to baseline. In contrast DXR-BMD increased in PsA over the study being higher at both 3 and 12 months compared to RA.

DXR-BMD loss was significantly higher in RA compared to PsA from baseline to 12 and 3 to 12 months. Among all patients with elevated BMD loss (>-0.25mg/cm<sup>2</sup>/month), change in DXR-BMD was significantly less marked in PsA compared to RA from baseline to 3 and 3 to 12 months.

**Conclusions:** This is the first prospective study showing hand bone loss as early as 3 months measured by DXR in both PsA and RA despite intervention of appropriate anti-rheumatic-drug. After 1 year of treatment we observed cortical bone gain in PsA but further bone loss in RA supporting the hypothesis of different pathomechanisms being involved in hand bone remodelling in PsA.

## Abstract 52 (13A166)

## Poster

### Serum CTX-I Predicts Systemic Bone Loss at the Hip over 1 Year in Patients with Early Psoriatic Arthritis





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<sup>1</sup>Department of Rheumatology, St. Vincent's University Hospital, Dublin, Ireland

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<sup>3</sup>DXA Unit, St. Vincent's University Hospital, Dublin, Ireland

**Introduction:** There is a growing interest in bone biomarkers that could be used predicting structural damage in inflammatory arthritis.

**Aims/Background:** To study changes in bone biomarkers and bone mineral density (BMD) in early PsA and RA prior to and after introducing an anti-rheumatic-drug and to investigate if bone biomarkers predict systemic bone loss.

**Method:** Recent-onset, treatment-naïve patients were recruited. We measured serum bone-specific-alkaline-phosphatase (bone-ALP), a bone formation marker, and C-terminal-cross-linking-telopeptide (CTX-I), a degradation marker at baseline 3 and 12 months by immunoassay. ALP/CTX-1 ratios were calculated. BMD was obtained at left hip and lumbar spine by DXA.

**Results:** 64 patients were included. 95% were commenced on a DMARD, 11.7% on a TNFi.

CTX-I levels decreased significantly after 3 months in RA and in the entire group remaining lower at 12 months. Bone ALP/CTX-I ratio was higher at 1 year compared to baseline in the entire group reflecting improvement in bone remodelling balance.

Hip BMD decreased in both diseases, spine BMD decreased in RA but increased in PsA. Baseline CTX-I levels correlated with delta-BMD of the hip over 12 month.

Multiple logistic regression analysis revealed significant associations of baseline CTX-I levels with delta-BMD of the hip over 12 months in PsA and in the entire cohort.

**Conclusions:** The improvement in bone remodelling balance seen in early PsA and RA patients is most likely due to decrease in bone resorption after 1 year of appropriate anti-rheumatic-therapy. High baseline levels of serum CTX-I may predict systemic bone loss at the hip over 1 year in patients with PsA.

#### Abstract 53 (13A167)

#### Poster

### Chemokine Expression in Systemic Lupus Erythematosus

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<sup>1</sup>Department of Rheumatology, Beaumont Hospital, Dublin

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<sup>3</sup>Department of Rheumatology, St. James's Hospital, Dublin

**Introduction:** Chemokines which are normally involved in leucocyte chemotaxis may be associated with tissue injury in SLE via promoting leucocyte infiltration.

**Aims/Background:** To investigate the role chemokines play in disease in SLE patients.

**Method:** Serum levels of CXCL10, CXCL13, CCL17 and CXCL8 were determined. Disease activity as per SLEDAI and damage scores (SLICC) at 5 year follow-up were recorded. Active disease was defined as a SLEDAI score > 6.

**Results:** 45 patients were recruited. Serum levels of all chemokines assayed were higher in SLE patients than controls (Table1). Higher levels of CXCL10 were observed earlier in disease course as well as in those patients with active disease (493.5pg/ml v 94.2 pg/ml, p=0.005) and those who suffered damage over the follow up period (407.1pg/ml v 94.2pg/ml, p=0.006). CCL17 and CXCL8 were also higher in patients with active disease with a significant association observed between SLEDAI and CCL17 expression [CCL17(211.7pg/ml v 108.2pg/ml, p<0.0001), CXCL8 (9.784pg/ml v 5.576pg/ml, p=0.02)].

Regarding clinical involvement CXCL10 levels were higher in those with CNS involvement (649.7pg/ml v 151.7pg/ml, p=0.02) whilst higher levels of CCL17 were observed in those with renal involvement (146.8pg/ml v 113.4pg/ml, p=0.04) and serositis (166.8pg/ml v 108.8pg/ml, p=0.04). CXCL10 and CXCL8 levels were elevated with immunological involvement.

Finally CXCL10 and CXCL13 levels correlated strongly in patients (Spearman r = 0.711, p<0.001).

	Patient(pg/ml)IQR range	Control(pg/ml)IQR range	P-Value
CXCL10	234.6 [85.49;499]	84.76 [46.59;107.3]	0.001
CXCL13	161.3 [45.2;1043]	117.1 [27.1;985]	0.0001
CCL17	211.7 [108.2;407.1]	108.2 [94.2;407.1]	0.0001
CXCL8	9.784 [5.576;16.6]	5.576 [3.5;9.784]	0.02

**Conclusions:** This is the first report to describe a relationship between CCL17 and both disease activity and renal involvement in SLE. High CXCL10 levels are associated with damage accrual.

#### Abstract 54 (13A169)

#### Poster

### Methotrexate and alcohol: a multi-centre study evaluating patient's practices and opinions

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**Introduction:** Methotrexate(MTX) is commonly prescribed in rheumatic conditions. It is necessary to monitor liver function (LFTs) in those taking MTX due to potential hepatotoxicity. Alcohol consumption with MTX increases the risk of hepatotoxicity. Patients prescribed MTX are advised to limit their alcohol consumption.

**Aims/Background:** This study was undertaken to evaluate the advice being given to patients and their understanding of the potential side-effects of MTX.

**Method:** A questionnaire was given to patients taking MTX in



two large teaching hospitals. This evaluated their dose, duration of therapy, drinking opinions and habits and history of liver abnormalities. Analysis was performed using SPSS version 18.0.

**Results:** We evaluated 248 patients taking MTX with a mean age of 55.9(SD 13.7) years. They had a mean dose of 14.7mg (SD 4.3) and mean duration of treatment was 54.7(SD43.8) months. The average alcohol consumption was 4.5units/week (SD 8.7), 41(16.5%) individuals were consuming in excess of 10 units/week and 9 in excess of 20 units. 41(16.5%) have a history of abnormal LFTs. In those who had a history of abnormal LFTs the mean consumption was 5.9units/week. In the remainder the mean alcohol consumption was 4.3units/week. This was non-significant. 14(5.6%) were not aware that liver function can be influenced by MTX. See Table for opinions.

**Conclusions:** There is a wide variation in practices and opinions regarding alcohol and MTX. The mean alcohol consumption in the group was 4.5units which is above that recommended by the ACR and BSR. A significant proportion of patients continue to drink to excess while taking MTX.

#### Patients opinion on alcohol and MTX

(patients could pick more than one option)

N (%)

Advised against alcohol altogether 72 (29%)

No alcohol day before, day of, day after 84 (32.6%)

One to two units per week 152 (58.9%)

Can drink without restriction 15 (5.8%)

Table1. Patients opinions regarding MTX and alcohol

#### Abstract 55 (13A173)

#### Poster

#### Resting and activated NK Cell function in SLE patients

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**Introduction:** Systemic Lupus Erythematosus(SLE) is characterised by complex interactions between both innate and adaptive immune systems. Natural Killer (NK) cells are increasingly recognised to play a significant role in the dysregulated immune response seen in SLE along with members of the Toll like receptor (TLR) family.

**Aims/Background:** To characterise the activation state of SLE NK cells.

**Method:** SLE patients surface activation of CD56+CD3-(NK) cells was characterised in the resting state and following TLR stimulation by flow cytometry using the following markers: CD69 and CD25. All samples were stimulated with TLR 3, 4, 7 and 9.

**Results:** 25 Patients with SLE were recruited. In the resting state SLE patients NK cells have higher expression of surface CD69 compared to controls (30.1% v 20.3%, p=.013). SLE patients on Hydroxychloroquine were observed to have significantly lower resting CD69 surface expression than those not on this medication. In addition a significant difference for CD 25 expression was seen in SLE patients NK cells compared to controls. No association was seen between disease activity and CD69 or CD25 expression.

Regarding responses to TLR ligands, TLR 7 stimulation resulted in a significant increase in NK cell surface expression of both CD69 and CD25 from the resting state in patients. Stimulation with the remaining TLR ligands resulted in increased NK Cell CD25 expression in SLE patients as compared to stimulated healthy controls.

**Conclusions:** Our results suggest that SLE patient NK cells are hyperactivated in their resting state compared to healthy controls. Despite this baseline hyperactivated state SLE patients demonstrate increased responsiveness to TLR ligands.

#### Abstract 56 (13A174)

#### Poster

#### Optimal Management of Foot and Ankle Disease in Rheumatoid Arthritis: Evaluation of Synovial Inflammation and Joint Erosion in the Foot and Ankle in Anti TNF inhibitors/Biologics Naïve RA patients using ultrasound

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**Introduction:** Erosive foot and ankle disease can be presenting feature in 30-50% of RA patients. Musculoskeletal ultrasonography (MSKUS) is helpful in detecting synovitis with greater sensitivity and specificity than clinical examination.

**Aims/Background:** To comprehensively evaluate foot and ankle disease using clinical and functional scores, biomechanical assessment and to compare with MSKUS in a cohort of diagnosed RA patients' prior to and 6 months after biological treatment.

**Method:** 18 patients with biologic naïve established RA, were recruited. Baseline and 6 month post biological treatment, assessments with ESR, CRP, DAS28, assessment of ankle, subtalar, all mid-tarsal, metatarsophalangeal and interphalangeal joints by Rheumatology nurse specialist (SL), Leeds Foot Impact Scale (LFIS) and MSKUS examination of feet and ankles (performed by an experienced physician (AS)).

**Results:** This preliminary data include 9 patients with completed follow-up. patients demographics shown in table 1. Following six months of therapy, marked reductions were observed in ESR, CRP, swollen and tender ankle and foot joints count with slight reductions in LFIS (table 1). DAS28CRP did show improvements in all patients when performed (4 patients). Baseline ultrasound findings did correlate well with disease activity but also demonstrated ongoing grey scale (GS) and Power Doppler (PD) synovitis in 3 patients with normal CRPs. At 6 months, 5 patients with clinical improvement still demonstrated persistent GS synovitis. Interestingly one patient (patient 2, Table 1) no CRP





available did show worsening disease on MSKUS imaging (GS and PD synovitis at multiple joints).

**Conclusions:** RA foot and ankle disease has huge impact on patient QoL. MSKUS of ankle and foot joints aid in better objective monitoring of disease activity.

#### Table: Demographics and Results

No	age	Duration months	BL ESR	ESR 6 mo	BL CRP	CRP 6 mo	feet & ankles SJC BL	feet & ankles SJC 6 mo	feet & ankle TJC BL	feet & ankle TJC 6mo	DAS CRP BL	DAS CRP 6 mo	LFIS BL	LFIS 6 mo
1	49	32	27	14	11.8	1	2	0	3	1	3.95	1.76	5	8
2	57	4	NA	NA	NA	NA	9	5	13	8	NA	NA	46	30
3	28	1	22	42	10.5	2.5	3	9	8	10	5.09	5.1	35	27
4	48	20	63	10	1.1	1.9	8	3	11	3	6.38	2.44	31	22
5	54	360	38	44	17.5	1	2	2	3	2	NA	NA	34	37
6	45	18	101	22	94.7	1	6	6	6	6	NA	NA	36	36
7	45	58	101	22	94.7	1	6	6	6	6	NA	NA	36	36
8	67	11	63	78	26.4	48	4	2	8	3	NA	NA	32	40
9	27	10	5	57	1	28.9	6	4	8	6	NA	NA	39	36
mean	49	57.1	40	33.1	20.5	10.5	4.4	3.4	7	4.6	4.98	2.96	33	31

**Anti-TNF therapy reduces platelet reactivity and is associated with improved insulin sensitivity in patients with inflammatory arthritis**

Mac Mullan PA<sup>1</sup>, Madigan AM<sup>1</sup>, Durcan L<sup>1</sup>, Egan K<sup>2</sup>, Bagaglia PM<sup>1</sup>, Kenny D<sup>2</sup>, McCarthy GM<sup>1</sup>

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<sup>2</sup>Cardiovascular Biology Lab, RCSI

**Introduction:** Patients with inflammatory arthritis (IA) die prematurely from cardiovascular disease (CVD).

**Aims/Background:** To assess the influence of anti-TNF therapy on platelet function, LDL cholesterol, and insulin metabolism in patients with IA.

**Method:** Patients with a diagnosis of IA were recruited and evaluated on 2 separate occasions, before commencing an anti-TNF agent and after 4 months. Disease activity assessment comprised of serological markers, patient measures, evaluator global assessment, and the DAS-28 score. Patients were classified as responders by reduction of at least 1 disease category in DAS-28. Samples of fasting LDL, glucose, and insulin were obtained. Platelet responses to multiple concentrations of several agonists were measured simultaneously using a modification of light transmission aggregometry.

**Results:** Data from 19 patients were analysed (n=15 responders [mean DAS 28 score 5.1 vs 3.18, p<0.01], n=4 non-responders (mean DAS-28 score 4.51 v 4.55)). Post treatment platelet responses to ADP were significantly reduced in responders only (EC50 1.97 vs 1.17, p<0.001, while in non-responders, pre and post treatment values were similar. (EC50 1.89 vs 1.94). Also, there were no differences in pre/post platelet responses to any of the other agonists for either group. Responders also demonstrated reduced insulin resistance (mean

[95%CI] HOMA-IR 1.995 [1.4-2.58] vs 1.19 [0.86-1.52] pre and post treatment, p<0.01) compared to non-responders (mean HOMA-IR 1.9 vs 2.05, pre and post treatment, respectively), while mean LDL values were similar across all subjects.

**Conclusions:** These data are a prospective demonstration of decreased platelet reactivity and improved insulin sensitivity in patients with active IA who respond to anti-TNF therapy, and may represent potential mechanisms by which anti-TNF therapy reduces CVD events in this high risk population.

#### Abstract 58 (13A176)

#### Poster

#### Immunology Testing in a Rheumatology Consult Service

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**Introduction:** When inpatients complain of symptoms suggestive of a rheumatic condition, there are a wide range of possible investigations that may be ordered, but the relevance of these largely depends on the presenting clinical features. The requesting of 'screening' tests when placing a rheumatology consult, especially those tests performed in the immunology laboratory that are time intensive or expensive, can place a significant burden on laboratory services.

**Aims/Background:** To assess the number of immunology tests ordered, number of positive results, and the relationship to diagnostic grouping, in patients reviewed by a rheumatology consult service in a university teaching hospital.

**Method:** We reviewed all consults sent to our rheumatology service over a year. Final diagnosis and immunology tests ordered within a two week period of the consult were recorded. Descriptive statistics were used to evaluate the total number of tests ordered, number of positive results, and the relationship to the diagnostic grouping.

**Results:** Over the 12 month study period 219 patients were seen as consults by the rheumatology service. Full details of the immunology tests performed are shown in Table 1. Immunology tests requested included ANA in 67 patients (14 positive, 7 with titre>1/160); 45 ENA (4 positive, all anti-Ro); and 38 ANCA (4 positive, all PR3/MPO negative). In the majority of cases, the patients did not have evidence of inflammatory disease.

**Conclusions:** A significant number of immunology tests are ordered when requesting a consult from the rheumatology service at St. James's Hospital. The time and cost burden of these tests warrants further assessment of their necessity.

#### Table 1: Immunology Testing in Consult Cohort



Test	Number	Positive	Type	CTD n (+)	IA* n (+)	Mechanical /Other n(+)
ANA	67	14	7 titre>1/160	11 (5+)	16 (2+)	40 (7+)
ENA	45	4	4 anti-Ro	11 (3+)	12 (0+)	22 (1+)
ANCA	38	4	3 pANCA 1 atypical	4 (1+)	11 (1+)	23 (2+)
dsDNA	5	0	-	2 (0+)	0 (0+)	3 (0+)
RF	48	13	11 >40IU/ml	3 (1+)	18 (10+)	27 (2+)
Anti-CCP	42	9	9 >40IU/ml	3 (1+)	18 (7+)	21 (1+)
LKS	21	5	3 Parietal 2 SMA	4 (1+)	6 (2+)	11 (2+)
C3/C4	22	3	2 low C3 (1 also low C4)	5 (1+)	6 (0+)	11 (1+)
Abbreviations: (+), positive results; CTD, connective tissue disease; IA, inflammatory arthritis; LKS, liver, kidney, smooth muscle; TTG, tissue transglutaminase; APL, antiphospholipid antibody	9	0	-	4 (0+)	2 (0+)	3 (0+)
TTG	21	0	-	4 (0+)	5 (0+)	12 (0+)
APL	10	0	-	3 (0+)	2 (0+)	5 (0+)

\*Inflammatory Arthritis defined as rheumatoid arthritis, psoriatic arthritis, spondyloarthritis, sarcoid arthritis, viral arthritis and undifferentiated inflammatory arthritis

\*\* 3 samples rejected as incorrect temperature

## Abstract 59 (13A177) Poster

### Audit of musculoskeletal ultrasound in department of rheumatology, Musgrave Park Hospital

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Department of Rheumatology, Musgrave Park Hospital, Belfast

**Introduction:** Musculoskeletal ultrasound (US) is an indispensable tool in current rheumatological practice

**Aims/Background:** We conducted a clinical audit evaluating its current use and compared this with a previous audit we presented at ISR 10 years ago.

**Method:** Data was collected over one month using paper proformas at all our Rheumatology clinics and wards. Results are presented as n (%) and compared with previous data from the unit.

**Results:** 130 proformas were completed by 12 operators. Mean patient age was 57 (sd 15, range 20-90) years. 89/130 (68%) were females. Data source were joint injection clinics (50%), OPD (36%), day-ward (6%) and others (8%). 182 regions were scanned: 37 (20%) shoulder, 35 (19%) wrist including carpal tunnel, 29 (16%) knee, 23 (13%) hand, 24 (13%) foot including plantar fascia, 24 (13%) ankle/Achilles, 7 (4%) hip and 3 (2%) elbow. Findings were 32 (25%) synovitis, 33 (25%) effusion, 33 (25%) bursitis, 15 (12%) osteoarthritis, 12 (9%) crystal deposition, 12 (9%) erosion, 20 (15%) tenosynovitis and other tendinopathy 3 (2%), double contour sign, 5 (4%) median nerve thickening and 19 (15%) no abnormality. US was useful in confirming suspected diagnosis (84/65%), judging disease severity (14/11%), therapy optimisation (17/13%), identifying sites of disease activity (13/10%), aiding US guided procedures (25/19%), localisation (44/34%), avoiding steroid injection (16/12%) and changing diagnosis (8/6%). 97% operators (compared to 70% previously) felt the US had an impact on patient management and that if US was unavailable 48% would have requested other imaging (37% previously). Operator

satisfaction with images obtained and in image interpretation was reported in 100%.

**Conclusions:** US remains an essential tool for the rheumatologist.

**Reference:** The integration of musculoskeletal ultrasound into routine rheumatological practice. ISR 2003, oral presentation. Cairns A.P., Wright G, Bell A, Rooney M, Wright S, Meenagh G, Matthews C, Taggart A.

## Abstract 60 (13A178) Poster

### NSAID Use and Knowledge in Patients with Ankylosing Spondylitis

Candice Low, Richard Conway, Fathelrahman Ibrahim, Michele F Doran, Gaye Cunnane, Finbar D O'Shea

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**Introduction:** Patient education on the use and adverse event profile of prescribed medications is an important aspect of clinical practice. Significant effort and time is devoted to education around biologic agents. Less time is devoted to other drugs, in particular Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), often on the presumption that patients are familiar with these products.

**Aims/Background:** To assess NSAID usage, as well as knowledge of potential adverse events among patients attending a dedicated ankylosing spondylitis clinic.

**Method:** Patients attending our ankylosing spondylitis clinic over a six month period completed a questionnaire regarding their usage and perception of the risks of NSAIDs.

**Results:** Thirty-eight patients completed the questionnaire. Six patients (16%) were using NSAIDs on a regular basis and 27 (71%) on an as required basis. Fourteen patients (37%) were prescribed biologic agents. Seven patients (21%) were co-prescribed a PPI. Eleven patients (33%) were unaware of any potential side effects of their medication, 25 patients (76%) were aware of the possibility of gastric ulceration, 23 patients (70%) of the possibility of renal dysfunction, 22 (67%) of hepatic dysfunction, while only 15 patients (45%) were aware of the increased risk of myocardial infarction and stroke. Six patients (18%) had had significant adverse events as a consequence of NSAID use – all gastric ulceration. Sixteen patients (48%) were prescribed alternative analgesia. Twenty-one patients (64%) had attempted NSAID cessation, 12 (36%) succeeded.

**Conclusions:** Knowledge regarding potential adverse events of NSAIDs is suboptimal, particularly for cardiovascular adverse events. This indicates the need for further patient education in the rheumatology outpatient setting.

## Abstract 61 (13A180) Poster

### Audit of trend in cholesterol levels in patients initiated on Tocilizumab

Kingston, C. Benson, C





Musgrave Park Hospital

**Introduction:** Tocilizumab is an IL-6 inhibitor, licensed in rheumatoid arthritis patients, who have failed standard disease modifying drugs.

**Aims/Background:** A rise in cholesterol levels is a recognised side effect of tocilizumab therapy. The mechanism by which IL-6 blockade raises cholesterol is not yet clear.

**Method:** An audit was performed of all patients who commenced tocilizumab therapy in the last 3 years at our institution. All patients who received 3 doses or more of tocilizumab were included. A retrospective chart review was performed and baseline lipid profile was recorded. Frequency and results of subsequent lipid profiles were documented, along with the dates of tocilizumab infusion. Patients were contacted directly to obtain a full history of prescribed lipid lowering agents. These results were compared to local guidelines.

**Results:** 56 patients received at least 8 weeks of tocilizumab therapy. Average duration of therapy was 383 days. Of these 56 patients, 38% had raised total cholesterol at baseline, rising to 50% at 8 weeks. Of the 30 patients who completed the more detailed survey, 18 had been on tocilizumab for 1 year or more. At 1 year 57% of this group were on a statin compared to 37% at baseline. At the 1 year mark 30% of patients with high cholesterol were not yet on a statin.

**Conclusions:** Hypercholesterolaemia remains an under-recognised comorbidity in our rheumatoid arthritis patients. A significant number of people required statin treatment, following initiation of tocilizumab. There is wide variation in the statin therapy used to treat raised cholesterol. Strict local guidelines need to be in place to ensure statin therapy is escalated as required.

#### Abstract 62 (13A183)

#### Poster

##### Clinical characteristics associated with infection during first year of biological therapy

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Department of Rheumatology Cork University Hospital

**Introduction:** Biological agents significantly increase risk of infection especially in the first twelve months of treatment.

**Aims/Background:** The objective of this study was to assess characteristics associated with infection (serious and non serious) in patients with rheumatoid arthritis (RA) and ankylosing spondylitis (AS) during the first year of treatment with a biological agent.

**Method:** Data on 63 patients receiving biological treatment for RA or AS was collected. A manual review of patients charts was performed and the following data were extracted: demographic data, underlying rheumatological condition, history of prior exposure to biological agents, the number and type of prevalent infections as documented in patient charts during the first year of

treatment.

**Results:** 63 patients were included in this study (35 males (56%), median age 50.8 years (IQR 41 – 60)). 42 patients (67%) had a diagnosis of RA; 21 (33%) of AS. 50 (79%) were on anti-TNF agents (etanercept 27 (43%), adalimumab 13 (21%), golimumab 8 (13%), certulizumab 2 (3%)). Other agents included abatacept 7 (11%), tocilizumab 4 (6%), and rituximab 2 (3%).

21 (33%) had a documented infection during the first year of therapy. The infection group was older with a mean age of 55 years versus 49 years in non-infection group ( $p=0.08$ ). 8 (38%) of the group who developed infection had prior exposure to other biological agents compared to 14 (33%) in the non-infection group (RR 1.14, 95% CI 0.6-2.3). 16 (76%) had a diagnosis of RA compared with 26 (62%) in the group that didn't develop infection (RR 1.2, 95% CI 0.9-1.7).

**Conclusions:** Patient characteristics including age, underlying diagnosis and prior treatment with biological therapy may increase infection risk with biological agents during the first year of treatment.

**References:** 1. Long-term anti-TNF therapy and the risk of serious infections in a cohort of patients with rheumatoid arthritis: Comparison of adalimumab, etanercept and infliximab in the GISEA registry Fabiola Atzeni et al, *Autoimmunity Reviews* 12 (2012) 225–229.

2. Evaluation of the RABBIT Risk Score for serious infections. Zink A, Manger B et al. *Ann Rheum Dis*. 2013 Jun 28.

3. Choice of Biologic Therapy for Patients with Rheumatoid Arthritis: The Infection Perspective. Filip De Keyser. *Curr Rheumatol Rev*. 2011 February; 7(1): 77–87.

#### Abstract 63 (13A184)

#### Poster

##### Monitoring for adverse events in patients on long-term glucocorticoid therapy

Bell L, Donnelly S

Mater Misericordiae University Hospital, Dublin

**Introduction:** Glucocorticoid (GC) therapy is beneficial in many inflammatory and rheumatic diseases, reducing disease activity and pain. Their use is restrained by the occurrence of adverse events (AEs).

**Aims/Background:** As the literature data was incomplete, EULAR published consensus-based recommendations on monitoring for GC-related AEs in daily practice. We investigated whether the daily practice in our out-patient department incorporated all these EULAR recommendations.

**Method:** We reviewed the charts of 50 patients who had been on GCs for over three months. We recorded GC dosage, duration and if the reasons for GCs were still valid. EULAR recommends the recording of blood pressure, ischaemic cardiovascular disease risks, examining for peripheral oedema at the start of GC therapy, questioning for peptic ulcer disease, fasting blood glucose levels, weight and height measurements at the start of GC therapy, DEXA scanning and, if there are risk factors for glaucoma, EULAR



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# ISR SPRING 2013



Audience participation



Prof. David Kane & Dr Maurice Barry



Kevin McDonagh & Karine Daly of Actelion



Theresa Atkinson & Gerard Walshe of Roche



Dr Carmel Silke, Roger Towey & Joe Murnane of Amgen



recommends ophthalmological evaluation prior to commencement of GCs. We recorded if the EULAR recommendations were met in these 50 patients.

**Results:** The most common conditions were rheumatoid arthritis (n=12) and temporal arteritis (n=12). Mean initial GC dosage was 35.6 ( $\pm$ 19.1) mg and mean duration of GC therapy was 38 months (range of 5 to 156 months). For all 50 patients the reasons for GC remained valid. Only 12 patients were examined for peripheral oedema and no patients were assessed for glaucoma risk factors. Cardiovascular, peptic ulcer disease, endocrine and osteoporosis monitoring recommendations were all met.

**Conclusions:** We need to expand our daily practice to include monitoring for peripheral oedema and glaucoma in patients on long-term GC therapy.

**References:**

Monitoring adverse events in glucocorticoid therapy: EULAR recommendations for clinical trials and daily practice. Ann Rheum Dis 2010; MC van der Goes et al

**Abstract 64 (13A185)**

**Poster**

**A one year audit of the role of the Rheumatology Clinical Nurse Specialist stable patient review service**

Miriam Molloy, Eileen O'Flynn, Douglas Veale, Eamonn Molloy, Ann-Barbara Mongey, Shafiq Alraqi and Oliver FitzGerald

St. Vincent's University Hospital, Elm Park, Dublin 4

**Introduction:** The current pathway of care for patients with chronic rheumatic disease does not include a reliable system of monitoring efficacy and safety of treatments in a primary care setting. As a consequence, many patients with stable rheumatic disease on on-going treatment continue to attend secondary care out-patient clinics when with support, they could equally be managed in a primary care setting.

**Aims/Background:** In early 2011, a pilot CNS-led outreach service was established. With much of the effort in the first year focused on the development of the service with clinics beginning in Arklow March 2012 and later in Newtownmountkennedy.

**Method:** Between March 2012 and February 2013 an audit was carried out on the 464 patients who were reviewed by the CNS-led service. Detailed data was captured including demographics, medications, problems identified, actions taken, patient satisfaction and effects of service on secondary care waiting lists and OPD activity.

**Results:** 42% attended the CNS-led clinic at SVUH, 24% were reviewed by telephone and 34% were reviewed in the community (Arklow 20%, Newtownmountkennedy 14%).

- For Patients:
- Reviewed in their community.
- Reduced travel time, no parking charges, less interruption in daily lives, reduced work absence – resulting in a 90% + satisfaction rate
- For Secondary care:

- 80% of patients were reviewed without the need for any other medical/OPD intervention
- Improved new:return ratio at outpatient clinics. During this 1 year period, the new: return ration fell from 1:7 To 1:4
- Increase in new-patient attendances. More urgent return slots

**Conclusions:** In the pilot year studied above, 371 outpatient visits were not required as a result of the CNS-led community service.

**Abstract 65 (13A186)**

**Poster**

**A study of radiation exposure in Yttrium radiosynoviorthesis - is it safe?**

David McCormick, Adrian Pendleton

Rheumatology Department, Musgrave Park Hospital, Belfast

**Introduction:** Radiosynoviorthesis is an option in patients who fail more conventional forms of treatment for chronic synovitis of a single joint. The radioisotope, yttrium-90, is commonly used for recurrent knee synovitis with good responses and potentially delays the need for surgical synovectomy.

Yttrium is injected aseptically alongside steroid via an intra-articular approach to the knee joint. In Musgrave Park Hospital a plaster of Paris is used post-procedure for 3 days to immobilise the joint (this is not standard practice in all centres). This also potentially gives protection against the radioactivity of yttrium.

**Aims/Background:** After a recent yttrium synovectomy session in Musgrave Park Hospital, there were concerns regarding the potential radiation exposure to healthcare staff from treated patients, especially in those who may be pregnant.

**Method:** Advice was sought from the Radiation Protection Service in Belfast Trust

**Results:** Radiation levels were measured on 6 patients who had received individual administrations of up to 180MBq of Yttrium-90. The maximum measured exposure levels were  $<20\mu\text{Svhr}$ -1 at 50 cm.

As a comparison, the average radiation exposure received in the UK from background radiation is approximately  $6\mu\text{Sv}$  per day.

**Conclusions:** These results show that since the yttrium-90 will be retained in the patients knee the exposure to staff or patient's relatives in the wards is negligible. This is further reduced by the use of plaster of Paris post-procedure.

Thankfully the data shows the radiation exposure from yttrium treatment is reassuringly low and will allow for optimal patient care to be continued without concern.

**Abstract 66 (13A187)**

**Poster**

**C5orf30 a novel mediator of joint damage in rheumatoid arthritis**

M Muthana, H Davies, S Khetan, A G Wilson





Infection & Immunity, Sheffield University

**Introduction:** A SNP (rs26232) in the 1st intron of the uncharacterised gene, C5orf30, has been associated at genome-wide significance levels with susceptibility to RA (1). In addition, in three European RA populations we have recently reported an allele dose association with the severity of radiological joint (2). C5orf30 encodes an uncharacterised protein of 206 amino acids.

**Aims/Background:** The aim was to determine the functional activities of C5orf30 in the rheumatoid joint.

**Method:** Immunohistochemistry was used to determine cellular expression of C5orf30 in RA and OA synovium, & confocal microscopy determine intracellular localisation. Biological activities of synovial fibroblasts (SF) was examined using siRNA technology to target C5orf30 in synovial fibroblasts. Binding partners were determined using immunoprecipitation and mass spectrometry.

**Results:** C5orf30 is highly expressed in synovial fibroblasts and macrophages and is expressed in both the nucleus and cytoplasm. Knockdown of C5orf30 in SF resulted in increased invasiveness into Matrigel and reduced expression of modulators of tissue destruction including TIMP3.

**Conclusions:** Using genetics approaches we have identified C5orf30 to be a novel mediator of tissue destruction in RA. Our functional data suggest that it has anti-inflammatory and anabolic properties in the synovium. Further functional studies in different cell types are ongoing.

**References:** 1. Stahl EA, et al. (2010) Genome-wide association study meta-analysis identifies seven new rheumatoid arthritis risk loci. *Nat. Genet.* 42(6):508-514.  
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## CASE POSTERS

### Abstract 67 (13A104) Case Poster

#### Relapsing polychondritis and tracheomalacia

David McCormick, Andrew Cairns

Musgrave Park Hospital, Belfast

A 64 year old female with a history of chronic obstructive pulmonary disease presented with a mild seronegative inflammatory arthritis which improved with azathioprine after failure of methotrexate and sulfasalazine. Inflammation of her nasal bridge was noted with subsequent indentation and saddle shaped deformity. Recurring inflammation of pinna 20 years prior had resulted in a deformity of right pinna. These features suggested relapsing polychondritis.

Worsening exertional breathlessness developed with a harsh non-productive cough and reduced exercise tolerance despite

maximally treated chronic obstructive pulmonary disease. Pulmonary function tests showed an intra and extrathoracic obstructive pattern and flow volume loops were flattened.

Dynamic expiratory phase of CT chest showed tracheobronchomalacia with widespread airway collapse and air trapping in keeping with a history of relapsing polychondritis. Bronchoscopy was abandoned on safety grounds due to marked subglottic stenosis distal to the vocal cords and biopsy was not attained.

This lady has since been treated with high dose intravenous steroids and now oral maintenance prednisolone. She has also been treated with Infliximab infusions 5mg/kg with limited benefit but no further clinical worsening. The cardiothoracic team have been involved, however, stenting is not felt to be feasible due to the extent of airway involvement. We are currently discussing with the patient the risks and benefits of proceeding with further infliximab as well as exploring any other possible options.

- images of clinical photos, pulmonary function tests, bronchoscopy and ct are all available and show some impressive findings.

### Abstract 68 (13A120)

### Case Poster

#### Refractory PMR with Aortitis: Life-Saving Treatment with Anti-IL6 Monoclonal Antibody (Tocilizumab) and Surgical Reconstruction of the Ascending Aorta

Fahd Adeeb Mohamed Ashraf, Shakeel Anjum, Orla Ni Mhuircheartaigh, Joe Devlin, Alexander Fraser

Department of Rheumatology, University Hospital Limerick, Ireland

**Introduction:** Aortitis is uncommon but well described in patients with polymyalgia rheumatica (PMR)<sup>(1,2,3)</sup>. While glucocorticoid remains the mainstay therapy for large-vessel vasculitis, there have been cases where tocilizumab therapy led to clinical and serologic improvement in patients with relapsing or refractory disease<sup>(4,5,6)</sup>. We report a case of life-threatening PMR with aortitis in the absence of manifestations related to GCA, which, having failed to respond to corticosteroid therapy was successfully treated with tocilizumab and emergency reconstruction of the ascending aorta. This case adds to the literature supporting the potential value of IL-6 inhibition in rare rheumatologic conditions such as inflammatory aortitis.

**Conclusions:** The case described here emphasizes the importance and the need of evaluation of the aorta as a recommendation for patients with PMR presented with cardiac symptoms.

- Early diagnosis and treatment of aortitis is crucial for improving survival and preventing postoperative complications.
- This case adds to the literature supporting the potential value of IL-6 inhibition in rare rheumatologic conditions such as in non-infectious inflammatory aortitis.

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## Abstract 69 (13A137)

## Case Poster

### Successful treatment of acute necrotising myocarditis in a patient with mixed connective tissue disease

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**Introduction:** A 53 year old gentleman with an eight year history of mixed connective tissue disease (MCTD), on hydroxychloroquine 200mg daily, was admitted with a six hour history of chest tightness. He had had flu like symptoms for the preceding 48 hours.

**Results:** His troponin T was over 7000 ng/l on admission and he received thrombolysis for a possible myocardial infarction. He clinically deteriorated with pulmonary oedema and was transferred for coronary catheterisation. No significant coronary artery disease was found. Echocardiogram showed severe left ventricular impairment and an intra-aortic balloon pump was inserted. Myocardial biopsy showed an acute necrotising lymphocytic myocarditis. His myocardial biopsy and serum were negative for viral PCR. His CRP was elevated at 328 mg/l and his ESR was 40 mm/hr. His complement was normal. He subsequently developed acute renal impairment with proteinuria and microscopic haematuria.

He had an acute flare of his skin disease. He was commenced on prednisolone 40mg daily and given intravenous immunoglobulin (0.4g / kg) for 5 days. He made a dramatic response, his cardiac function improved and by day 6 his balloon pump was removed. His renal function normalised. By day 10 his ECHO showed normal left ventricular function. He was discharged on reducing dose of oral prednisolone and commenced on mycophenolate mofetil. Four months later he remains very well.

**Conclusions:** Despite negative viral PCR an underlying viral aetiology cannot be excluded. This case illustrates the safe and successful treatment of necrotising myocarditis, in a patient with MCTD, with prednisolone and immunoglobulin.

## Abstract 70 (13A141)

## Case Poster

### Between a Rock and a Hard Place – Disseminated Morphoea Profunda Successfully Treated with anti-CTLA4 Mono-Clonal Antibody

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**Introduction:** Morphoea Profunda (MP) is a vanishingly rare autoimmune disease associated with diffuse severe skin sclerosis and thickening. It is progressive and highly destructive leaving patients with total body rock like skin, joint contractures, restrictive breathing deficits, severe pain and ultimately in the worst cases early death. To date no treatments have been reported to be successful. Recent research has implicated TH-17 cells in skin sclerosis so T cell directed therapies may be indicated. Recently 2 cases of successful treatment of MP with Abatacept were reported in Denmark.

**Aims/Background:** To report a case of Disseminated Morphoea Profunda Successfully Treated with abatacept.

**Method:** A 55 yo lady presented with history of skin swelling, itch and pain. She had whole body skin thickening with rock like skin of her legs and knee contractures. In conjunction with the Munster Dermatology a diagnosis of MP was made. Her Rodnan skin score was 34/60 which is exceptionally high. She underwent comprehensive disease staging with skin biopsies, high resolution dermal microscopy, high resolution dermal ultrasound and whole body MRI. Following recent reports from Denmark and bearing in mind this lady's extreme disease, we decided to treat her with Abatacept together with modest dose corticosteroid and Methotrexate.

**Results:** At 6 months her disease has dramatically improved. Skin scores, whole body MRI, HRUS and microscopy have all improved. Her pain and joint contractures have resolved completely.

**Conclusions:** This case further offers support for the use of Abatacept in cases of severe MP, a dreadful, disfiguring and life threatening disease with apparently no effective treatment until now.

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## Abstract 71 (13A146)

## Case Poster

### Small bowel perforation with Churg-Strauss Vasculitis

Kerry Aston





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**Introduction:** This case reports a 55 year old lady with a diagnosis Churg-Strauss Vasculitis. Her disease was initially treated with azathioprine and had been quiescent for many years. Immunosuppression had been stopped in 2007. Her disease flared in August 2012 with symptoms of widespread arthralgia and paraesthesia in her hands and feet and she was commenced on mycophenolate. Bloods at this stage showed pANCA titres had risen from 20 to 80, associated with a MPO titre greater than 8.0.

She was reviewed a few months later. At this stage she complained of nausea and abdominal bloating. It was felt symptoms were secondary to her medication and it was discontinued.

Several weeks later she presented with a peripheral neuropathy and increased abdominal pain. CT angiogram of abdomen was performed which showed no acute abnormalities. She was treated with high dose methylprednisolone. A few days later she became acutely unwell with signs of abdominal perforation. She was transferred to the surgical unit and underwent emergency laparotomy. Multifocal ischaemia was visible intra-operatively and she underwent double barrell ileostomy for perforated small bowel. Pathology the small bowel shows focal ischaemia which is arising as a consequence of widespread vasculitis.

Treatment with high dose methylprednisolone and cyclophosphamide was started. She complained of on going paraesthesia and burning sensation in hands and feet and subsequently developed a right sided foot drop after several weeks of treatment.

She remains on cyclophosphamide and reducing dose of steroids. Her disease appears to be in remission with falling pANCA titres.

#### Abstract 72 (13A149)

#### Case Poster

##### Aortitis in relapsing Polychondritis

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**Introduction:** Relapsing Polychondritis (RP) is a rare inflammatory disease affecting cartilaginous tissues. This case highlights RP complicated by Aortitis despite intensive immunosuppressant regimes. This is the third reported case of treatment of Aortitis in RP with anti-TNF therapy<sup>1,2</sup>. It is the first, however, that has utilised serial PET-CT scans as a clinical tool to guide immunosuppressant therapies.

**Aims/Background:** A 51 year old male presented with a prodrome of arthralgia, intermittent oral ulceration and raised inflammatory markers for one year. He had been fully worked up by Infectious Diseases and Rheumatology, however no diagnosis could be established. Eventually, he presented with ear swelling and ear biopsy confirmed auricular chondritis. CT Thorax to evaluate tracheal cartilage demonstrated incidental aortic dilatation. ECHO revealed aortic incompetence and PET-CT showed increased FDG accumulation in the ascending aorta,

leading to a diagnosis of Aortitis secondary to RP.

Initial therapy was with Prednisone 1mg/kg and Methotrexate (25mg weekly). However, inflammatory markers failed to settle and Infliximab (5mg/kg 6 weekly) was added. Interval PET CT scans at 18 months demonstrated progression of Aortitis despite Prednisolone, Methotrexate and Infliximab. Infliximab was increased to 10mg/kg 6 weekly and after 12 months CRP has fallen to the normal range, allowing a decrease in Prednisolone to 7.5mg.

**Conclusions:** This case adds weight to the growing evidence to suggest that biological targeted therapies are effective treatment options in vasculitis secondary to RP when conventional therapies have failed<sup>3</sup>. Further, the case demonstrates the clinical utility of PET-CT in the surveillance of large vessel vasculitis.

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#### Abstract 73 (13A150)

#### Case Poster

##### Macrophage Activation Syndrome Secondary to Adult Onset Still's Disease; An Important Sepsis Mimic

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**Introduction:** Adult Onset Still's disease (AOSD) is a systemic inflammatory disorder of unknown aetiology<sup>(1)</sup>. Rarely, it may be complicated by Macrophage Activation Syndrome (MAS), a multisystem inflammatory syndrome caused by massive cytokine release from activated lymphocytes and macrophages.

**Aims/Background:** We report the case of a 31-year-old female who presented with a 3-week history of arthralgia, myalgia, fever and sore throat.

**Method:** Blood tests revealed a serum ferritin >2000ug/L, ESR 55mm/hr and C-reactive protein 205mg/L. Blood cultures, rheumatoid factor, ANA and ANCA were negative. AOSD was diagnosed and oral prednisolone commenced. One-week later the patient was admitted with a 2-day history of diarrhoea, fatigue and pyrexia. She was haemodynamically unstable with deranged LFT's and grossly elevated serum ferritin (9000ug/L). Haemoglobin and platelet count fell acutely with associated hypofibrinogenaemia and coagulopathy. Bone marrow biopsy demonstrated haemophagocytosis. MAS was diagnosed and IV methylprednisolone commenced. The patient was transferred to ICU due to persistent hypotension despite fluid resuscitation. She received IV immunoglobulins, packed red-cells, cryoprecipitate and FFP transfusion. Cyclosporine was commenced and she stabilised after 5-days. Anakinra was introduced for treatment of



AOSD and marked improvement was noted over the following weeks.

**Results:** Complete resolution of symptoms noted at four-month follow-up, with normal FBC, LFTs, coagulation-screen and inflammatory markers.

**Conclusions:** This case highlights the fact that active AOSD and MAS can mimic sepsis. MAS is rare, and is most commonly seen secondary to underlying inflammatory disease. It is important that MAS is promptly recognised and treated, given its high mortality rate, despite treatment<sup>(2)</sup>.

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## Abstract 74 (13A155)

## Case Poster

### Gleich Syndrome – A Case Report

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**Introduction:** Rheumatologists are often involved in the management of patients with hypereosinophilia (loosely defined as peripheral eosinophil count >1500/mm<sup>3</sup> with tissue damage). The diagnostic work up of a hypereosinophilic disorder begins with exclusion of secondary/reactive causes. Thereafter the possibility of a clonal eosinophilia should be considered. Finally, evaluation for one of the primary hypereosinophilias, which vary in clinical severity and significance, should be performed.

**Method:** A 34 year old female presented with episodic arthralgia and rash associated with oedema of the affected area. The frequency and severity of episodes had recently increased and it was now troubling her approximately once per month. She had a marked eosinophilia and an extensive work-up for a hypereosinophilic disorder ensued.

**Results:** There was no evidence of a secondary eosinophilic process or a malignant hypereosinophilia. A skin biopsy was consistent with eosinophilic cellulitis (Well's Syndrome). A diagnosis of Gleich Syndrome was made. Corticosteroids were initiated with rapid resolution of all symptoms and rash.

**Conclusions:** Gleich Syndrome is a rare disorder that typically presents with episodic oedema, fever and urticaria. Eosinophilia and hypergammaglobulinaemia (usually IgM) are characteristic laboratory findings. It is thought to be a T-helper (TH) cell driven process with increased interleukin-5 (IL-5) production. As there is no visceral involvement, the prognosis in Gleich Syndrome is believed to be benign. Corticosteroids remain the mainstay of treatment. This case highlights the importance of a thorough diagnostic evaluation in the setting of hypereosinophilia that enables focused treatment, prognostication and prediction of

organ involvement.

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## Abstract 75 (13A157)

## Case Poster

### Inflammatory Pancreatic Mass Secondary to Temporal Arteritis

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**Introduction:** A 68-year-old female was admitted with "aches and pains". ESR and CRP were elevated, 114 and 238, respectively. A diagnosis of Polymyalgia Rheumatica was made and Prednisolone 15mg od commenced.

**Aims/Background:** Despite one week of treatment, symptoms persisted and ESR remained elevated. No active infections noted. An ECHO showed no evidence of endocarditis. Urinary Bence-Jones protein was negative. A CT Chest, Abdomen and pelvis revealed a 3.1 x 2.5 x 2.6cm smooth walled, well-defined cyst within the head of the pancreas.

**Method:** This lady had on-going myalgia and new headaches despite 15mg prednisolone od. A temporal artery biopsy was non-diagnostic. A working diagnosis of Temporal Arteritis was made and prednisolone was up-titrated. Given the presence of a pancreatic cyst on CT, Ca19-9 levels were checked (16 (0-37)). Endoscopic ultrasound was performed and it was felt that this was a non-complex simple pancreatic cyst. Aspiration was unsuccessful. MRCP confirmed these findings.

**Results:** Follow-up MRI 6 months later showed reduction in size of the cystic abnormality, measuring 2.0cm x 1.6 cm. Repeat MRI at 12 months showed the cystic mass had resolved. Over this period Prednisolone dose was tapered to 10mg po od. Methotrexate was added as a steroid-sparing agent.

**Conclusions:** Full resolution of pancreatic cyst was noted with treatment of underlying temporal arteritis. It is most likely that this was secondary to the underlying inflammatory process, and resolution occurred following treatment with steroids. Pancreatic cysts in the setting of Temporal Arteritis have not previously been reported, however, similar cases have been reported in the setting of Systemic Lupus Erythematosus<sup>(1)</sup>.

## References:

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## Abstract 76 (13A163)

## Case Poster

### Granulomatosis with Polyangiitis Presenting as Sudden Blindness, a case report

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**Introduction:** Granulomatosis with polyangiitis (GPA) is a small vessels vasculitis. Ocular manifestations are less common compared to kidneys and respiratory tract features.

**Aims/Background:** We present a case of unusual GPA presentation with sudden onset unilateral blindness in a middle aged patient. The patient was found to have branch retinal artery occlusion.

**Method: The Case:** A 65 year old man presented to ophthalmology clinic with sudden onset right side blindness, which started as complete blindness then partially improved at the time of assessment with residual right superior hemianopia. Fundoscopy revealed branch retinal artery occlusion. He admitted history of nasal discharge and blockage, hearing impairment and generalized joint pain in the preceding three weeks.

**Results:** His CRP was 257, ESR 92 and WCC 18. Urgent echocardiogram was negative for Subacute Bacterial Endocarditis. Urgent vasculitis screen was performed. His cANCA was positive at 1:320 and PR3 was elevated at 356. Accordingly the patient was considered as having GPA complicated by branch retinal artery occlusion. He received methylprednisolone followed by high dose of prednisolone in addition to methotrexate and aspirin. Thoracic CT showed right lung infiltrate with no cavitation. Audiometry revealed bilateral conductive deafness. The patient showed great improvement after one week with near normal visual acuity. CRP was 7 on discharge.

**Conclusions:** Retinal artery occlusion is an uncommon feature of GPA. The diagnosis needs high index of clinical suspicion with detailed medical history. Immediate intensive immunosuppression is required to improve the prognosis. Our patient was diagnosed and received methylprednisolone within 4 hours of presentation to the hospital.

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## Abstract 77 (13A164)

## Case Poster

### Life Threatening Antiphospholipid Syndrome – Response to B Cell Depletion Therapy

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**Introduction:** Antiphospholipid syndrome (Hughes' Syndrome) is an autoimmune disorder which is also known as autoimmune coagulopathy. It is characterized by a thrombophilic state with pregnancy complications associated with presence of circulating antiphospholipids antibodies, which include anticardiolipin, lupus anticoagulant, and /or anti  $\beta_2$  glycoprotein.

**Aims/Background:** We present a case of limb threatening APS in a young man who developed severe thrombosis with gangrene while fully anticoagulated

**Method: The Case:** A previously healthy 44 year old male was referred to the hospital by his general practitioner for left leg swelling, which was preceded by rash of his legs. Initially he was diagnosed as thrombo-phlebitis. The patient represented for the second time for right leg swelling which was found to be deep venous thrombosis and he was started on anticoagulation. Despite adequate warfarinisation he developed massive pulmonary embolism. Surviving this he some weeks later, again fully anti-coagulated, developed severe gangrene of his right foot to the mid-foot. Full malignancy screening was negative but thrombi in femoral arteries were noted at arteriography.

**Results:** Lupus anticoagulant was positive and then a positive anticardiolipin ab was detected together with ANA 1/800. The patient is diagnosed with severe antiphospholipid syndrome. Following discussion with Haematology and literature review this patient was treated with Rituximab APP. Consequently he has had no further clotting episodes and appears likely to retain his leg and foot which initially seemed unlikely.

**Conclusions:** We present this case of limb and life threatening APS progressing rapidly despite aggressive anti-coagulation, treated apparently successfully to date with B cell depleting mono-clonal antibody therapy.

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## Abstract 78 (13A170)

## Case Poster

### Novel therapy and novel therapeutic pathways in gout – how to “cure” advanced gout?

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**Aims/Background:** A severe case of gout is presented as a clinical therapeutic challenge to rheumatologists and as a challenge to our understanding of conventional mechanisms of gout pathogenesis.

**Method:** A 70-year-old male presented with confirmed chronic tophaceous gout for 33 years. He developed polyarticular disease over the period but never experienced any pain in the left hand. He had a past history of chronic residual weakness in the left arm and leg due to a forceps injury, high alcohol consumption and stable chronic renal failure. Current medications were Allopurinol 300 mg daily, Colchicine 0.5 mg daily. On examination he had polyarthritis with multiple tophi and a non-healing ulcer over a large tophus on the left first metatarsophalangeal joint. Neurological evaluation confirmed grade 4/5 power in the left upper limb with 3/5 power on hand grip. He had grade 4/5 power in the left lower limb with slightly reduced touch sensation in left hand and foot. A normal neurological examination on right side except slightly reduced grip due to painful joints.

**Results:** Serum urate of 346  $\mu\text{mol/L}$ . Plain radiography confirmed destructive gouty arthritis with relative sparing of left hand. Hand ultrasound demonstrated bilateral double contour sign of uric acid crystal deposition and multiple tophi in hands despite the fact he never experienced pain in his left hand. Dual energy CT scan showed severe symmetrical tophaceous gout and erosions.

**Conclusions:** A novel therapy was administered. Patient hand function has been restored and the patient lives independently. A novel therapeutic pathway regulating the clinical phenotype of gout is presented.

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## Abstract 79 (13A172) Case Poster

### A rare cause of stress fractures in a young female

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**Introduction:** Osteoporosis (OP) is common in Ireland. Secondary screening is important in evaluating OP patients <50 years.

**Method:** A 37 year old female presented to her GP with 3 weeks history of spontaneous right foot pain after vigorous physical exercise. She had an MRI scan of the foot after a normal radiograph and persistent pain, which showed fractures of right

2nd and 3rd metatarsal shafts. She also had plaque psoriasis and was receiving fumaric acid 240mgs tds from dermatology. A DXA scan showed T score of -2.5 at L1-L4 ( -2.7 at L2) and T score -1.4 at neck of femur. She attended rheumatology for ongoing symptoms and advice on osteoporosis management. On examination she had ribcage tenderness and minimal psoriasis but no active joint disease.

**Results:** She had a normal secondary screen for osteoporosis. Further investigations revealed raised alkaline phosphatase 208  $\text{mmol/L}$ , reduced serum phosphate 0.49  $\text{mmol/L}$  (0.8-1.4), normal urinary calcium, phosphate and markedly elevated Urinary amino acids. She also had proteinuria, glycosuria and elevated urinary PCR and was awaiting nephrology review. Her bone scan raised a concern of metastatic disease due to multiple asymmetrical areas of increased uptake with subsequent negative CT TAP for malignancy. A diagnosis of acquired Fanconi syndrome with proximal renal tubule dysfunction secondary to fumaric acid treatment was made. Fumaric acid esters were discontinued. Within 4 weeks, she had marked clinical improvement with normalization of serum phosphate and urinalysis.

**Conclusions:** Fanconi syndrome is a rare side effect of fumaric acid. Stress fractures in a young patient require cautious investigations prior to treatment.

## Abstract 80 (13A181) Case Poster

### A case of retinal vein thrombosis in a patient with Anti-Phospholipid Antibody Syndrome (APS) and Systemic Lupus Erythematosus (SLE) following commencement of Rivaroxiban

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**Introduction:** A 33 year-old woman with Rothmund-Thomson syndrome, Systemic Lupus Erythematosus (SLE) and Anti-Phospholipid antibody Syndrome (APLS) attended the Rheumatology clinic in Beaumont Hospital with sudden loss of vision in her right eye.

**Aims/Background:** Rothmund-Thomson syndrome is a rare autosomal recessive condition. The affected gene is located on chromosome 81. Features of the syndrome include bone, ocular and skin abnormalities<sup>(1,2,3)</sup>.

**Method:** At 25 years of age this patient was diagnosed with low grade SLE. She was intolerant of Hydroxychloroquine and Azathioprine and was managed successfully on intermittent short courses of steroids.

She had a history of several miscarriages and one full term pregnancy. In 2012 she was diagnosed with APS when she presented with an extensive right lower limb deep vein thrombosis requiring stenting and the insertion of an inferior vena caval filter. She was commenced on Warfarin and maintained an INR of approximately three. Unfortunately due to extensive hair loss attributable to Warfarin she was switched to Rivaroxiban three weeks before presentation.

**Results:** Right central retinal vein occlusion secondary to thrombosis. She was restarted on Warfarin and Aspirin.

**Conclusions:** This young lady developed complete and





permanent loss of vision in one eye three weeks after switching from Warfarin to Rivaroxaban. This highlights the devastating consequences of suboptimal anticoagulation. In Atrial Fibrillation studies have shown that Rivaroxaban is inferior to Warfarin for the prevention of embolization or stroke<sup>4</sup>. Perhaps the newer anticoagulation agents should not be used in patients with APS until randomized controlled trials demonstrate efficacy.

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#### Abstract 81 (13A182)

#### Case Poster

##### **A Life Threatening Complication of Treatment for Systemic Vasculitis**

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**Introduction:** A 66 year old lady presented to rheumatology services in September 2012 with a 4 month history of fevers, lethargy and myalgia. Elevated inflammatory markers and P-ANCA (at 320 with MPO >8.0) suggested a p-ANCA vasculitis which responded well to 3 pulses of IV methylprednisolone and subsequent rituximab 1g. Mycophenolate mofetil was then commenced as a steroid sparing agent and she managed well on reducing doses of oral prednisolone until January 2013 when she developed persistent diarrhoea. Stool cultures were negative and CMV titres were 79000. She was managed conservatively on a medical ward and discharged on prednisolone 40mg and mycophenolate 1g BD. She was then readmitted a few weeks later with worsening diarrhoea and signs of sepsis. Blood cultures and MSSU grew coliforms and IV Tazocin and gentamicin were commenced. Repeat CMV titres serially increased to 90500000. During subsequent ganciclovir treatment she became acutely unwell and developed an acute abdomen. CT scan of abdomen confirmed pneumoperitoneum and pelvic fluid in keeping with perforated viscus. Laparotomy revealed 3 sigmoid colonic perforations, necessitating a Hartmann's procedure. Pathology showed a CMV colitis with shallow and deep penetrating ulceration lined by granulation tissue with multiple CMV antibody positive cytoplasmic and nuclear inclusions in

endothelial cells. After 4 days in ICU and 3 weeks of ganciclovir treatment, CMV titres fell to 32400. She was discharged on reducing doses of oral prednisone and mycophenolate has remained on hold with no evidence of recurrence of vasculitis thus far.

#### Abstract 82 (13A188)

#### Case Poster

##### **Anti-Ro 52 positive Dermatomyositis Presenting as Rapidly Progressive Interstitial Lung Disease**

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**Introduction:** Dermatomyositis is frequently accompanied by interstitial lung disease. This varies greatly in severity, from an asymptomatic imaging finding to a fatal rapidly progressive disease.

**Aims/Background:** We present a successfully treated case of rapidly progressive anti-Ro 52 positive dermatomyositis related interstitial lung disease.

**Method:** A 48-year-old man presented with a six week history of dry cough, exertional dyspnoea, generalised rash, fevers and 15kg weight loss. Examination revealed a generalised erythematous rash affecting the face, torso and limbs. There were bibasal lung crepitations and subtle muscle weakness in the proximal upper limb muscles. Erythrocyte sedimentation rate was 65 mm/hr, C-reactive protein 48 mg/L, creatine kinase 272 units/L.

**Results:** Antinuclear antibodies were negative however anti-Ro 52 antibody was strongly positive. Chest radiograph revealed widespread inflammatory change in both lungs. CT thorax demonstrated ground glass changes throughout both lungs. Skin biopsy was consistent with dermatomyositis. A diagnosis of dermatomyositis with interstitial lung disease was made and treatment with methylprednisolone and monthly intravenous cyclophosphamide instituted.

**Conclusions:** His clinical condition deteriorated rapidly over two weeks with the development of respiratory failure necessitating intubation and admission to the ICU. Treatment with methylprednisolone and cyclophosphamide was continued. A turbulent clinical course ensued with superimposed hospital acquired pneumonia, pulmonary oedema and pulmonary emboli successfully treated. A tracheostomy and a prolonged period of rehabilitation were needed due to myopathy secondary to a combination of dermatomyositis and critical illness myopathy. He was discharged home five months later on tapering prednisolone to continue monthly outpatient cyclophosphamide infusions. Follow-up chest radiograph demonstrated complete resolution of all changes.

#### Abstract 83 (13A189)

#### Case Poster

##### **Myositis Ossificans following Brain Stem Infarction**

Richard Conway, Finbar D O'Shea, Michele F Doran, Joseph Harbison, Gaye Cunnane

Departments of Rheumatology and Medical Gerontology, St.



# ARCOXIA®

etoricoxib

## DEMONSTRATED POWERFUL PAIN RELIEF<sup>1,a</sup>



### For the symptomatic relief of<sup>1</sup>

**Osteoarthritis<sup>b</sup>** **30-60mg**  
once daily

**Rheumatoid Arthritis** **90mg**  
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once daily

### For the short-term treatment of<sup>1</sup>

**Postoperative Moderate Dental Surgery Pain** **90mg**  
once daily,  
maximum 3 days.

**Acute Gouty Arthritis** **120mg**  
once daily,  
maximum 8 days.

**ARCOXIA® (etoricoxib) ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing. **PRES-ENTATION** Tablets: 30mg, 60 mg, 90 mg and 120 mg tablets each containing 30mg, 60 mg, 90 mg or 120 mg of etoricoxib respectively. **INDICATIONS** Symptomatic relief of osteoarthritis, rheumatoid arthritis (RA), ankylosing spondylitis (AS) and the pain and signs of inflammation associated with acute gouty arthritis. The short-term treatment of moderate pain associated with dental surgery. Base the decision to prescribe a selective COX-2 inhibitor on an assessment of the individual patient's overall risks. **DOSAGE AND ADMIN-ISTRATION** Take orally with or without food. Onset of action may be faster when administered without food, and should be considered when rapid relief is needed. **Osteoarthritis:** 30 mg once daily. In some patients with insufficient relief from symptoms, an increased dose of 60 mg once daily may increase efficacy. **Rheumatoid arthritis:** 90 mg once daily. **Ankylosing spondylitis:** 90mg once daily. For acute pain conditions, etoricoxib should be used only for the acute symptomatic period. **Acute gouty arthritis:** 120 mg once daily limited to a maximum of 8 days. **Postoperative dental surgery pain:** 90 mg once daily, limited to a maximum of 3 days. Some patients may require additional postoperative analgesia. Each dose above is the maximum recommended dose for each condition and should not be exceeded. As the cardiovascular risks of etoricoxib may increase with dose and duration of exposure, use for the shortest duration possible and use the lowest effective daily dose. Re-evaluate periodically the patient's need for symptomatic relief and response to therapy, especially in osteoarthritis patients. **Hepatic insufficiency:** mild (Child-Pugh score 5-6): regardless of indication, do not ex-ceed a dose of 60 mg daily; moderate (Child-Pugh score 7-9): regardless of indication, do not exceed 30 mg once daily. **Renal insuf-ficiency:** No dosage adjustment necessary for patients with creatinine clearance  $\geq 30$  ml/min. **CONTRAINDICATIONS** History of hy-persensitivity to any component of this product. Active peptic ulceration or gastro-intestinal (GI) bleeding. Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema or allergic type reactions after aspirin or NSAIDs including COX-2 inhibitors. Pregnancy and lactation. Severe hepatic dysfunction (serum albumin  $<25$  g/l or Child-Pugh score  $\geq 10$ ). Estimated creatinine clearance  $<30$  ml/min. Children and adolescents under 16 years of age. Inflammatory bowel disease. Con-gestive heart failure (NYHA II-IV). Patients with hypertension whose blood pressure is persistently elevated above 140/90mmHg and has not been adequately controlled. Established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular dis-ease. **PRECAUTIONS AND WARNINGS** **Gastro-intestinal effects** Upper GI complications (perforations, ulcers or bleedings), some with fatal outcome have occurred in patients taking etoricoxib. Caution is advised in patients most at risk of developing a GI complication with NSAIDs: elderly, those on any other NSAID or aspirin concomitantly, or those with a prior history of GI disease. There is a further increase in the risk of GI adverse effects (GI ulceration or other GI complications) when etoricoxib is taken together with as-pirin (even at low doses). A significant difference in GI safety between selective COX-2 inhibitors + acetylsalicylic acid vs NSAIDs + acetylsalicylic acid has not been demonstrated in long-term clinical trials. **Cardiovascular** Clinical trials suggest that the selective COX-2 inhibitor class of drugs may be associated with a risk of thrombotic events (especially MI and stroke), relative to placebo and some NSAIDs. As the cardiovascular risks of etoricoxib may increase with dose and duration of exposure, use for the shortest du-ration possible and use the lowest effective daily dose. Re-evaluate periodically the patient's need for symptomatic relief and response to therapy, especially in those with osteoarthritis. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with etoricoxib after careful consideration. COX-2 selective in-hibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thromboembolic diseases because of their lack of antiplatelet effect. Therefore antiplatelet therapies should not be discontinued. **Renal effects** Consider monitoring renal function in patients with pre-existing significantly impaired renal function, uncompensated heart failure, or cirrhosis. **Fluid retention, oedema and hypertension** Exercise caution in patients with a history of cardiac failure, left ventricular dysfunction, or hypertension and pre-exis-ting oedema from any other reason, as fluid retention, oedema and hypertension have been observed in patients taking etoricoxib. All Nonsteroidal Antiinflammatory Drugs (NSAIDs), including etoricoxib, can be associated with new onset or recurrent congestive heart failure. Take appropriate measures, including discontinuation of etoricoxib where there is clinical evidence of deterioration in the condition of these patients. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIDs including COX-2 inhibitors, particularly at high doses. Therefore, hypertension should be controlled before treatment with etoricoxib (see section 4.3) and special attention should be paid to blood pressure monitoring during treatment with etoricoxib. Blood pressure should be monitored within two weeks after initiation of treatment and periodically thereafter. If blood pressure rises significantly, consider alternative treatment. **Hepatic effects** Elevations of ALT and/or AST ( $>3$  times the upper limit of normal) have been reported in approximately 1% of patients treated in trials with etoricoxib 30mg, 60 mg and 90 mg for up to one year. Monitor any patient with symptoms/signs of liver dysfunction or in whom an abnormal liver function test has occurred. Discontinue etoricoxib if signs of hepatic insufficiency occur, or if persistently abnormal liver function tests (3 times the upper limit of normal) are detected. **General** Take appropriate measures and consider discontinuation, if during treatment, patients deteriorate in any of the organ system func-tions described above. Maintain appropriate medical supervision when treating the elderly and patients with renal, hepatic or cardiac dysfunction with etoricoxib. Use caution when initiating treatment in patients with considerable dehydration. Rehydrate patients prior to starting therapy with etoricoxib. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported very rarely, associated with the use of NSAIDs and some selective COX-2 inhibitors. Discontinue at the first signs of skin rash, mucosal lesions or any other signs of hypersensitivity as hypersensitivity reactions (anaphylaxis, angioedema) have been reported. Etoricoxib may mask fever. Arcoxia® tablets contain lactose: do not use in patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **INTER-ACTIONS** **Interactions (pharmacodynamic):** Oral anticoagulants: Exercise caution when coadministering with warfarin and other oral anticoagulants. Closely monitor the prothrombin time INR when therapy with etoricoxib is initiated or the dose changed in patients receiving oral anticoagulants or similar agents, particularly in the first few days. **Diuretics, ACE-inhibitors and Angiotensin II Antago-nists:** NSAIDs may reduce the effect of diuretics and antihypertensive drugs. In some patients with compromised renal function, the co-administration of an ACE inhibitor or AIIA and cyclo-oxygenase inhibitors may result in further deterioration of renal function in-cluding possible acute renal failure, which is usually reversible. Administer cautiously, especially in the elderly. Patients should be adequately hydrated. Consider monitoring renal function at initiation of therapy and periodically thereafter. **Aspirin:** etoricoxib can be used concomitantly with aspirin at doses used for cardiovascular prophylaxis (low dose aspirin). However, concomitant adminis-tration of low dose aspirin with etoricoxib may result in an increased rate of GI ulceration or other complications compared to use of etoricoxib alone. Concomitant administration of etoricoxib with doses of aspirin above those for cardiovascular prophylaxis, or with other NSAIDs is not recommended. **Ciclosporin/tacrolimus:** monitor renal function when etoricoxib and either ciclosporin or tacrolimus is used in combination. **Interactions (pharmacokinetic):** The effect of etoricoxib on the pharmacokinetics of other drugs: Lithium: the plasma concentration of lithium is increased by NSAIDs, therefore monitor and adjust blood lithium and lithium dosage if necessary. **Methotrexate:** adequate monitoring is recommended for methotrexate-related toxicity when etoricoxib and methotrexate are

administered concomitantly. **Oral Contraceptives (OC):** Administration of etoricoxib 60 mg with an OC containing 35 mcg ethinyl estro-diol (EE) and 0.5 to 1 mg norethindrone for 21 days increased the steady state  $AUC_{0-24h}$  of EE by 37%. Administration of etoricoxib 120 mg with the same OC, concomitantly or separated by 12 hours, increased the steady state  $AUC_{0-24h}$  of EE by 50 to 60%. Consider this increase in EE concentration when selecting an oral contraceptive for use with etoricoxib. An increase in EE exposure can increase the incidence of adverse events associated with oral contraceptives. **Hormone Replacement Therapy:** 120 mg etoricoxib administered with 0.625 mg Premarin™ (Wyeth) for 28 days increased the mean steady state  $AUC_{0-24h}$  of unconjugated estrone (41%), equilin (76%) and 17- $\beta$ -estradiol (22%). Although the clinical significance is unknown, take into consideration the increase in estrogenic concentra-tion when selecting HRT as the increase in estrogen exposure might increase the risk of adverse events associated with HRT. **Di-goxin:** Patients at high risk of digoxin toxicity should be monitored for an increase in digoxin  $C_{max}$  when etoricoxib and digoxin are administered concomitantly. **Effect of etoricoxib on drugs metabolised by sulfo-transferases:** Etoricoxib is an inhibitor of human sulfo-transferase activity, particularly SULT1E1 and has been shown to increase the serum concentrations of ethinyl estradiol. It may be prudent to exercise care when administering etoricoxib concurrently with other drugs primarily metabolised by human sulfo-transferases (e.g. oral salbutamol and minoxidil). **Effect of etoricoxib on drugs metabolised by CYP isoenzymes:** Based on *in vitro* studies, etoricoxib is not expected to inhibit cytochromes P450 (CYP) 1A2, 2C9, 2C19, 2D6, 2E1 or 3A4. In a study in healthy subjects, daily ad-ministration of etoricoxib 120 mg did not alter hepatic CYP3A4 activity as assessed by the erythromycin breath test. **Effects of other drugs on the pharmacokinetics of etoricoxib:** The main pathway of etoricoxib metabolism is dependent on CYP enzymes. CYP3A4 appears to contribute to the metabolism of etoricoxib *in vivo*. **Ketoconazole:** a potent inhibitor of CYP3A4, dosed at 400 mg once a day for 11 days to healthy volunteers did not have any clinically important effect on the single-dose pharmacokinetics of 60 mg etoricoxib (43% increase in  $AUC$ ). **Voriconazole and Miconazole:** Co-administration of either oral voriconazole or topical miconazole oral gel, strong CYP3A4 inhibitors, with etoricoxib caused a slight increase in exposure to etoricoxib, but is not considered to be clinically meaningful based on published data. **Rifampicin:** Co-administration of etoricoxib with rifampicin, a potent inducer of CYP enzymes, produced a 65% decrease in etoricoxib plasma concentrations, an interaction which may result in recurrence of symptoms. **Antacids:** Antacids do not affect the pharmacokinetics of etoricoxib to a clinically relevant extent. **PREGNANCY AND LACTATION** **Pregnancy:** contra-indicated in the first, second and third trimesters of pregnancy. **Lactation:** contra-indicated. **Fertility:** Use of etoricoxib is not recommended in women attempting to conceive. **SIDE EFFECTS** The following undesirable effects were reported at an incidence greater than placebo in clinical trials in patients with OA, RA, AS or chronic low back pain treated with etoricoxib 30mg, 60mg or 90mg up to the recommended dose for up to 12 weeks, in MEDAL Program studies for up to 3 years, in short term acute pain studies for up to 7 days or in post-marketing experience: [Very common ( $\geq 1/10$ ) Common ( $\geq 1/100$  to  $<1/10$ ) Uncommon ( $\geq 1/1000$  to  $<1/100$ ) Rare ( $\geq 1/10,000$  to  $<1/1000$ ) Very rare ( $<1/10,000$ ) not known (cannot be estimated from the available data)] **Infections and infestations:** Common: **alveolar osteitis** Uncommon: gastro-enteritis, upper respiratory infection, urinary tract infection. **Blood and lymphatic sys-tem disorders:** Uncommon: anaemia (primarily associated with gastrointestinal bleeding), leukopenia, thrombocytopenia. **Immune system disorder:** Uncommon: hypersensitivity \*\* Rare: angioedema, anaphylactic/anaphylactoid reactions including shock. **Metabo-lism and nutrition disorders:** Common: oedema/fluid retention Uncommon: appetite increase or decrease, weight gain. **Psychiatric disorders:** Uncommon: anxiety, depression, mental acuity decreased, hallucinations. Rare: confusion, restlessness. **Nervous system disorder:** Common: dizziness, headache. Uncommon: dysgeusia, insomnia, paraesthesia/hypaesthesia, somnolence. **Eye disorders:** Uncommon: blurred vision, conjunctivitis. **Ear and labyrinth disorders:** Uncommon: tinnitus, vertigo. **Cardiac disorders:** Common: pal-pitations, arrhythmia Uncommon: atrial fibrillation, tachycardia, congestive heart failure, non-specific ECG changes, angina pectoris, myocardial infarction\*. **Vascular disorders:** Common: hypertension. Uncommon: flushing, cerebrovascular accident\*, transient is-chaemic attack, hypertensive crisis, vasculitis. **Respiratory, thoracic and mediastinal disorders:** Common: bronchospasm Uncom-mon: cough, dyspnoea, epistaxis. **Gastro-intestinal disorders:** Very common: abdominal pain Common: Constipation, flatulence, gas-tritis, heartburn/acid reflux, diarrhoea, dyspepsia/epigastric discomfort, nausea, vomiting, oesophagitis, oral ulcer Uncommon: abdominal distention, bowel movement pattern change, dry mouth, gastroduodenal ulcer, peptic ulcers including gastrointestinal perforation and bleeding, irritable bowel syndrome, pancreatitis. **Hepatobiliary disorders:** Common: ALT increased, AST increased. Rare: hepatitis, hepatic failure, jaundice. **Skin and subcutaneous tissue disorders:** Common: ecchymosis Uncommon: facial oedema, pruritus, rash, erythema, urticaria. Rare: Stevens-Johnson syndrome, toxic epidermal necrolysis, fixed drug eruption. **Musculoskel-et and connective tissue disorders:** Uncommon: muscular cramp/spasm, musculoskeletal pain/stiffness. **Renal and urinary disor-ders:** Uncommon: proteinuria, serum creatinine increased, renal failure/renal insufficiency. **General disorders and administration site conditions:** Common: asthenia/fatigue, flu-like disease. Uncommon: chest pain. **Investigations:** Uncommon: blood urea nitrogen in-creased, creatine phosphokinase increased, hyperkalaemia, uric acid increased. Rare: blood sodium decreased. The following seri-ous undesirable effects have been reported in association with the use of NSAIDs and cannot be ruled out for etoricoxib: nephrotic-syndrome including interstitial nephritis and nephrotic syndrome. \* Based on analyses of long-term placebo and active controlled clinical trials, selective COX-2 inhibitors have been associated with an increased risk of serious thrombotic arterial events, including myocar-dial infarction and stroke. The absolute risk for such events is unlikely to exceed 1% per year based on existing data (uncommon). \*\* Hypersensitivity includes the terms "allergy", "drug allergy", "drug hypersensitivity", "hypersensitivity", "hypersensitivity NDS", "hypersensitivity reaction" and "nonspecific allergy". **PACKAGE QUANTITIES** 30 mg and 60 mg Tablets: packs of 28 tablets. 90 mg Tablets: packs of 5 and 28 tablets. 120 mg Tablets: packs of 7 and 28 tablets. **Legal Category:** POM. **Marketing Authorisation num-bers:** Tablets 30 mg PA 1286/7/1, Tablet 60 mg PA 1286/7/2, Tablet 90 mg PA 1286/7/3, Tablet 120 mg PA 1286/7/4. **Marketing Authorisation holder:** Merck Sharp & Dohme Ireland (Human Health) Limited, Red Oak North, South County Business Park, Leopardstown, Dublin 18. **Date of revision:** April 2013. © Merck Sharp & Dohme Ireland (Human Health) Limited 2013. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. **Date of preparation:** May 2013

**References:** 1. Arcoxia SPC. a. Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied. Due to cardiovascular risks, the shortest duration possible and the lowest effective daily dose of ARCOXIA® should be used. b. The recommended dose for osteoarthritis is 30 mg once daily. An increased dose of 60 mg once daily may increase efficacy. The dose for osteoarthritis should not exceed 60 mg daily.



## ISR SPRING 2013



Sinéad Bailey, Mike Arnold,  
Business Manager Ireland/Scotland & Eugene O'Connor all of UCB



James Donohue & colleagues of Hospira



Dr Gary Wright & Dr Eithne Murphy



James Hospital, Dublin, Ireland

**Introduction:** A 39 year old man developed right hip pain 6 months after a brain stem stroke following basilar artery thrombosis. His inpatient stay had been complicated by a prolonged ICU admission following small bowel infarction.

**Aims/Background:** He complained of right hip pain limiting his movement. Clinical examination revealed diffuse tenderness of the right buttock and thigh with decreased range of movement of the right hip and knee. Plain radiography and computed tomography (CT) revealed a large area of calcification surrounding the right hip. Isotope bone scan demonstrated intense tracer uptake at the right hip suggestive of ongoing metabolic activity.

**Method:** A diagnosis of myositis ossificans secondary to prolonged immobility was made. Surgical resection, extracorporeal shock wave lithotripsy and radiotherapy were considered but not performed due to the size of the involved area. Intravenous zoledronic acid was administered to attempt to reduce progression.

**Results:** While there was no clinical improvement, CT showed no progression in the ossification and repeat isotope bone scan revealed a dramatic decrease in metabolic activity. He progressed slowly with physiotherapy and was discharged to a rehabilitation facility.

**Conclusions:** Myositis ossificans is a rare benign condition characterised by heterotopic bonelike deposits in muscle. This condition of unknown pathogenesis most commonly occurs following trauma however an association with prolonged immobility and acute brain injury has been reported. Surgical resection is the definitive treatment, extracorporeal shock wave lithotripsy, NSAIDs and radiotherapy have also been utilised. The use of bisphosphonates is theoretically attractive and has been reported in a small number of cases.

#### Abstract 84 (13A190)

#### Case Poster

##### **Hyperferritinaemia, Osteopenia, Polydactyly and Syndactyly – A Proposed Role for the WNT-signalling Pathway**

Richard Conway, Finbar D O'Shea, Michele F Doran, Gaye Cunnane

Department of Rheumatology, St. James Hospital, Dublin, Ireland

**Introduction:** A 39 year old man was referred with unexplained hyperferritinaemia and a distant history of joint pains.

**Aims/Background:** He reported arthralgia in his hands and wrists five years previously while working in construction. There was no history of joint swelling and he had no joint symptoms in the intervening five years. He had a background of polydactyly with removal of a toe from each foot, two of his children had identical abnormalities. He was a carrier of alpha-1-antitrypsin deficiency with the MZ genotype, a heterozygote for the C282Y mutation of haemochromatosis and had 4 cousins with confirmed haemochromatosis. He consumed 15 units of alcohol weekly.

**Method:** On examination he had ankylosis of the thumb

interphalangeal joints with syndactyly and pes planus in his feet bilaterally. The remainder of his joints were normal. Investigations revealed an elevated ferritin of 1560µg/L, the remainder of his routine bloods including transferrin saturation were normal. Plain radiographs demonstrated diffuse osteopenia, ankylosis of the thumb interphalangeal joints and congenital shortening of the first metatarsal bilaterally with pes cavus. Liver biopsy revealed haemosiderosis but no fibrosis.

**Results:** Polydactyly is frequently associated with other skeletal abnormalities and genetic disorders. Many of the genetic disorders associated with polydactyly develop liver fibrosis. There has been a suggested role for ciliary dysfunction as an underlying pathogenic mechanism. The WNT-signalling pathway is important in ciliary function and also in bone metabolism.

**Conclusions:** We hypothesise a common pathogenesis for this man's skeletal abnormalities, abnormal iron metabolism and osteopenia involving the WNT-signalling pathway and ciliary dysfunction.

#### Abstract 85 (13A191)

#### Case Poster

##### **Hickam's Dictum or Occam's Razor: Searching for a sign**

Len Harty, Deirdre Morley, John O'Grady, Joanne Maher, Sinead Harney, Catherine Molloy, John Ryan

Department of Rheumatology, Cork University Hospital, Wilton, Cork.

**Introduction:** Antibodies to Signal Recognition Peptide (SRP) are present in 4-6% necrotising myopathy patients, are pathogenic and rarely associated with other autoimmune conditions.(1,2) Myositis in SRP myopathy is greater than in lupine or other myopathies unrelated to SRP (mean CK 6782 v 1535 U/L, p<0.001).(3)

**Aims/Background:** Steroid monotherapy is ineffective; MTX, cyclophosphamide, ciclosporin, IVIg, rituximab (RTX) and plasma apheresis have all been used with varying results.(3-6) We describe successful plasma apheresis of anti-SRP myopathy occurring contemporaneous to renal lupus.

**Method:** A 53yr old man presented with bilateral leg cramps, fatigue and anorexia of 2wks duration. Clinical examination revealed upper and lower limb bilat. proximal muscular weakness(2/5). Lower limb oedema ensued. History and examination were otherwise unremarkable. Abnormal tests are shown in table-1. Nephrotic syndrome, class V lupus nephritis and necrotising myopathy were confirmed. CT TAP outruled paraneoplastic syndrome. MMF and prednisolone 1mg/kg were commenced following IV MP 250mg. RTX 375mg/m<sup>2</sup> x 2 was given without effect. 6wks after presentation thrice weekly plasma apheresis over 3wks was commenced.

**Results:** After 3 plasma apheresis, proximal power returned(4/5) and CK decreased to 1247. No significant adverse reactions were encountered and the patient recovered with both his necrotising myositis and lupus nephritis remitting.

**Conclusions:** Anti-SRP necrotising myopathy is a difficult to treat, debilitating and potentially fatal condition. Identification of anti-SRP in myopathic patients guides therapy, suggesting the need for plasma apheresis which as we have shown was an





effective rescue strategy in our patient for whom MMF with corticosteroids and RTX was ineffective. Drug discontinuation is associated with relapse.(3)

**References:** 1. Benveniste O. et al., "Correlation of anti-signal recognition particle autoantibody levels with creatine kinase activity in patients with necrotizing myopathy." *Arthritis Rheum.* 2011 Jul;63(7):1961-71.  
2. Römisch K, et al. "Human autoantibodies against the 54 kDa protein of the signal recognition particle block function at multiple stages." *Arthritis Res Ther.* 2006;8(2):R39.  
3. Hengstman GJD, et al. "Anti-signal recognition particle autoantibodies: marker of a necrotising myopathy." *Ann Rheum Dis* 2006;65:1635-1638  
4. Whelan BR, Isenberg DA. "Poor response of anti-SRP-positive idiopathic immune myositis to B-cell depletion." *Rheumatology (Oxford).* 2009 May;48(5):594-5.  
5. Valiyl R, et al. "Rituximab therapy for myopathy associated with anti-signal recognition particle antibodies: a case series." *Arthritis Care Res (Hoboken).* 2010 Sep;62(9):1328-34.  
6. Savey L, et al. "Necrotizing myopathy associated with anti-SRP auto-antibodies: transient efficacy of a therapeutic strategy associating plasma exchanges and rituximab." *Presse Med.* 2012 Oct;41(10):1035-7.

**Table 1. Abnormal results**

ESR	117
CRP	37
CK	40,000
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ANF	Strong, homogenous
ENA	SSA, SRP
dsDNA	77
C3	0.68
C4	0.12
IgG	21
Abstract 86 (13A192)	Case Poster
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# Management of Sjogrens syndrome related neuropathy

24hr Urinary Protein 7g  
Murphy CL, Fathelrahman I, McCarthy C, Donnelly S, McCarthy G  
Kidney Biopsy Class V renal lupus  
Department of Rheumatology, Mater Hospital, Dublin 7  
Quadriceps Biopsy Necrotising Myopathy

**Introduction:** Peripheral neuropathy is a rare but well

documented primary manifestation of Sjogrens syndrome.

**Aims/Background:** A 56 year old gentleman presented with pain, paresthesia and numbness in both hands and feet. He had marked difficulty with activities of daily living such as dressing, shaving and could no longer play golf. His symptoms progressed over five years. He had no sicca symptoms.

**Method:** MRI cervical spine revealed degenerative disease. Lumbar puncture was unremarkable. Nerve conduction studies revealed a sensorimotor neuropathy. Sural nerve biopsy revealed epineurial fibrosis but no vasculitis.

Further tests revealed ANA, Ro and La were positive. He denied dry or gritty eyes, however Schirmers test was positive. Lip biopsy negative. He was started on hydroxychloroquine and subsequently developed a rash. Skin biopsy revealed a large number of eosinophils.

**Results:** He was thoroughly investigated by neurology, dermatology and rheumatology teams. It was felt that his peripheral neuropathy was secondary to Sjogren's syndrome. Extraglandular manifestations of Sjogrens are rare but can be a primary manifestation of the disease. He was treated with IV methylprednisolone and had minor improvement in his symptoms.

**Conclusions:** Sjögren's syndrome-related peripheral neuropathy is rare and no treatment has been shown to improve its outcome. There is little in the literature regarding management of this condition. The use of amitriptyline is generally avoided because of anticholinergic side effects. Intravenous Immunoglobulin is useful in the treatment of Sjogrens Syndrome-associated sensorimotor neuropathies or nonataxic sensory neuropathy without any necrotizing vasculitis. The benefit in Sjogrens Syndrome-related ataxic neuropathy seems less clear.

**References:** 1. Rist S et al. Experience of intravenous immunoglobulin therapy in neuropathy associated with primary Sjögren's syndrome: a national multicentric retrospective study. *Arthritis Care Res (Hoboken).* 2011 Sep;63(9):1339-44. doi: 10.1002/acr.2049  
2. Levy Y, Uziel Y, Zandman GG, Amital H, Sherer Y, Langevitz P, Goldman B, Shoenfeld Intravenous immunoglobulins in peripheral neuropathy associated with vasculitis *Ann Rheum Dis.* 2003;62(12):1221

## IRHPS ABSTRACTS

### ORAL PRESENTATIONS

#### Oral Presentation No.1

#### Physiotherapy Awareness of Inflammatory Back Pain / Ankylosing Spondylitis



Martina Fitzpatrick<sup>1</sup>, Maria Flynn<sup>2</sup>, Sinéad O'Malley<sup>2</sup>, Caitriona Cunningham<sup>2</sup>

<sup>1</sup>Physiotherapy Department, St. Vincent's University Hospital, Dublin, Ireland

<sup>2</sup>School of Public Health, Physiotherapy and Population Science, University College Dublin, Dublin, Ireland

**Aim/Introduction:** Inflammatory back pain (IBP) and Ankylosing Spondylitis (AS) are associated with long diagnostic delays. This study aims to investigate awareness and knowledge of features of IBP and AS, initial physiotherapy management and related educational preferences among physiotherapists in Ireland.

**Method:** An online survey, based on the Assessment of Spondyloarthritis International Society (ASAS) and Berlin criteria<sup>1,2</sup>, was distributed to all members of the private practice and community care employment groups of the Irish Society of Chartered Physiotherapists. Questions regarding IBP features, associated rheumatologic features, initial physiotherapy management and educational preferences were included. Data were analysed with descriptive statistics using the statistical package for the social sciences (SPSS v. 20).

**Results:** The survey was completed by 100 physiotherapists, representing a 20 % response rate. Only 11% of respondents listed 4 features of inflammatory back pain corresponding with the Berlin and ASAS criteria, while only 7.8 % of respondents identified all the Berlin back pain elements from a random list. Forty per cent did not believe peripheral joint symptoms were associated with inflammatory back pain and 4.6 % were 'unsure' about the significance of enthesitis. Group exercise and Self management were commonly cited management approaches. Of the respondents, 80% were interested in further education with most favouring written information or online materials.

**Conclusion:** Private practice and community care physiotherapy respondents demonstrated a lack of awareness and knowledge regarding diagnostic criteria for inflammatory back pain and Ankylosing Spondylitis, indicating the need for related education.

**References:** 1. Rudwaleit M, van der Heijde D, Landewé R, Listing J, Akkoc N, Brandt J, Braun J, Chou CT, Collantes-Estevez E, Dougados M, Huang F, Gu J, Khan MA, Kirazli Y, Maksymowych WP, Mielants H, Sørensen IJ, Özgöçmen S, Roussou E, Valle-Oñate R, Weber U, Wei J, Sieper J. The development of Assessment of SpondyloArthritis international Society classification criteria for axial spondyloarthritis (part II): validation and final selection. *Ann Rheum Dis*. 2009 Jun;68(6):777-83. doi:10.1136/ard.2009.108233. Epub 2009 Mar 17. PubMed PMID: 19297344.

2. Rudwaleit M, Metter A, Listing J, Sieper J, Braun J. Inflammatory back pain in ankylosing spondylitis: a reassessment of the clinical history for application as classification and diagnostic criteria. *Arthritis Rheum*. 2006 Feb;54(2):569-78. PubMed PMID: 16447233.

## Oral Presentation No.2

### The effectiveness of education and aerobic exercise in 'high functioning' patients with fibromyalgia: evaluation of a new service

Catherine Cullinane<sup>1</sup>, Dr. Claire Sheehy<sup>1</sup>, Bindu Irudayaraj<sup>1</sup>, Joseph G McVeigh<sup>2</sup>

Waterford Regional Hospital<sup>1</sup>  
University of Ulster<sup>2</sup>

**Introduction/Aim:** Fibromyalgia syndrome (FMS) is characterised by chronic widespread pain, fatigue and reduced physical function. Exercise has positive effects on physical function, fatigue and well-being in FMS<sup>1</sup>. However, patients find it difficult to engage in exercise and often have low self-efficacy for exercise. The aim of this study was to evaluate a new early access service consisting of a 6-week education and aerobic exercise intervention in patients with FMS, who were classified as 'high functioning.'

**Method:** Participants (n=32) were referred from WRH rheumatology department and attended a 6-week exercise and education intervention delivered by physiotherapist and occupational therapist. Participants completed the Fibromyalgia Impact Questionnaire (FIQ), Hospital Anxiety and Depression Score (HAD) Six-Minute-Walk Test (6MWT) and Exercise Self-Efficacy Scale (ESES). Follow up was carried out post and 3 months post programme.

**Results:** Participants who completed the intervention had a significant improvement in mean (SD) pain from baseline 7.01 (1.8) to the end of the programme 5.6 (2.9), p=0.03. Mean (SD) 6MWT improved from 386m (96) to 416m (57) at the end of the programme (p=0.05), this was maintained at 3 month follow-up. There was no significant change in total FIQ score or the HAD scale, however, participants' exercise self-efficacy significantly improved from 58.2 (18.6) to 68 (11.6), p=0.01.

**Conclusion:** Improvements were recorded post programme in exercise capacity, exercise self-efficacy and VAS pain. Improvement was maintained at 3 months follow up. Anticipated service developments are use of FIQ to subgroup<sup>2</sup>, longer term follow up, vocational rehabilitation and pedometer use to evaluate exercise adherence.<sup>3</sup>

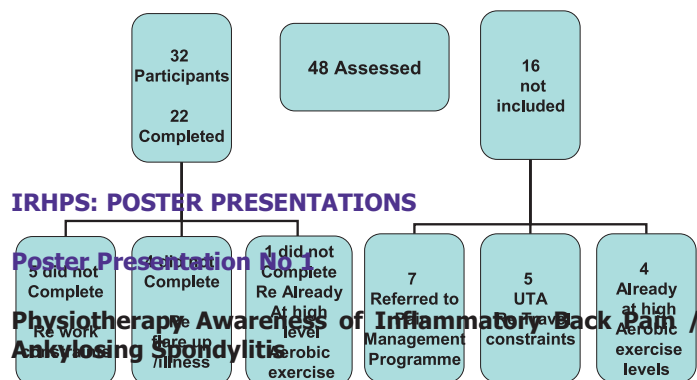
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*International Journal of Behavioural Nutrition and Physical Activity* 8:80





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**Aim/Introduction:** Inflammatory back pain (IBP) and Ankylosing Spondylitis (AS) are associated with long diagnostic delays. This study aims to investigate awareness and knowledge of features of IBP and AS, initial physiotherapy management and related educational preferences among physiotherapists in Ireland.

**Method:** An online survey, based on the Assessment of Spondyloarthritis International Society (ASAS) and Berlin criteria<sup>1,2</sup>, was distributed to all members of the private practice and community care employment groups of the Irish Society of Chartered Physiotherapists. Questions regarding IBP features, associated rheumatologic features, initial physiotherapy management and educational preferences were included. Data were analysed with descriptive statistics using the statistical package for the social sciences (SPSS v. 20).

**Results:** The survey was completed by 100 physiotherapists, representing a 20 % response rate. Only 11% of respondents listed 4 features of inflammatory back pain corresponding with the Berlin and ASAS criteria, while only 7.8 % of respondents identified all the Berlin back pain elements from a random list. Forty per cent did not believe peripheral joint symptoms were associated with inflammatory back pain and 4.6 % were 'unsure' about the significance of enthesitis. Group exercise and Self management were commonly cited management approaches. Of the respondents, 80% were interested in further education with most favouring written information or online materials.

**Conclusion:** Private practice and community care physiotherapy respondents demonstrated a lack of awareness and knowledge regarding diagnostic criteria for inflammatory back pain and Ankylosing Spondylitis, indicating the need for related education.

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### Poster Presentation No 2

#### An Examination of self-report physical activity and its relationship with psychological factors in inflammatory arthritis

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**Aim/Introduction:** The benefits of physical activity (PA) in inflammatory arthritis (IA) patients are well-established. However, levels of PA in the IA population are suboptimal and the determinants of PA are poorly understood. In order to develop interventions aimed at increasing PA in IA determination of the factors associated with PA participation in this population is warranted. The aim of this study was to establish the correlates of PA for these populations.

**Method:** A cross-sectional study of 102 people with rheumatoid arthritis and psoriatic arthritis was conducted to explore the association between demographic, health-related, and psychological variables such as perceived health, self-efficacy and activity beliefs and levels of PA and energy expenditure (EE). PA was recorded using the Yale Physical Activity Survey (YPAS). Statistical analysis consisted of descriptive statistics, correlational and hierarchical regression analysis.

**Results:** Age was the only socio-demographic variable to correlate with PA over the past month ( $p=0.04$ ). Physical health perception was associated with PA levels ( $p=0.02$ ) and EE over the past week ( $p=0.01$ ). Beliefs about PA were shown to correlate with levels of PA and EE, and remained significant when age ( $p=0.03$ ) and physical health perception ( $p=0.02$ ) were controlled for.

**Conclusion:** Beliefs about PA and perceived physical health influenced levels of self-report PA and EE in this population. These data provide a useful signpost for guiding and designing interventions to improve PA levels in IA populations by altering



beliefs about PA and health perceptions.

### Poster Presentation No 3

#### Physical Activity and Fatigue in Fibromyalgia

Dr. Norelee Kennedy & Sarah O'Connell

Department of Clinical Therapies, University of Limerick

**Aim/Introduction:** Fibromyalgia (FM) is a chronic condition associated with widespread pain and fatigue. Fatigue is often described as the most troublesome symptom of FM, resulting in reduced levels of physical activity (PA) (Ryan 2011). The aim of the study is to describe fatigue, self-report PA and fibromyalgia impact in a population with FM through the use of an online questionnaire. To determine if correlations exist between self-report PA and fatigue levels.

**Method:** A quantitative cross-sectional study design was used. Male and female participants over 18, with a diagnosis of FM were recruited through Arthritis Ireland. Participants completed an online survey consisting of a demographics questionnaire, the Fibromyalgia Impact Questionnaire, the Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) and the Fatigue Severity Scale. SPSS version 20 was used to analyze the data using descriptive and correlational statistical tests - Spearman's Rho, Mann-Whitney U, Kruskal-Wallis

**Results:** Overall response rate was 31.28% (n=61). Of the respondents 50.82% (n=31) fully completed the survey. An overall low negative correlation between self-report PA and fatigue ( $\rho=-0.206$ ) was found, but this was not statistically significant ( $p=0.226$ ). A strong, statistically significant negative correlation ( $\rho=-0.857$ ,  $p=0.007$ ) was found between self-report PA and fatigue for the SQUASH 4<sup>th</sup> quartile results.

**Conclusion:** This pilot study found high levels of fatigue and low PA levels in participants. A significant negative correlation between higher levels of PA and fatigue was found. Further research with larger sample sizes is required to further explore these findings.

### Poster Presentation No 4

#### To Investigate the correlation between physical activity, fatigue and self-efficacy in rheumatoid arthritis

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<sup>2</sup>Department of Rheumatology, University Hospital Limerick

**Aim/Introduction:** Physical Activity (PA) levels in rheumatoid arthritis (RA) have been shown to be lower than international recommendations. Fatigue is a significant, debilitating symptom in RA. Psychological traits such as self-efficacy may be a mediator in the relationships between fatigue and physical activity in this population. The aim of the study is to explore the correlations between self-reported PA, fatigue and self-efficacy in RA.

**Method:** A cross-sectional survey study design was used. People with RA attending rheumatology out-patient clinics over an eight week period were surveyed using the International Physical Activity Questionnaire (IPAQ), Bristol RA Fatigue-Multidimensional Questionnaire (BRAFMQ) and the RA Self-Efficacy Questionnaire (RASE). Data was analysed using descriptive statistics in SPSS.

**Results:** Seventeen (15 female) people participated in the survey. The mean time since diagnosis was 5.48 years ( $\pm$ SD 4.7). The mean total self-report PA score was moderate (2,263.92 MET-minutes/week,  $\pm$ SD 3,160.34). Mean fatigue score was moderate (30.8  $\pm$  19.59). Mean SE was high (99.21  $\pm$  12.64). Moderate negative correlations were found between PA and fatigue ( $r = -0.487$ ,  $p = 0.128$ ) and between fatigue and SE ( $r = -0.327$ ,  $p = 0.276$ ). A small positive correlation between PA and SE ( $r = 0.023$ ,  $p = 0.947$ ) was found.

**Conclusion:** This pilot study identified trends in the association between fatigue, physical activity and self-efficacy in people with RA. People with higher levels of PA had higher self-efficacy and lower fatigue scores. Larger studies are needed to further explore the relationships between these variables.

### Poster Presentation No 5

#### Early diagnosis of incomplete atypical femoral fractures in patients on prolonged bisphosphonate therapy using DXA

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Osteoporosis Centre, DXA Unit, St. Vincent's University Hospital, Dublin 4

**Aim/Introduction:** Atypical femoral fractures (AFF) are associated with prolonged bisphosphonate therapy. A feature of incomplete AFF is a localized periosteal reaction. It has been suggested that extending the length of the femur image at the time DXA may diagnose an incomplete AFF.

**Method:** In patients over 50 years old on bisphosphonate therapy for more than 5 years, we extended femur length at time of routine DXA. Patients with abnormal DXA images were referred for pelvis X-ray with views of lateral femurs.

**Results:** We studied 257 consecutive patients who meet the selection criteria. Abnormal DXA images were suggested in 19 of 257 (7.4%). On X-ray, 7 (2.7%) showed no abnormality, 7 (2.7%) showed evidence of AFF, and 5 (2.0%) showed an unrelated radiographic abnormality. Of the 7 cases with X-ray evidence of AFF, 5 had a periosteal flare and 2 had a visible fracture line, both of whom needed insertion of an intramedullary nail. Of the 7 cases with X-ray evidence of AFF, 5 had a periosteal flare and 2 had a visible fracture line, both of whom needed insertion of an intramedullary nail.

**Conclusion:** We demonstrated that it is feasible to detect incomplete AFF early using extended femur length imaging with prevalence in our sample of 2.7% (95% CI, 1.7 to 3.7%). We are





now exploring the feasibility of single-energy imaging of the entire length of each femur as means of improving the diagnostic utility because this gives much higher resolution that approximates the quality of plain X-ray.

#### Poster Presentation No 6

##### **Review of an advanced practice Physiotherapist's experience in a musculoskeletal ultrasound clinic (MSKUS) within a Rheumatology setting**

Grainne Cussen, Clinical Specialist Physiotherapist in Rheumatology, Dr D. O'Gradaigh, Dr C. Sheehy

Physiotherapy Dept, Waterford Regional Hospital, Ireland  
Rheumatology Dept, Waterford Regional Hospital, Ireland

**Aim/Introduction:** To evaluate an advanced practice Physiotherapist's experience in a MSKUS and injection clinic within a Rheumatology service from January 2011 to May 2013. Ultrasound is widely recognised as a tool to complement clinical diagnosis of both musculoskeletal (MSK) and inflammatory conditions [1,2,3]. Physiotherapists working in advanced roles have acquired this skill to enhance patient management, including triaging to the appropriate service following US evaluation.

**Method:** Patients were referred to the MSKUS clinic from Rheumatology, Primary Care (PCCC) Physiotherapists and MSK Triage Physiotherapists. Patients were assessed clinically and then examined with MSKUS by the advanced practice Physiotherapist.

**Results:** Of 261 patients referred, 188 (72%) were from Rheumatology, 55 (21%) were from PCCC Physiotherapists and 18 (7%) were from MSK Triage physiotherapists.

The joint areas referred were: Shoulder 177(68%), foot and ankle 40 (15%), wrist and hand 25 (10%), hip 11 (4%), elbow 5 (2%) and knee 3 (1%).

Background history of the patients included: MSK 154 (59%), inflammatory arthritis 78 (30%) and a query of inflammatory disease 29(11%).

Patients were subsequently referred to the following pathways: Injection by the Physiotherapist and follow up Physiotherapy 104(40%), US guided injection with the Consultant 23(8%), Physiotherapy 50(19%), Orthopaedic Consult 39(15%), consult with the Rheumatologist 66(25%), further investigation 5(0.1%), of which 3 were MRI and 2 CT. 2 patients did not attend.

**Conclusion:** Physiotherapists working in advanced roles with the support of a Rheumatologist can enhance patient management; and reduce the need for MRI which is costly and difficult to access.

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#### Poster Presentation No 7

##### **Differential Diagnosis Algorithm for a Painful, Swollen Knee in the Absence of Trauma**

Patricia Kavanagh (CNS), Dr Barry Sheane, Dr Conor McCarthy

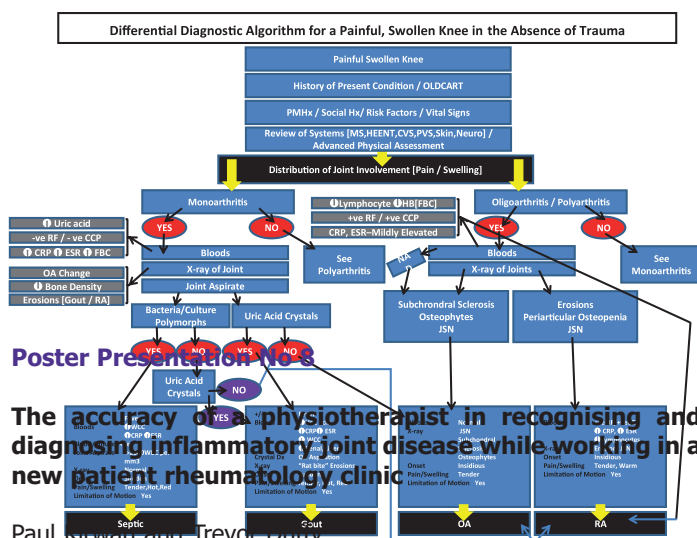
Department of Rheumatology Mater University Hospital

**Aim/Introduction:** Monoarthritis of the knee is a common presentation to a rheumatology clinic. A definitive diagnosis is essential so that treatment can be commenced immediately and improved outcomes achieved. If not diagnosed promptly and if appropriate treatment is not initiated rapidly the condition may be more difficult to treat. Joint pain can be associated with a variety of different conditions and it is necessary to establish if the cause of pain is from within the joint or adjacent soft tissues. In order to correctly diagnose, the exact position of pain and swelling is essential. The aim of the algorithm is to benefit overall practice and to serve as a pathway to stimulate thought processes for the advanced nurse practitioner.

**Method:** Adapting a problem based framework can serve to enhance judgement and advanced decision making in clinical practice. Potentially this algorithm can be utilised in diagnosing other rheumatologic conditions.

**Results:** On designing the algorithm a logical approach has been adopted with all differential diagnosis falling within the remit of rheumatology clinical practice: septic arthritis, gout, osteoarthritis and rheumatoid arthritis in the absence of trauma the four differential diagnoses could present as a monoarthritis.

**Conclusion:** A considered and informed approach has been adopted in reaching as accurate a diagnosis as possible and out ruling possible diagnoses. A problem solving logical approach has been applied. Evidence based practice and clinical experience has contributed to determining a most accurate diagnosis as possible.



Rheumatology Department, Connolly Hospital, Blanchardstown, Dublin 15

**Aim/Introduction:** Physiotherapists working in triage roles are well established in orthopaedic and spinal clinics, but there is less literature available on their role in rheumatology. There is a dearth of research investigating the accuracy of a physiotherapist in diagnosing inflammatory joint conditions. The aim of this audit was to assess the accuracy of a physiotherapist in recognising and diagnosing inflammatory joint disease while working in a new patient rheumatology clinic.

**Method:** Data was collected consecutively on all patients assessed by the Physiotherapist at the Rheumatology New Patient Clinic from December 2010 to June 2013. Patients with a suspected inflammatory diagnosis were assessed and appropriate initial diagnostic tests were ordered. These patients had follow up appointments scheduled with a consultant rheumatologist in order to confirm or refute the initial diagnosis. Medical charts were reviewed to ascertain if the Physiotherapist's initial diagnosis concurred with that of the Consultant Rheumatologist.

**Results:** A total of 210 patients were assessed over the time period. Forty six patients were suspected of having an inflammatory arthritis. Thirty six of the 46 patients (78%) were confirmed by the Rheumatologist as having an inflammatory arthritis, 11% were still pending diagnosis. Eleven percent of the patients were given alternative diagnoses upon review by the Consultant Rheumatologist.

**Conclusion:** The data indicate that a physiotherapist with specialist training in rheumatology can work effectively and safely in a rheumatology new patient clinic. It also highlights the high number of non-inflammatory conditions seen in a rheumatology new patient clinic, confirming the efficacy of a physiotherapist working in this capacity.

#### Poster Presentation No 9

#### 'Reviewing the Impact of a Multi-Disciplinary Group Education Programme for Patients with Fibromyalgia'

Katie McCausland (OT) & Petrina Donohue (PT)

Rehabilitation Dept, Our Lady's Hospital, Navan

**Aim/Introduction:** A MDT group education programme is provided to Fibromyalgia patients from the North-East region in conjunction with pharmacological management. The impact of this programme was reviewed as part of a quality initiative, using the FIQ and Patient Satisfaction Questionnaire.

**Method:** An analysis of the database (n=66) was conducted including percentage of participation in the programme, geographical distribution, severity of FM and patient satisfaction.

**Results:** There was a high level of satisfaction feedback from all group participants but only a proportion of patients had clinically significant improvements in symptoms and QOL. It was found that there was equal participation among the participants between the mid, moderate and severe groups. Among the 'severe' group there were very high levels of self-reported anxiety and depression.

**Conclusion:** The group education format for patients with Fibromyalgia is an efficient use of resources for a busy Rheumatology MDT. However, despite high rates of patient satisfaction, the programme does not always provide clinically significant changes of patient symptoms. A high incidence of depression and anxiety among the patients (as indicated by FIQ Q. 9 & 10) indicates a need for psychological interventions as part of their treatment. There is a need for ongoing review of current practice and evidence-based research to provide an effective and efficient treatment programmes for people with FM.

#### Poster Presentation No 10

#### A Qualitative Exploration of the Impact of Fibromyalgia on Meaningful Occupational Engagement

Claire O'Brien (BSc in Occupational Therapy), Eimear Lyons (MSc Clinical Therapies; BSc Occupational Therapy)

Rheumatology Unit Our Lady's Hospice and Harold's Cross

**Aim/Introduction:** Current literature suggests that living with fibromyalgia can have detrimental effects on participation in daily life and cause disruption to global health status (Campos & Vazquez, 2012; Creek & Hughes, 2008; Sim & Madden, 2008). There is a growing body of qualitative research regarding the consequence of fibromyalgia on overall health and well-being, however there is a paucity of research on the perceived impact of fibromyalgia on occupational participation. This study aims to gain an understanding of the impact that fibromyalgia can have on meaningful occupational engagement.

**Method:** This is a descriptive study based on a qualitative research design. Semi-structured one to one interviews were completed in an in-patient rheumatology service with a group of women (n=6) women living with fibromyalgia. The interviews were audio-recorded and transcribed verbatim by the researcher. Thematic analysis was used to analyse and code the data into prevailing themes.

**Results:** Findings are represented by five main themes:





disruption to daily routine, role change, impact on self-identity, coping methods and future care recommendations. Diminished engagement in valued occupations was evident for all participants.

**Conclusion:** These findings describe the negative effects that fibromyalgia can have on meaningful occupational engagement for affected individuals. This knowledge may lead to an increased understanding among health professionals working with this client group and encourage a holistic approach to practice. These findings also have potential to guide resource allocation, system planning and development of care pathways for this client group.

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#### Poster Presentation No 11

##### **"Working with Arthritis": Study Protocol of a Cohort Study to Determine the Outcomes of an Occupational Therapy Led Vocational Rehabilitation Programme for People with Arthritis**

Eimear Lyons (MSc. Clinical Therapies; BSc. Occupational Therapy),

Dr. Katie Robinson, PhD (Lecturer/ Course Director MSc Occupational Therapy, University of Limerick)

Miriam Noonan (BSc. Occupational Therapy)

Department of Clinical Therapies, University of Limerick

**Aim/Introduction:** Work disability is pervasive among people with arthritis (Bevan *et al* 2009). Vocational Rehabilitation (VR) can reduce work disability and associated economic, social and human costs (Waddell *et al* 2008). Here we report the study design of 'Working with Arthritis: Strategies & Solutions' an OT led VR programme aiming to reduce work disability among people with arthritis.

**Method:** Study design will be a prospective cohort study of working age people with arthritis, in receipt of illness/disability payments, living in the Border, Western and Midland regions of Ireland. The program aims to recruit 250 people with arthritis over a 2 year period. It is designed to overcome the barriers people with arthritis face when accessing, remaining in, or returning to work. Psychosocial, environmental and occupational factors influencing work ability will be identified and evaluated. Data will be collected at three time points; programme commencement, conclusion and at six month follow up.

**Results:** The primary outcomes of the study are work/education participation. Secondary outcomes include symptom experience and quality of living. Economic evaluation of the program will also be completed.

**Conclusion:** Study findings will contribute to the evidence base

for VR programmes and will inform social policy regarding the key determinants of work ability and participation for those with arthritis of working age.

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#### Poster Presentation No 12

##### **The development of a Rheumatology community outreach programme**

Eileen O'Flynn, Miriam Molloy, Oliver FitzGerald

Department of Rheumatology, St. Vincent's University Hospital Dublin

**Aim/Introduction:** The current care pathway for patients with chronic rheumatic disease does not include a reliable system of monitoring efficacy and safety of treatments in primary care settings. Many patients with stable rheumatic disease continue to attend outpatient clinics when with support, they could equally be managed in a primary care setting.

**Method:** A prospective sample of patients was referred to the CNS-led service by a consultant rheumatologist at a point where the patients had stable disease but required ongoing out-patient review to assess efficacy and safety of continued medication. During a twelve month period a total of 464 patients were reviewed by the service. 42% attended SVUH, 24% were reviewed by telephone and 34% were reviewed in the community (Arklow 20%, Newtownmountkennedy 14%).

**Results:** In relation to outcomes 73% had stable disease; 16% required a medical review appointment; 4% required admission to Harold's Cross rheumatology rehabilitation unit; 3% and 4% respectively were referred for physiotherapy and single joint injection. Thus, 80% or 371 patients were reviewed by the CNS-led service, clinical outcome measures obtained, drug safety issues reviewed and repeat prescriptions provided with **no additional outpatient visits required**. Feedback ascertained from 100 patients rated the service very good or excellent.

#### Conclusion:

- 464 patients were reviewed in the community by the CNS-led service over a twelve month period
- It facilitated more timely access for new patients and urgent returns to the rheumatology outpatient clinics.
- New : return ratio fell from 1:7 to 1:4 at outpatients clinics.

#### Poster Presentation No 13

##### **Abatacept at Home, The Sunny South East Experience**

Una Martin, Paula Dreelan, Shane Brennan

Waterford Regional Hospital, VHI Home Care Service

**Aim/Introduction:** A combination of technology and economic



# Improve Strength Reduce Fractures<sup>1</sup>

Protelos is indicated for the treatment of severe osteoporosis in men and postmenopausal women at increased risk of fracture to reduce the risk of vertebral and hip fractures<sup>1</sup>

**1 sachet daily**

\* This medicinal product is subject to additional monitoring. Protelos (strontium ranelate) abbreviated prescribing information. Please refer to the Summary of product Characteristics before prescribing. **COMPOSITION**: Protelos 2 g, sachet of granules for oral suspension containing 2 g strontium ranelate. Contains aspartame as an excipient. **INDICATIONS**: Treatment of severe osteoporosis in postmenopausal women at high risk for fracture to reduce the risk of vertebral and hip fractures. Treatment of severe osteoporosis in adult men at increased risk of fracture. The decision to prescribe strontium ranelate should be based on an assessment of the individual patient's overall risks. **DOSE AND ADMINISTRATION**: The recommended dose is one 2 g sachet orally once daily preferably at bedtime, at least two hours after eating. Due to the nature of the treated disease, strontium ranelate is intended for long-term use. Patients treated with strontium ranelate should receive vitamin D and calcium supplements if dietary intake is inadequate. Treatment should only be initiated by a physician with experience in the treatment of osteoporosis. Elderly (>65): No dosage adjustment is required in relation to the elderly. Patients with hepatic impairment: No dosage adjustment is required in patients with hepatic impairment. **Pediatric Population**: The safety and efficacy of Protelos in children aged below 18 years have not been established. No data are available. **CONTRAINDICATIONS**: Hypersensitivity to the active substance or to any of the excipients; current or previous venous thromboembolic events (VTE), including deep vein thrombosis and pulmonary embolism; temporary or permanent immobilisation due to e.g. post-surgical recovery or prolonged bed rest; established, current or past history of (ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease, uncontrolled hypertension. **WARNINGS**: Patients with renal impairment: No dosage adjustment is required in patients with mild-to-moderate renal impairment (30-70 mL/min creatinine clearance). Strontium ranelate is not recommended in patients with severe renal impairment (creatinine clearance below 30 mL/min). Venous thromboembolism: Protelos is associated with an increased risk for VTE. The cause of this finding is unknown. Protelos is contra-indicated in patients with a past history of VTE and should be used with caution in patients at risk of VTE. When treating patients over 80 years at risk of VTE, the need for continued treatment should be re-evaluated. Strontium ranelate should be discontinued as soon as possible in the event of an illness or a condition leading to immobilisation and adequate preventive measures taken. Therapy should not be restarted until the initiating condition has resolved and the patient fully mobile. When a VTE occurs, strontium ranelate should be stopped. **Cardiac ischaemic events**: In pooled randomised placebo-controlled studies of post-menopausal osteoporotic patients, a significant increase in myocardial infarction has been observed in Protelos treated patients compared to placebo. Before starting treatment and at regular intervals, patients should be evaluated with respect to cardiovascular risk. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with strontium ranelate after careful consideration. Treatment should be stopped if the patient develops ischaemic heart disease, peripheral arterial disease, cerebrovascular disease or if hypertension is uncontrolled. **Skin reactions**: Life-threatening cutaneous reactions (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug rash with eosinophilia and systemic symptoms (DRESS)) have been reported with the use of Protelos. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) (e.g. progressive skin rash often with blisters or mucosal lesions) or Drug rash with eosinophilia and systemic symptoms (DRESS) (e.g. rash, fever, eosinophilia and systemic involvement (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease)). The highest risk for occurrence of SJS or TEN is within the first weeks of treatment and usually around 3-6 weeks for DRESS. If the patient has developed SJS, TEN or DRESS, the treatment must be stopped immediately and not be re-started at any time. A higher incidence, although still rare, of hypersensitivity reactions including skin rash, SJS or TEN in patients of Asian origin has been reported. **Interaction with laboratory test**: Strontium interferes with colorimetric methods for the determination of blood and urinary calcium concentrations. **Excipient**: Protelos contains a source of phenylalanine which could be harmful for people with phenylketonuria. **INTERACTIONS**: Not recommended: oral tetracycline, quinolone antibiotics. Protelos therapy should be temporarily suspended if a patient is on a course of oral quinolone or tetracycline antibiotics as it may hinder their absorption. With precautions: antacids. Administration of strontium ranelate with food, milk and derivative products, and medicinal products containing calcium and antacids may reduce the bioavailability of strontium ranelate, therefore separate administration by at least two hours. **FERTILITY, PREGNANCY and BREASTFEEDING**: Contra-indicated, there are no data from the use of strontium ranelate in pregnant women. Physicochemical data suggest excretion of strontium ranelate in human milk. Protelos should not be used during breast-feeding. No effects were observed on males and females fertility in animal studies. **DRIVE AND USE MACHINES**: No or negligible influence. **UNDESIRABLE EFFECTS**: Overall incidence rates for adverse events with strontium ranelate did not differ from placebo and adverse events were usually mild and transient. Adverse reactions, defined as adverse events considered at least possibly attributable to strontium ranelate treatment in phase III studies are listed below using the following convention (frequencies versus placebo): very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000, <1/100); rare (>1/10,000, <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). Common: headache (3.3% vs. 2.7%), disturbances in consciousness (2.6% vs. 2.1%), memory loss (2.5% vs. 2.0%), myocardial infarction (1.7% vs. 1.1%), venous thromboembolism (2.7% vs. 1.9%), nausea (7.1% vs. 4.6%), diarrhoea (7.0% vs. 5.0%), loose stools, dermatitis (2.3% vs. 2.0%), eczema (1.8% vs. 1.4%), Blood Creatine phosphokinase (CPK) increased (1.4% vs. 0.6%). Uncommon: seizures (0.4% vs. 0.1%). Rare: DRESS. Very rare: Severe cutaneous adverse reactions (SCARs): Stevens-Johnson syndrome and toxic epidermal necrolysis (rare in patients of Asian origin). Frequency unknown: confusional state, insomnia, paraesthesia, dizziness, vertigo, bronchial hyperactivity, vomiting, abdominal pain, oral mucosal irritation (stomatitis and/or mouth ulceration), gastro oesophageal reflux, dyspepsia, constipation, flatulence, dry mouth, hepatitis, hypersensitivity skin reactions (rash, pruritus, urticaria, angioedema), alopecia, musculoskeletal pain (muscle spasm, myalgia, bone pain, arthralgia and pain in extremity), peripheral oedema, malaise, bone marrow failure, in association with hypersensitivity skin reactions: serum transaminase increased, pyrexia, eosinophilia, lymphadenopathy. **OVERDOSE**: **PROPERTIES**: In vitro, strontium ranelate increases bone formation in bone tissue culture as well as osteoblast precursor replication and collagen synthesis in bone cell culture; and reduces bone resorption by decreasing osteoclast differentiation and resorbing activity. This results in a rebalance of bone turnover in favour of bone formation. **PRESENTATION**: Box containing 28 sachets of Protelos 2 g. **LEGAL CATEGORY**: POM. **MARKETING AUTHORISATION NUMBERS AND HOLDER**: EU/1/04/288/001-006, LES LABORATOIRES SERVIER, 50 rue Carnot 92284 Suresnes cedex France, www.servier.com. **DATE OF PREPARATION OR LAST REVIEW**: July 2013. **FULL PRESCRIBING INFORMATION IS AVAILABLE FROM**: Servier Laboratories, Block 2, West Pier Business Campus, Old Dunleavy Road, Dun Laoghaire, Co. Dublin, Tel: (01) 6638110, Fax: (01) 6638120. \*For complete information, please refer to the complete summary of product characteristics. Date of preparation of item: July 2013.

1. Protelos Summary of Product Characteristics





Dr Anne Gilleece, Consultant Microbiologist, Connolly Hospital



Audience in jovial mood



pressures has imposed pressure for health care resources to be delivered in a more timely and proficient manner. Patients can have the choice of home infusion service for delivery of Abatacept. In our experience this service has brought numerous personal benefits to the patient, advantages to the rheumatology department as well as the organisation as a whole.

**Method:** We have availed of the home infusion service to manage our patients since 2008 and to date over 18 patients have availed of the service and 15 of these patients are continue to use the service.

**Results:** Of the 15 patients that are receiving the service, 9 patients are female and 6 male. The average age is 53 with the average female age of 50 and male 60. The age range is between the age of 36 and 82. Thirteen of the 15 patients live outside the county of Waterford 2 of the female patients are engaged in full time employment. The advantages to the patient include minimal disruption to work, family and lifestyle as well as a reduction in the cost of travelling and other associated costs. This service has created increased capacity within our own infusion service to treat other patients in addition to added cost savings to the hospital.

**Conclusion:** A patient satisfaction survey supports the success of the programme. In our experience the success of the programme can be attributed to the collaboration between the nursing staff, selection of appropriate patients and well defined policies and transferable standards of care.

#### Poster Presentation No 14

##### Quality of Life and Juvenile Idiopathic Arthritis (JIA) in Ireland

Dr. Mary O'Hara<sup>1</sup>, Dr. Margaret Hodgins<sup>2</sup>

<sup>1</sup>School of Nursing & Midwifery, National University of Ireland, Galway

<sup>2</sup>Discipline of Health Promotion, National University of Ireland, Galway

**Introduction:** JIA is an autoimmune inflammatory disease diagnosed during childhood before the age of 16 with an incidence of 1 in 10000<sup>1</sup>. Characterized by persistent synovial inflammation which can cause functional impairment, pain and activity limitation; these may affect quality of life. Treatment modalities are not curative and aim to control the inflammatory process. Parents and clinicians discussed the impact of this condition.

**Method:** Fourteen parents of young people aged 12-18 years with JIA and four clinicians from one geographical area in Ireland were interviewed, using semi-structured and in-depth interviewing techniques. The impact of the condition and its treatment; service provision, education and future prospects were considered. Interviews were transcribed verbatim and analyzed.

**Results:** In general terms, parents considered that their young people had a good quality of life. Parental recognition of the practical difficulties that children were encountering and pride in

the efforts of the young people to adapt to difficult situations was a major theme. Service provision and service organization were frequently encountered as problematic. Safety considerations relating to the long-term effects of medications and the transition to adult services were significant parental concerns. Social support and an easily accessible and supportive healthcare team were found to be protective factors for the young people and their families in buffering the impact of juvenile idiopathic arthritis.

**Conclusion:** Person-centred care from the onset of JIA is needed to meet the needs of young people across their lifespan, to optimize their life opportunities and quality of life.

**Reference:** <sup>1</sup>Beresford, M.W. (2011) 'Juvenile idiopathic arthritis, new insight into classification, measures of outcome and pharmacotherapy', *Pediatric Drugs*, 13, (3), pp. 161-173.

#### Poster Presentation No 15

##### Respiratory problems in patients on Etanercept

McKee H. and Whitehead E.

Rheumatology Department, Antrim Hospital

**Aim/Introduction:** Etanercept use is established. Interstitial lung disease is listed as an "uncommon" side effect. We describe four rheumatoids with respiratory problems within six months of commencing etanercept.

**Method:** Information from patients notes.

##### Results:

###### Patient 1

58yr old female non smoker, on leflunomide. 3 months after starting etanercept 50mg weekly, presented with hypoxia sats 86%. CT scan showed ground glass changes predominantly upper lobe and a right lower lobe pulmonary embolus. There was complete resolution after steroids and drug withdrawal.

###### Patient 2

67yr female. Mild asthma, non smoker, on methotrexate 17 years. CXR mild chronic R basal changes. Commenced etanercept 50mg weekly, 6 months later presented with increasing shortness of breath. CT scan showed bilateral patchy infiltrates and profound hypoxia. Improved with prednisolone and drug withdrawal.

###### Patient 3

58yr female, smoker, diabetic, not on methotrexate (intermittently abnormal LFTs). with a history of a previous hospital admission with a chest infection and some R sided basal changes. 3 months after starting etanercept with increasing shortness of breath and hypoxia. Chest x ray showed lung "white out". Symptoms improved with drug withdrawal, steroids and antibiotics.

###### Patient 4

61yo female, smoker. Normal CXR. On methotrexate 15mg weekly. Commenced etanercept 50mg weekly. Presented 9 weeks later with cough and pleuritic pain. Symptoms resolved on drug withdrawal. CT chest showed no acute changes.

**Conclusion:** These patients, all female, presented with acute





respiratory symptoms within 6 months of starting etanercept. None had evidence of TB. All improved with drug withdrawal.

#### Poster Presentation No 16

##### **An evaluation of a home occupational therapy programme for adults with rheumatoid arthritis prescribed Cimzia® within the Irish healthcare system**

Trish Fitzgerald<sup>1</sup> and Oriel Corcoran<sup>2</sup>

<sup>1</sup>Ashfield Healthcare

<sup>2</sup>Dept of Rheumatology, Waterford Regional

**Aim/Introduction:** Given the incidence of rheumatoid arthritis (RA), the evidence for best practice supporting early occupational therapy intervention and the Irish health service advocating accessible services, there is a pressing need for early and accessible occupational therapy services to be available to adults with RA. This evaluation aims to identify the outcomes of a 12 week home occupational therapy programme for adults diagnosed with RA prescribed Cimzia® at 5 designated rheumatology sites.

**Method:** Adults with RA prescribed Cimzia® were referred to the service by a member of their rheumatology team and received three sessions of Occupational Therapy (OT). Data was collected during the initial and at final OT sessions using the following outcome measures; Multi-Dimensional Health Assessment Questionnaire, Arthritis Impact Measurement scale 2 – short form, Joint protection knowledge questionnaire, Grip Strength and Grip Ability Test, Arthritis Self Efficacy Scale Short Version, Canadian Occupational Performance Measure and patient satisfaction questionnaire.

**Results:** Participants (n<sub>21</sub>: 16 women; 6 men). Mean age 50.6 (SD 16.4) years; RA mean duration 6.4 (SD 8.9) years; Mean duration prescribed Cimzia® 4.7 (SD 8.0) months.

There are a further 7 participants currently engaging in the programme and results awaiting analysis.

Preliminary results suggest significant improvement in participant's performance in everyday activities, self-efficacy and knowledge of self-management techniques.

**Conclusion:** This project is due for completion October 2013, thus data analysis is ongoing with a view to determining clinical and statistical significance. This evaluation is important as it is the first Irish home based OT rheumatology programme providing local and early access to OT in areas where rheumatology OT resources are limited in primary care.

#### Poster Presentation No 17

##### **Patient satisfaction of Advanced Practice Physiotherapists (APPs) working in an extended role in Rheumatology and Orthopaedic clinics**

Ashton J\*, Breen R<sup>^</sup>, Callanan E<sup>∞</sup>, FitzGerald O<sup>□</sup>

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Dublin 9

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<sup>∞</sup> Physiotherapy Department, Galway University Hospitals, Galway

<sup>□</sup> Rheumatology dept, St. Vincent's University Hospital, Elm Park, Dublin 4

**Aim:** i) Measure patient satisfaction with the APP assessment in a Rheumatology or Orthopaedic clinic using a standardised tool (VSQ 9) (Kennedy et al 2010).

As part of the Rheumatology and Orthopaedic clinical care programmes, APPs were employed nationally from 2011 as part of a waiting list reduction initiative. Physiotherapists assessed patients previously seen by Consultants therefore it was imperative to evaluate the patient experience. It has previously been shown that patient satisfaction can be reduced if their expectations are not met (Jackson and Kroenke 2001 cited by Kennedy et al 2010).

**Method:** A sample of convenience was recruited of consecutive patients that agreed to complete the questionnaire from January to June 2013 across 10 hospital sites nationally. Questionnaires were anonymously completed post clinic visit and given to the administrative staff to reduce any bias. 340 questionnaires were collected. Questionnaires were collated, inputted and analysed centrally by an independent researcher using Microsoft Excel 2007.

**Results:** Mean scores (95% confidence intervals) are detailed in table 1 and showed that all questions scored over 85/100. In terms of overall satisfaction with the APP assessment, 93% of patients rated it as excellent or very good; there were no poor responses.

**Conclusion:** Overall satisfaction was mostly excellent or very good with all aspects of the patient's visit with the APP. Further analysis is needed to compare satisfaction with Consultants and Physiotherapists.

#### **Reference:**

Kennedy D, Roberts S and Woodhouse L (2010) *Patients are Satisfied with Advanced Practice Physiotherapists in a role traditionally performed by orthopaedic surgeons. Physiother Can; 62: 298- 305*

#### **Table 1: Summary of results for satisfaction questionnaires**



	APP Mean score (95% confidence interval)
Q1 Getting through to the outpatient clinic by phone	86.4 (83.48-89.3289)
Q2 Length of time waiting once you arrived for your appointment	86.4 (83.88-88.92)
Q3 Time spent with the healthcare provider you saw	86.4 (82.57-90.23)
Q4 Answers to your questions	86.4 (82.58-90.22)
Q5 Explanation of the results of the tests	86.4 (82.58-90.22)
Q6 Advice and information about the management of your condition	86.4 (82.74-90.06)
Q7 The technical skills of the healthcare provider you saw	86.4 (82.32-90.48)
Q8 The personal manner of the healthcare provider you saw	86.4 (81.68-91.15)
Q9 The visit overall	86.4 (83.50-91.70)

A.Brennan<sup>1</sup>, G.Kelly<sup>1</sup>, F.MacLeid<sup>1</sup>, E.Barker<sup>1</sup>, E.McGrane<sup>2</sup>, R.Mullan<sup>4</sup>, D.Moore<sup>3</sup>, D.Kane<sup>4</sup>.

Departments of Physiotherapy<sup>1</sup>, Orthopaedics<sup>3</sup>, Rheumatology<sup>4</sup> Adelaide and Meath incorporating the National Children's Hospital, Tallaght, Dublin 24

Department of Physiotherapy<sup>2</sup>, Naas General Hospital, Co. Kildare

**Introduction/Aim:** In 2012, three Extended Scope Physiotherapists (ESP) were appointed, through the Clinical Strategy and Programmes Directorate of the HSE, to provide orthopaedic and rheumatology triage services in Naas General Hospital (NGH) and Tallaght Hospital (TH). The aims were to reduce the waiting time for outpatient consultation for orthopaedic and rheumatology patients. To establish a diagnosis and triage patients along the most appropriate care pathway according to their diagnosis.

**Method:** Suitability Criteria for inclusion for triage services were established and agreed. Separate orthopaedic and rheumatology triage waiting lists were established. All triage clinics ran alongside consultant clinics which offered a one stop shop for patients, support with clinical diagnosis and with the ordering of investigations and with management of patients as appropriate. Patients were assessed by the ESP and if required by the Orthopaedic or Rheumatology Consultants or Registrars on the day.

**Results:** From January to December 2013 1753 patients were seen by ESP's in the Musculoskeletal Triage Service between NGH and TH. Of this 1287 (73%) patients were assessed and discharged at their clinic visit; 367 (21%) patients required medical input on the day of their clinic visit; 142 (8%) patients required a return visit to the ESP clinic and 347 (20%) patients required a return visit at either the medical orthopaedic or rheumatology clinics.

**Conclusion:** Appropriately trained and supported ESP's can assist in the management of both Orthopaedic and Rheumatology waiting lists. Further investigation is required to ensure that

patients at these clinics are appropriately managed according to best practice guidelines.

## Poster Presentation No 19

### An Investigation into the Use and Benefit of Permanent Custom Made Orthotics Prescribed by Physiotherapists - A Pilot Study

A. Brennan, G. Kelly

Department of Physiotherapy<sup>1</sup>, Tallaght Hospital, Tallaght, Dublin 24

**Aim/Introduction:** In Tallaght Hospital Physiotherapy Department, permanent custom made orthotics (PCMO) are provided to patients for biomechanical anomalies. For patients with Medical cards, these are funded by the General Medical Card Scheme (GMS). The aim of this study was to investigate the use and benefit of PCMO in patients who received their PCMO through GMS funding.

**Method:** A questionnaire regarding the use and benefit of PCMO was devised by two Physiotherapists. In February 2013, thirty-eight questionnaires were sent to a sample of patients who had received PCMO funded by the GMS between January 2010 and December 2012. Patients were asked to complete the questionnaire anonymously and return to the Physiotherapy Department, via stamped addressed envelopes provided.

**Results:** Seventeen completed questionnaires were returned (response rate 45%). Seventy-six percent (n=13) reported wearing their PCMO full time. The reasons outlined for not wearing the PCMO full time were; that they did not fit in their footwear (18%; n=3) and that they were not helpful (6%; n=1). Seventy-six percent of respondents (n=13) reported that the PCMO prescribed provided full resolution of their symptoms. Maximum benefit of PCMO was observed to be between 0-6 months in 35% (n=6) and >6 months in 12% (n=2) of respondents.

**Conclusion:** PCMO prescribed by Physiotherapists provide benefit to patients with biomechanical anomalies. It may be important to review patients following provision of funded PCMO to ensure cost effectiveness of this funding. This pilot has shown that it may be necessary to provide a service to review patients 6 months following receiving their PCMO.

## Poster Presentation No 20

### A pilot of a new Fibromyalgia Physiotherapy Management Pathway in Tallaght Hospital

Sarah O'Driscoll

Physiotherapy Department, Tallaght Hospital, Tallaght, D24





**Aim/Introduction:** A standardised Fibromyalgia Physiotherapy Management Pathway (FPMP) was introduced in Tallaght Hospital in October 2012. The aim of the pathway was to: streamline care of FMS patients in line with EULAR guidelines (EULAR, 2007), improve patient education and self management.

**Method:** In October 2012, all FMS patients referred to Tallaght Hospital physiotherapy department were assessed. Outcome measures including Fibromyalgia Impact Questionnaire (FIQ) and a timed repeated sit-stand test were taken. Following assessment, patients were enrolled into the FPMP. This included an education class and 6 week course of hydrotherapy. The class included information on FMS, exercise management, pacing, exercise diaries, sleep and stress management and stretching exercises. Following the FPMP, outcome measures were retaken and patients completed a satisfaction questionnaire.

**Results:** Forty patients were referred to the FPMP from October 2012 to June 2013 (female 39, male 1). Thirty patients (75%) attended the education class. Fourteen patients completed satisfaction questionnaires (35%) and 11 (28%) completed all outcome measures. All outcome measures improved post attendance of FPMP (average FIQ: pre 1.48, post: 1.1, average sit to stand pre: 19.4 seconds, post: 14.29 seconds). Patient satisfaction scores (n=14) revealed 100% of patients rated the FMS education class as good/excellent. Ninety-three percent (n=13) reported they were very satisfied with the amount of help received.

**Conclusion:** The FPMP streamlined patient care in line with EULAR 2007 guidelines. It showed positive changes re FIQ, sit to stand tests and patient satisfaction. Further research is necessary with a large profile of patients.

#### Poster Presentation No 21

##### **Pregnancy and Inflammatory arthritis: A descriptive study of clinical practice and patient experience related to medication management and care**

Louise Moore<sup>1</sup>, Patricia Minnock<sup>1</sup>, Joan Lalor<sup>2</sup>, Douglas Veale<sup>3</sup>

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<sup>2</sup>School of Nursing and Midwifery, Trinity College Dublin, Dublin 2

<sup>3</sup>St Vincent's University Hospital, Elm Park, Dublin 4

**Aim:** To investigate approaches to prescribing practice and care, from the perspective of both rheumatology clinicians and female patients who had a pregnancy wish or a pregnancy within the last five years.

**Method:** A questionnaire (adapted with permission) was employed to collect data from members of the Irish Society of Rheumatology and Irish Rheumatology Nursing Forum (n = 114). In addition six interviews were undertaken with women who had received care in rheumatology clinics to explore their experience of the clinicians' response to their health care needs in relation to medication management and overall care whilst pregnant.

**Results:** A response rate of 62% (n = 71) was achieved. Variations existed with prescribing practice and advice with

respect to synthetic DMARDs (excluding methotrexate and leflunomide) and all biological DMARDs most notably in the pre-conception phase. Ninety per cent (n = 62) were in favour of a national register to record pregnancy outcomes for women with inflammatory arthritis. The main theme that emerged from the qualitative enquiry was that women need support, knowledge and education on the potential impact of their arthritis on their pregnancy and on medication management during all stages of pregnancy from all clinicians involved in their care.

**Conclusion:** Findings confirm a discrepancy between knowledge of prescribing recommendations among clinicians. This led to dissatisfaction among women with the care clinicians offered. The findings from this research process will be utilised to develop a specific care pathway for patients during all stages of pregnancy incorporating support, medication and disease management and health promotion.



Prof Viet van Riel, University Medical Centre Nijmegen



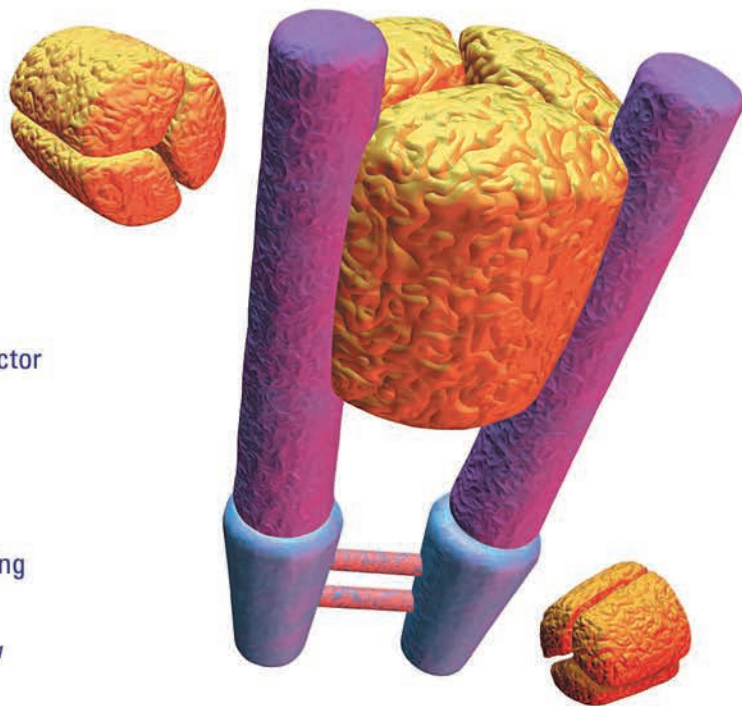
Dr Etaoin Kent, Rotunda Hospital/RCSI



Mr Andrew McCann, Citizens Information Centre, Swords



# ENBREL is Different



## A unique mechanism of action

- Enbrel is the only fully human soluble tumour necrosis factor (TNF) receptor<sup>1,2,3,4,5,6</sup>
- It works differently than MAB's<sup>1</sup>

## No neutralising antibodies<sup>1</sup>

- Enbrel is not associated with the production of neutralising antibodies in humans

## Enbrel has a short half life (<3 days)<sup>1</sup>

- The half-life of anti-TNF agents should be taken into account if a treatment break is required

## Efficacy

- Registry data and Cochrane Review data support efficacy & safety of Enbrel<sup>7,8</sup>



**ABBREVIATED PRESCRIBING INFORMATION** Before prescribing Enbrel® please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC®): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthritides (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. **Children aged 6-17 years:** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. **Adults:** RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS and PsA – 25 mg twice weekly or 50 mg once weekly. **Children aged 2-17 years:** JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the

Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients identified as carriers of hepatitis B virus and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy < 18 years of age) in the postmarketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life threatening infections and sepsis.

Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) has also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. **Legal Category:** POM. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **S1B:** Product subject to a prescription which may be renewed. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. For full prescribing information see the Summary of Product Characteristics. 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. **API Reference Number:** EN 6\_1. **Date of Prescribing Information:** December 2012

**References:** 1. Enbrel SPC July 2010 2. Remicade SPC 3. Humira SPC 4. Orencia SPC 5. Mabthera SPC 6. Simponi SPC 7. Singh J et al. CMAJ: 2009;DOI:10.1503 8. Hetland ML et al. Arthritis & Rheumatism. Vol 62, no 1, January 2010.

Date of preparation: April, 2013  
ENB/2013/085/1

**Pfizer** Specialty Care





IN DMARD-IR AND TNF-IR RA PATIENTS,  
WHEN COMBINATION WITH MTX IS NOT AN OPTION...

THINK  
ROACTEMRA<sup>1</sup>

**RoACTEMRA<sup>®</sup>**  
tocilizumab

RoACTEMRA, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.<sup>2</sup>

**ABRIDGED PRESCRIBING INFORMATION.** (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). RoActemra<sup>®</sup> (tocilizumab) 20mg/ml Concentrate for Solution for Infusion.

**Indications:** (i) In combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoActemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate. (ii) As monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX, for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients  $\geq 2$  years of age, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. **Dosage and Administration:** Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA or sJIA and all patients should be given the Patient Alert Card. **RA Patients:** Recommended posology is 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by iv infusion over 1 hour. For patients weighing  $> 100$ kg, doses  $> 800$ mg per infusion are not recommended. No data on doses above 1.2g. **Dose adjustments:** Dose modification, interruption or in some cases discontinuation of RoActemra recommended in the event of raised liver enzymes, low absolute neutrophil count (ANC) or low platelet count (see SmPC for details). In patients not previously treated with RoActemra, initiation not recommended in patients with an ANC below  $2 \times 10^9/l$ . Closely monitor renal function in patients with moderate to severe renal impairment as RoActemra has not been studied in these patients. No data in patients with hepatic impairment. **sJIA Patients:** No data in patients  $< 2$  years of age. **Posology:** 8mg/kg diluted to a final volume of 100ml for patients  $\geq 30$ kg or 12mg/kg diluted to a final volume of 50ml for patients  $< 30$ kg once every 2 weeks by iv infusion over 1 hour. Check patient's weight at each visit – refer to SmPC. In the event of raised liver enzymes, low ANC or low platelet count, interrupt/discontinue RoActemra dose or modify/stop concomitant MTX and other medications where appropriate – see SmPC for details. Reduction of RoActemra dose due to laboratory abnormalities not studied in sJIA patients. Clinical improvement is generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement is seen in this timeframe. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings and Precautions:** Serious (sometimes fatal) infections reported in patients receiving immunosuppressive agents including RoActemra. Do not initiate in patients with active infection. If serious infection develops interrupt therapy until infection controlled. Caution in patients with history of recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which may predispose patients to infection. Vigilance for the timely detection of serious infection recommended. Advise all patients and parents/guardians of sJIA patients to contact their healthcare professional immediately when symptoms suggestive of an infection appear. Screen for latent TB prior to starting therapy. Treat latent TB with standard anti-mycobacterial therapy before initiating RoActemra. Risk of false negative tuberculin skin and interferon-gamma TB blood test results, especially in severely ill/immunocompromised patients. Advise patients to seek medical attention if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever) suggestive of TB infection occur during or after treatment with RoActemra. Viral reactivation (e.g. hepatitis B) reported with biologic therapies for RA. Patients screening positive for hepatitis excluded from clinical trials. Events of diverticular perforations as complications of diverticulitis reported uncommonly with RoActemra in RA patients. Exercise caution in patients with a history of intestinal ulceration or diverticulitis. Evaluate patients with symptoms of complicated diverticulitis promptly. Serious hypersensitivity reactions reported – may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous infusions even if they have received premedication with steroids and anti-histamines. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, stop administration of RoActemra immediately and discontinue therapy permanently. Use with caution in patients with active hepatic disease or hepatic impairment. Not recommended in patients with baseline ALT or AST  $> 5 \times$  ULN; use with caution in patients with ALT or AST  $> 1.5 \times$  ULN. Monitor ALT and AST levels for RA and sJIA patients according to SmPC – other liver function tests including bilirubin should be considered where indicated. If raised, follow dosage recommendations in SmPC for RA and sJIA patients. Risk of neutropenia may be increased in patients previously treated with a TNF antagonist. Continued therapy not recommended in patients who develop an ANC  $< 0.5 \times 10^9/l$  or platelet count  $< 50 \times 10^9/l$ . In patients not previously treated with RoActemra, initiation not recommended where ANC is below  $2 \times 10^9/l$ . Caution in patients with low platelet count; monitor neutrophils and platelets in RA and sJIA patients according to SmPC. If reduced, follow dosage recommendations in SmPC for RA and sJIA patients. Elevations in lipid parameters seen – refer to SmPC. Assess lipid parameters according to SmPC if elevated, manage patients according to local guidelines for hyperlipidaemia. Potential for central demyelination with RoActemra currently unknown; physicians should be vigilant for symptoms of new onset disease. Immunosuppressive medicines may increase malignancy risk in RA patients. Do not give live and live attenuated vaccines concurrently with RoActemra as safety not established – refer to SmPC for further details on immunisations. RA patients should have CV risk factors managed as part of usual standard of care. Not recommended for use with other biological agents. Macrophage activation syndrome (MAS) is a serious life-threatening disorder that may develop in sJIA patients – RoActemra has not been studied in patients during an active MAS episode. Advise patients experiencing dizziness not to drive or use machines until dizziness resolved. Product contains 26.55mg sodium per 1200mg. **Drug Interactions:** In RA patients, levels of simvastatin (CYP3A4) were decreased by 57% one week following a single dose of tocilizumab to levels similar to or slightly higher than those observed in healthy subjects. Monitor patients taking medicines which are individually adjusted and metabolised via CYP3A4 (e.g. 1A2 or 2C9) when starting or stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. The effect of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy. Refer to SmPC for further details on the effects of RoActemra on cytochrome CYP450 and drug interactions generally. **Fertility, Pregnancy and Lactation:** No adequate data from use in pregnant women. Animal study showed an increased risk of spontaneous abortion/embryo-foetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. Women of childbearing potential should use effective contraception during and up to 3 months after treatment. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Side Effects and Adverse Reactions:** RA: ADRs occurring in patients with RA receiving tocilizumab as monotherapy or in combination with MTX or other DMARDs: Very Common ( $\geq 1/10$ ): upper respiratory tract infections and hypercholesterolaemia. Common ( $\geq 1/100$  –  $< 1/10$ ): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. sJIA: In general, the ADRs were similar to those seen in RA patients. Infections – Serious infections of varicella and otitis media reported, in addition to infections for RA. Infusion reactions – Hypersensitivity reactions requiring treatment discontinuation occurred in  $< 1\%$  of patients. Other events occurring within 24 hours of infusion in 16% of patients included, but were not limited to rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. IgG – decreased levels during therapy. Other – decreases in neutrophil and platelet counts, hepatic transaminase elevations, lipid parameter increases and anti-tocilizumab antibodies observed. **Serious or Potentially Serious:** active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), gastrointestinal perforations (as complications of diverticulitis), serious hypersensitivity reactions. Refer to SmPC for a complete listing of adverse events for RA and sJIA. **Legal Category:** Limited to sale and supply on prescription only. **Presentations and Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Sharn Hall, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4697000. Fax: (01) 4697091. **Date of Preparation:** January 2013. p17.01/13. Copyright © 2013 by Roche Products (Ireland) Ltd. All rights reserved. **References:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. *Int J Clin Rheumatol*. (2012) 7(1): 9-19. 2. SmPC. RoActemra (tocilizumab) Summary of Product Characteristics, 13 December 2012.

