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Irish Society for Rheumatology

Autumn Meeting 2018

19-21 September 2018
Killashee Hotel
Naas, Co. Kildare

Bristol-Myers Squibb janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson ucb

Transforming lives[1]

- The 1st approved **anti-TNF in RA**[2-7]
- Over **5 million** patient years of collective clinical experience[8]
- More than **400 trials** and over **7,000 publications**† [9,10]

CELEBRATING 18 YEARS with Enbrel[1]

Enbrel® etanercept
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 25mg and 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains either 25mg or 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. Non-radiographic axial spondyloarthritis (nr-axSpA).Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). ***Children aged 2-17 years:*** Juvenile idiopathic arthritis (JIA). Polyarthritis (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, nr-axSpA 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:** In order to improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded (or stated) in the patient file. 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 (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known preexisting cardiovascular disease, including patients under 50 years of age. 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 previously infected with hepatitis B 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 post marketing 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 lifethreatening infections and bacterial 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, elevated liver enzymes, worsening of CHF, rare reports of tuberculosis, opportunistic infections, anaemia, leucopoenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, interstitial lung disease, and very rare reports of: toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely 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 I 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. See section 4.8 of the SmPC for how to report adverse reactions. **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 either 25mg or 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 prefilled 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) 25 mg: EU/1/99/126/023 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. **Legal Category:** S1A **European Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. **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 13_0
Pfleet number: 2018-0039445
Date of Prescribing Information: July 2018
† Across all approved indications

References:
1. Scott LJ. Drugs. 2014;74:1379-1410. **2.** Enbrel Summary of Product Characteristics. **3.** Humira Summary of Product Characteristics. **4.** Remicade Summary of Product Characteristics. **5.** Cimzia Summary of Product Characteristics. **6.** Simponi Summary of Product Characteristics. **7.** Remicade EMA report **8.** Data on File, February 2016. **9.** www.clinicaltrials.gov Date accessed: February 2018 **10.** www.ncbi.nlm.nih.gov/pubmed. Date accessed: February 2018

PP-ENB-IRL-0217 **Date of preparation**: August 2018

Welcome Message from the ISR President Dr Sinéad Harney

Dear Colleagues and Friends

It gives me great pleasure to welcome you to Killashee Castle for the 2018 ISR Autumn meeting. I hope you will enjoy the educational experience and of course the social aspect too. I am very grateful to Dr John Ryan and Dr Grainne Murphy who along with myself put together what we hope will be a varied and interesting programme.

We are covering genetics and genomics, metabolic aspects of psoriatic arthritis, early detection of psoriatic arthritis, mechanical stress and effects on MRI and the care of patients pre and peripartum. We hope too to delve into some aspects of compiling a business case. We are also excited about the lecture on the role of the re-programmed Krebs cycle in the therapeutics of inflammatory disease.

We would like to thank our guest speakers for taking the time to travel here to deliver their lectures – this includes Prof J Gulcher, Prof I Giles, Prof T Jones, Prof Lihi Eder and Prof L O'Neill. We are also grateful to Prof P Nash for delivering the satellite symposium on Thursday evening. We would like to thank all of our scientific and clinical presenters.

I would also like to invite everyone to attend the early morning meeting on private practice. As always Michael Dineen, Marie Caston and colleagues have worked tirelessly behind the scenes to organise this meeting – we thank them for that.

We also extend our gratitude to all of our colleagues who corrected abstracts, reviewed the patient grant scheme and submissions for this meetings.

Lastly, I would like to thank our colleagues in the pharmaceutical industry who continue to support the ISR and individual departments around Ireland

In my new role as ISR President my main aim is to keep our speciality relevant within the HSE and government and also to re-emphasise some of the complexities of conditions we treat which may get overlooked. Additionally the multi-disciplinary nature of our speciality means that our close relationships with nursing, physiotherapy and occupational therapy which have been developed over many years should be a model for the HSE to embrace meaningfully. Lastly, the lack of proper infrastructure within many departments needs to be highlighted and rectified as a priority.

Enjoy the meeting

Dr Sinéad Harney
ISR President

Proud of our Heritage...

Remicade®
INFLIXIMAB

Guaranteed Irish
All together better

...Committed to our future

Remicade® 100mg Powder for Concentrate for Solution for Infusion (infliximab)
ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing. PRESENTATION Powder for concentrate for solution for infusion. **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. *Psoriatic Arthritis (PsA):* 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:* 5mg/kg given as an intravenous infusion followed by an additional 5mg/kg infusion 2 weeks after the first infusion. If a patient does not response after 2 doses, no additional treatment should be given. *Adult, fistulising, active CD:* 5mg/kg intravenous infusion followed by additional 5mg/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:* 5mg/kg given as an intravenous infusion followed by additional 5mg/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:* 5mg/kg given as an intravenous infusion followed by additional 5mg/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:* 5mg/kg given as an intravenous infusion period followed by additional 5mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. *PsO:* 5mg/kg given as an intravenous infusion followed by additional 5mg/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 in CD and RA 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. 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 following disease flare, 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, use of a re-induction regimen is not recommended. 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. **CONTRAINDICATIONS** 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** *Infusion 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 infusion 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 TNFα 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:* 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:* The concurrent administration of live vaccines with Remicade is not recommended. Prior to initiating Remicade therapy, it is recommended that paediatric patients be brought up to date with all vaccinations. Administration of live vaccines (e.g. BCG vaccine) to infants exposed to infliximab in utero is not recommended for at least 6 months after birth. *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-TNFα 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. Postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. Most 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 at increased risk for, or with a prior history of dysplasia or colon carcinoma 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. In women, cervical cancer has been reported, periodic screening should continue in women treated with Remicade, including those over 60 years of age. *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. **Overdose:** No case of overdose has been reported. Single doses up to 20mg/kg have been administered without toxic effects. **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. **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 at least 6 months after birth. 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, hypotension, 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.*** **PACKAGE QUANTITIES** 1 vial of 100mg of infliximab. **Legal Category:** POM. **Marketing Authorisation Number:** EU/1/99/116/001. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Date of Revision:** June 2016. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin D18X5K7 or from www.medicines.ie. Date of preparation: February 2018. Remicade/PI-IRE/06-16.

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

MSD
Red Oak North, South County Business Park,
Leopardstown, Dublin D18X5K7 Ireland

RHEU-1145323-0001

ISR Autumn Meeting

19-21 September, Killashee Hotel, Co. Kildare

Programme

Wednesday, 19 September

19.30 **MSD Satellite Meeting**
Dr Anthony O'Connor,
Prof Trevor Duffy and Dr Derek Richards
"Identifying and Managing mental health symptoms in patients with chronic disease"

Thursday, 20 September

08.00-09.30 **Registration - Coffee 09.30**

08.00-09.00 **CAG Meeting for Consultant Members**

09.00-09.30 **Private Practice Meeting**

09.45 **Welcome Address by ISR President: Dr Sinead Harney**

09.50-11.00 **Oral Abstract – 4 Clinical, 4 Scientific**

11.00-11.30 **Coffee, Poster Viewing and Visit the Industry**

11.30-12.00 **RPIF Winner presentations (5 x 5 minute presentations)**

12.00-12.45 **Prof Dirk Elewaut**
Consultant Rheumatologist,
Ghent University, Belgium.
"The Gut in Spondyloarthritis vs the Joint in Inflammatory Bowel Disease: Two sides of the same Coin?"

12.45-13.45 **Lunch, Poster Viewing and Visit the Industry**

13.45-14.30 **Dr Ian Giles**
Consultant Rheumatologist,
University College Hospital, London.
"Optimising the management of women of child bearing potential living with rheumatic disease"

14.30-15.00 **Dr Tim Jones**
Associate Lecturer at Oxford Brookes University UK
"Building a business case for funding"

15.00-15.15 **Bernard Connor Medal Award**

15.15-16.00 **Prof Luke O'Neill**
Professor of Biochemistry in the School of Biochemistry and Immunology at Trinity College Dublin.
"Krebs Cycle reprogrammed for cytokines: new therapeutic options for inflammatory diseases?"

16.00 **Meeting Concludes**

16.05-16.55 **ISR AGM**

17.00-18.00 **Novartis Satellite Meeting**
Professor Peter Nash,
University of Queensland, Australia
"Developments in Management of Psoriatic Arthritis"

20.00 **Conference Dinner**

Friday, 21 September

08.00-09.00 **AbbVie Satellite Meeting**
Dr Lihi Eder
Assistant Professor of Medicine,
University of Toronto, Canada
"From psoriasis to psoriatic arthritis – Can we improve early detection?"

09.15-10.15 **4 Clinical Cases – Audience Participation**

10.15-11.00 **Dr Jeff Gulcher**
Neurologist, Chief Scientific Officer for WuXi NextCODE, Co-Founder of GMI
"Role of Genetics in Health Care"

11.00-11.30 **Coffee, Poster Viewing and Visit the Industry**

11.30-11.50 **Young Investigator Award**

11.50-12.30 **Dr Lihi Eder**
Assistant Professor of Medicine,
University of Toronto, Canada.
"Cardio-metabolic diseases in PsA".

12.30-12.45 **Best Five Poster Presentations (3 minutes each)**

12.45-13.00 **Award Ceremony**

13.00 **Close of Meeting**

FIGHT BACK FOR RA PATIENTS
WITH POOR PROGNOSTIC FACTORS

ACPA-positive RA patients tend to have a more aggressive disease course resulting in swollen joints and bone erosion, which can lead to a poorer quality of life.[1,2]

ORENCIA is the only licensed biologic that acts early in the inflammation cascade with a unique mode of action, specifically targeting T-cell activation which deactivates B-cells, reducing ACPA levels.[3–5]

ORENCIA (in combination with methotrexate) has a proven clinical response with greater DAS reduction in high ACPA-positive vs. low ACPA-positive patients.[6]

Early treatment with ORENCIA (in moderate to severe RA patients) effectively reduces bone erosion and pain, and improves daily function in ACPA-positive patients with poor prognostic factors, whilst maintaining an established safety profile.[7-11]

ORENCIA® (abatacept)
CLICKJECT®
PRE-FILLED PEN

ORENCIA, in combination with methotrexate, is indicated for:

- **The treatment of moderate to severe active RA in adult patients who responded inadequately to previous therapy with one or more DMARDs including MTX or a TNF-alpha inhibitor**
- **The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with MTX**

Consider ORENCIA as your first choice biologic for adult RA patients with poor prognostic factors

Bristol-Myers Squibb

July 2018 427IE1804122-01

ORENCIA® (abatacept)
PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing and for full information on the medicinal product

PRESENTATION: 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial; each ml contains 25 mg of abatacept, after reconstitution. 125 mg pre-filled syringe and ClickJect pre-filled pen, for SC injection; each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.
INDICATION: Rheumatoid arthritis (RA) (IV infusion, SC pre-filled syringe and pen):
Orencia, in combination with methotrexate, is indicated for:
- The treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor.
- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.

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. ***Psoriatic Arthritis ((PsA) IV infusion, SC pre-filled syringe and pen)***: Orencia alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required. ***Polyarticular Juvenile Idiopathic Arthritis (pJIA) {IV infusion only}***: Orencia in combination with methotrexate 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. **DOSAGE:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA or PsA. Orencia 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 to ≥ 100 kg: 750 mg (3 vials). Patients weighing > 100kg: 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 75 kg 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, Orencia IV 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. Orencia 125 mg solution for injection (SC *pre-filled syringe and pen*) *Adults and elderly*: Orencia SC may be initiated with or ithout an IV loading dose. Orencia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. *Children:* The safety and efficacy of Orencia SC in children below 18 years of age have not been established. 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. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orencia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactic reaction. *Infections:* Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orencia 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 Orencia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orencia. Co-administration of Orencia 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). Orencia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. *Malignancies:* The potential role of Orencia in the development of malignancies is unknown. However periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. *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 Orencia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orencia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orencia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Abatacept may cross the placenta into the serum of infants born to women treated with abatacept during pregnancy. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to infants exposed to abatacept in utero is not recommended for 14 weeks following the mother's last exposure to abatacept during pregnancy. 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 clinical trials and post-marketing experience, the following adverse drug reactions were reported. *Very Common (≥ 1/10)*: upper respiratory tract infection including tracheitis, nasopharyngitis, sinusitis. *Common (≥ 1/100 to < 1/10)*: Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), pneumonia, influenza, headache, dizziness, hypertension blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), fatigue, asthenia, local injection site reactions*, systemic injection reactions* (e.g. pruritus, throat tightness, dyspnea) *Uncommon (≥ 1/1,000 to < 1/100)*: Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, rhinitis, ear infection, basal cell carcinoma, skin papilloma, thrombocytopenia, leukopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, paraesthesia, conjunctivitis, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, blood pressure decreased, hot flush, flushing, vasculitis, chronic obstructive pulmonary disease exacerbated, bronchospasm, wheezing, dyspnea, throat tightness, gastritis, increased tendency to bruise, dry skin, alopecia, pruritus, urticaria, psoriasis, acne, erythema, hyperhidosis, arthralgia, pain in extremity, amenorrhea, menorrhagia, influenza like illness, weight increased. *Rare (≥ 1/10,000 to < 1/1,000)*: Tuberculosis, bacteraemia, gastrointestinal infection, pelvic inflammatory disease, lymphoma, lung neoplasm malignant, squamous cell carcinoma. *Orencia SC, see SmPC for information on other undesirable effects.
LEGAL CATEGORY: POM
MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE [*UK only*]: Orencia 250 mg concentrate for solution for infusion
- EU/1/07/389/001, 1 vial pack: £302.40
Orencia 125 mg solution for Injection (pre-filled syringe)-EU/1/07/389/008 and ClickJect pre-filled pen - EU/1/07/389/011,
4 pre-filled syringes with needle guard: £1209.60
4 pre-filled pens: £1209.60
MARKETING AUTHORISATION HOLDER:
Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.
Tel: 0800-731-1736
LOCAL REPRESENTATIVE IN UK:
Bristol-Myers Squibb Pharmaceuticals Limited, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.
Tel: 0800-731-1736
LOCAL REPRESENTATIVE IN IRELAND:
Bristol-Myers Squibb Pharmaceuticals uc, Plaza 254, Blanchardstown Corporate Park 2, Ballycoolin, Dublin, D15 T867, Ireland. Tel: 01 483 3625
DATE OF LAST REVISION: July 2017
ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Adverse events should be reported. Reporting forms and information can be found at: UK - www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store; Ireland - Freepost HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. Adverse events should also be reported to Bristol-Myers Squibb via medical.information @bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland).

REFERENCES: 1. van der Helm-van Mil et al, Ann Rheum Dis 2005;64:1744–9 **2.** Fleischmann R et al, Presented at ACR/ARHP 2013; Poster 424 **3.** ORENCIA® (abatacept) Summary of Product Characteristics **4.** Choy E et al, Clin Exp Rheumatol 2009;27:510–8 **5.** Scarsi M et al, J Rheumatol 2014;41:666–72 **6.** Sokolove J et al. Ann Rheum Dis 2016;75:709–14 **7.** Smolen JS et al, Ann Rheum Dis 2014;17:492–509 **8.** Schiff M et al, Ann Rheum Dis 2014;73:86-94 **9.** Fleischmann R et al, Arthritis Care Res 2016;68:907–13 **10.** Weinblatt ME et al, Arthritis Rheum 2013;65:28–38 **11.** Data on File

ABBREVIATIONS: ACPA, Anti-Citrullinated Protein Antibodies; DAS, Disease Activity Score; DMARD, Disease Modifying Anti-Rheumatic Drugs; MTX, methotrexate; RA, Rheumatoid Arthritis; TNF, Tumour Necrosis Factor.

February 2018
427IE1800443-01

Programme for IRHPS Autumn Meeting & AGM

September 20th & 21st 2018,
Killashee Hotel, Naas, Co. Kildare

Thursday 20th September 2018

08.00-9.30	**Registration / Meet the industry**
09.45	**ISR Programme**
10.30	**IRHPS Programme** Chairs: **Rhona Galway & Trish Fitzgerald**
10.30- 10.35	Welcome by **IRHPS Chairperson; Trish Fitzgerald**
10.35 – 11.05	**Oral Presentation 1:** ***Uptake of influenza vaccination in patients on immunosuppressant agents for rheumatological disease attending nurse-led review appointments.*** **Geraldine Byrne,** Rheumatology CNS Northwestern Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim.
11.00 – 11.35	**Oral Presentations 2:** ***"Addressing Employment": A Profile of the Demographics and Work- Related Status of Working-Aged Clients Referred to Rheumatology*** Occupational Therapy Services in Ireland. **Yvonne Codd,** Senior Occupational Therapist (Rheumatology) & PhD Researcher, Naas General Hospital , Naas, Co. Kildare and Discipline of Occupational Therapy, Trinity College Dublin.
11.35-12.00	***"Bridges self-management - The secrets of working with not for Patients"*** **Romayne Orr** – Advance Clinical OT, South Eastern Trust, Belfast, United Kingdom.
12.00-12.45	**ISR Programme**
12.45-13.30	**Lunch / Poster viewing / Meet the industry**
13. 30- 16.15	**Keynote Speakers:** **IRHPS Programme** Chairs: Derek Deely, Una Martin
13.30-14.15	***"Adolescent Rheumatology Care"*** **Dr. Valerie Rogers**, Consultant Rheumatologist, University Hospitals Bristol, NHS Foundation Trust.
14.15-15.05	***"An Integrated Therapy Approach to Managing Chronic Pain in Adolescent Rheumatology Patient"*** **Edel Carberry,** Senior Paediatric Physiotherapist in Rheumatology, Our Lady's Hospital Crumlin, Dublin **Rosalind Peart,** Senior Paediatric Occupational Therapist, Our Lady's Hospital, Crumlin, Dublin
15.05-16.00	**ISR Programme**
16.00	**IRHPS AGM**
20.00	**Gala Dinner**


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Date of Preparation: February 2018
IREABV180069

Biographical Sketches

Speakers

Prof Dirk Elewaut
Consultant Rheumatologist,
Ghent University, Belgium.

Dirk Elewaut is a full professor of rheumatology and immunology and Chair of the Department of Rheumatology at Ghent University Hospital, a EULAR and FOCIS center of excellence. He obtained his MD at Ghent University in 1991 and his PhD in 1997 at the same institution. Following postdoctoral research at the University of California San Diego and the La Jolla Institute for Allergy and Immunology he joined the faculty of the Department of Rheumatology at Ghent University Hospital in 2001. He has published more than 230 scientific publications, and is heading a team of 20 researchers of the Laboratory of Molecular Immunology and Inflammation at the same department. He joined the Inflammation Research Center (IRC) of the Flanders Research Institute for Biotechnology (VIB) in 2015 as principal investigator. His research interests are centered around translational aspects of immune regulation to combat inflammatory arthritis and associated joint damage, with special focus on iNKT cells and related innate like T cells.

Dr Ian Giles
Consultant Rheumatologist,
University College Hospital, London.

Ian Giles qualified from the Royal London Hospital and carried out general medical and rheumatology clinical training in various London hospitals. He then carried out Arthritis Research UK funded clinical research (PhD) and Clinical Scientist Fellowships at University College London. He is now Professor and Honorary Consultant Rheumatologist at University College London Hospital. His specialist clinical and research interests focus upon the diagnosis and long term management of patients with autoimmune rheumatic diseases and management of these conditions in pregnancy. One of his long term translational research interests through an Arthritis Research UK programme grant and now MRC developmental pathway funding scheme funding has been development of a first in class product to prevent thrombosis in patients with APS. Through his interest in pregnancy in rheumatic disease he chaired the recent BSR guidelines on prescribing anti-rheumatic drugs in pregnancy. He has also formed a national collaborative network of specialist centres, the Pregnancy in Rheumatic disease Investigation NeTwork (PRINT) to establish a prospective study of patients with inflammatory rheumatic disease in pregnancy to address many unmet needs in this patient group.

Dr Tim Jones
Associate Lecturer at Oxford Brookes University UK

Tim Jones is the Commissioning Advisor for the NOS in the UK and is the architect of the FLS Benefits Calculator which has been successfully used to generate FLS funding in more than 20 UK hospitals. He is a regular presenter at International Osteoporosis meetings on the topic of developing a business case to fund FLS that demonstrate cost benefit to the healthcare system. He has published widely on the cost saving benefits of secondary prevention of fragility fractures.

Prof Luke O'Neill
Professor of Biochemistry,
Trinity College Dublin.

Professor Luke O'Neill holds the Chair of Biochemistry at Trinity College Dublin where he leads the Inflammation Research Group. He has a PhD in Pharmacology from the University of London and carried out Post-Doctoral research at Cambridge U.K. His research is in the area of the molecular basis to inflammation with a particular focus on innate immunity, Toll-like receptors, inflammasomes and metabolic reprogramming in macrophage activation. In 2016 he was named by Clarivates/Thompson Reuters as one of the world's most influential scientists, being in the top 1% in Immunology. He is co-founder of 3 Spin-out companies - Opsona Therapeutics, Inflazome and Sitryx, which are developing new treatments for inflammatory diseases. He has won numerous awards for his research including the European Federation of Immunology Societies medal, the International Cytokine and Interferon Society Milstein Award, The Royal Dublin Society Boyle Medal for Scientific Excellence, The Royal Irish Academy Gold Medal for Life sciences. He was elected a Fellow of the Royal Society in 2016.

Professor Peter Nash
University of Queensland, Australia

Peter Nash is Associate Professor in the Department of Medicine at the University of Queensland, and Director of the Rheumatology Research Unit on the Sunshine Coast. Dr Nash has chaired the Professional Affairs Committee and the Therapeutics Committee, the NHMRC musculoskeletal panels and serves on the Scientific Advisory Committee of the Australian Rheumatology Association. He is a former member of the Therapeutics Committee of the Australia and New Zealand Bone and Mineral Society. He remains on the International Steering Committee for GRAPPA. He is on the editorial board of Annals of the Rheumatic Diseases and RMD Open.

Dr Nash and his group at the Rheumatology Research Unit have been involved with pivotal registration clinical trials

for all modern targeted biologic therapies and osteoporosis therapies. He has published more than 100 peer-reviewed papers and 5 book chapters, and acts as reviewer for a number of journals. His special interests include metabolic bone disease and novel therapeutics.

Dr Lihi Eder
Assistant Professor of Medicine,
University of Toronto, Canada

Clinician Scientist, Women's College Research Institute, Toronto, Canada Director, Psoriatic Arthritis Clinic, Women's College Hospital, Toronto, Canada Co-Director, Cardio-Rheumatology Program, Women's College Hospital, Toronto, Canada Dr Lihi Eder is a rheumatologist with a particular interest in psoriatic disease. She graduated from the Ben-Gurion University of the Negev Medical School, Beer-Sheva, Israel, in 2002, and completed her rheumatology training at the Rheumatology Division, University of Toronto, Canada. During this period, she obtained a PhD in Genetic and Clinical Epidemiology from the Institute of Medical Science at the University of Toronto. She then completed a post-doctoral research fellowship, investigating cardiovascular morbidities in patients with psoriatic disease.
Currently, Dr Eder is appointed as Assistant Professor of Medicine at the University of Toronto, and Clinician Scientist at the Women's College Research Institute. Dr Eder is the Director of the Psoriatic Arthritis Program and co-Director of a combined Cardio-Rheumatology Program at Women's College Hospital. Her research area includes the transition from psoriasis to psoriatic arthritis, and co-morbidities in patients with psoriatic disease.
Dr Eder is an active member in several international research networks and societies in the field of psoriatic disease and musculoskeletal ultrasound, including the Group for Research and Assessment in Psoriasis and Psoriatic Arthritis (GRAPPA) and the International Psoriasis and Arthritis Research Team (IPART). She also serves as Research Director of the Canadian Rheumatology Ultrasound Society (CRUS). Dr Eder's research efforts have resulted in 75 peer-reviewed publications and numerous presentations at national and international medical conferences. Dr Eder was awarded New Investigator Award from the Arthritis Society and Early Researcher Award from the Ontario Ministry of Science Research and Innovation.

Dr Jeff Gulcher
Neurologist, Chief Scientific Officer
for WuXi NextCODE, Co-Founder of GMI

Jeff Gulcher is Chief Scientific Officer for WuXi NextCODE. Previously he was Chief Scientific Officer and co-founder of deCODE Genetics. Dr. Gulcher was on staff in the Department of Neurology at Beth Israel Hospital and Harvard Medical School from 1993 to 1998. He received his Ph.D. and M.D. from the University of Chicago in 1990, and completed his neurology residency Brigham and Women's Hospital and Beth Israel Hospital of Harvard Medical School in 1996. He received a Bachelor Degree in Chemistry/Physics from Michigan State University in 1981. He has co-authored 198 peer-reviewed publications on the genetics of common/complex diseases.

ISR Board members

Dr Sinéad Harney
President

Dr Sinéad Harney graduated from UCG in 1994 and did her specialist training in Rheumatology and General Medicine in Dublin. She completed her training in Oxford in 2005 and was awarded a DPhil by thesis titled "Major Histocompatibility Genetics of Rheumatoid Arthritis". She was appointed to a Consultant Rheumatologist post in Cork University Hospital in 2005 and has worked there since. She completed a Masters in Sports and Exercise Medicine in UCC in 2007. Her research interests include – Genetics of inflammatory arthritis and occult cardiovascular disease in Rheumatoid Arthritis and she has over 90 publications. She is currently the treasurer of the Irish Society of Rheumatology and a board member of the TUE committee of the Irish Sports Council.

Dr Clare Matthews
Honorary Secretary

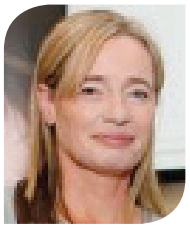
Consultant Rheumatologist, Ulster Hospital, Belfast Dr Clare Matthews graduated from Queens University Belfast in 1994. She completed registrar training with CCT in Rheumatology and general medicine in 2007. She completed an MD "Clinical, genetic and immunohistochemical findings of early inflammatory arthritis" from The Queen's University, Belfast in 2004. She trained in Belfast with a period of training in St Vincent's University Hospital Dublin through her research interest in synovial disease. Dr Matthews was first appointed as a consultant in Belfast City Hospital and moved to her current post in The South Eastern Trust in 2009.

Dr John Ryan
Honorary Treasurer

Dr John Ryan is a graduate of the Royal College of Surgeons in Ireland, he completed his higher medical training in rheumatology and general internal medicine in Ireland. He undertook a fellowship at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in Bethesda, Maryland. During this time he undertook translational research into disordered innate immunity manifesting as recurrent fever syndromes. He joined Dr Sinead Harney in the Rheumatology service at Cork University Hospital in 2010. The Rheumatology department has since expanded to include Dr Grainne Murphy. In July 2017 he took up the post of National Specialty Director for Rheumatology.

Dr Shawn Chavrimootoo
Shawn Chavrimootoo is a Consultant Rheumatologist at Our Lady's Hospital, Navan, Co. Meath. He graduated in Medicine from RCSI, Dublin in 2002 and developed an interest in Rheumatology during his Senior House Officer years in Connolly Hospital, Blanchardstown. Following this, he completed higher specialist training in Cork University Hospital, Kerry General Hospital, Connolly Hospital and St Vincent's University Hospital in Dublin. He was appointed to his Consultant Rheumatologist post in 2013 when he joined Dr Ramakrishnan at Our Lady's Hospital, Navan, from where they currently provide a regional Rheumatology service for the North East of Ireland. His clinical interests include osteoporosis as well as gout, inflammatory arthritis, spondyloarthritis, connective tissue disease and vasculitis.

Prof. Suzanne Donnelly
Associate Professor Suzanne Donnelly is a consultant rheumatologist at the Mater Misericordiae University Hospital Dublin & Associate Dean (Education) in UCD School of Medicine. She is a graduate of Trinity College Dublin and trained in Dublin and Oxford before being appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. Her clinical interests include systemic autoimmune disease, Systemic Lupus Erythematosus and pregnancy in the rheumatic diseases . Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London. She joined UCD as Director of Clinical Education in 2008, and was appointed Associate Dean, UCD School of Medicine in 2017. In partnership with Arthritis Ireland , she initated a patient educator programme to enhance medical students' education in rheumatological disease. The programme has enabled over 2000 medical students to meet patients with arthritis first hand. Suzanne is rheumatology author for the medical textbook Medicine at A Glance and a contributing author to The Rheumatology Handbook. She was ISR nominee to the board of Arthritis Ireland (2008-13), a board member of Raynauds and Scleroderma Ireland (2007-10) and medical patron of Lupus Group Ireland.



Professor Ursula Fearon
Professor Ursula Fearon is head of Molecular Rheumatology, School of Medicine, Trinity Biomedical Sciences Institute, Trinity College Dublin. Professor Fearon's research is a bench-to-beside translational approach, focusing on understanding the underlying mechanisms that drive disease pathogenesis; her team specifically examine components of joint inflammation at a cellular and molecular level to dissect out the signalling and gene pathways that are involved in the pathogenesis of inflammatory arthritis and rheumatic diseases. She has established strong collaborative research networks across Europe, USA and Singapore. Professor Fearon, has been awarded significant research funding from Arthritis-Ireland, Health Research Board, Science Foundation Ireland, IRCSET, European-ASPIRE, JU Innovative Medicines Initiative (IMI) and Maeve Binchy Funding for Arthritis Research, in addition to industry collaborative partnerships. She has published extensively in high impact peer-reviewed journals, and her research has been awarded several National/International awards.

Dr Sandy Fraser
Consultant Rheumatologist, General Physician and Honorary Senior Lecturer, University Hospitals Limerick. Dr. Alexander Fraser graduated in medicine from Trinity College Dublin in 1991. He began practicing Rheumatology in 1996 and the following year was appointed Specialist Registrar in Rheumatology at the Yorkshire Deanery. Training with Professor Emery's group in Leeds he developed a research interest in clinical, immunological and therapeutic aspects of Rheumatoid Arthritis, Psoriatic Arthritis and the Sero-negative Spondyloarthropathies. He was appointed Consultant Rheumatologist and Honorary Senior Lecturer at the Leeds Teaching Hospitals NHS Trust, working at The Leeds General Infirmary and St. James' University Hospital in October 2001, and working closely with Professor Emery and Professor Doug Veale he published in the area of Angiogenesis, Vascularity and Inflammation in early and established arthritis and Biomarkers of cartilage turnover. Dr Fraser took up his current appointment as Consultant Rheumatologist, General Physician and Honorary Senior Lecturer at the University Hospitals Limerick in 2006. In conjunction with the University of Limerick Graduate Entry Medical School (GEMS) Dr. Fraser and his team have continued their strong academic interests while managing a busy clinical practice.

Dr Orla Killeen

Dr Orla Killeen qualified from UCG (NUI) Galway in 1996. She trained in General Paediatrics in Our Lady's Hospital for Sick Children, Crumlin and in Temple Street University Hospital, Dublin before sub-specialising in Paediatric Rheumatology. She undertook her paediatric rheumatology training at Great Ormond Street Children's Hospital, London and went on to complete a Barbara Ansell Fellowship in Paediatric Rheumatology in the Royal Hospital for Sick Children, Glasgow. She was appointed as Ireland's first Paediatric Rheumatologist in 2004, and is based at Our Lady's Children's Hospital, Crumlin and St Vincent's University Hospital, Dublin since July 2006. She is the Clinical lead for the National Centre for Paediatric Rheumatology (NCPR), providing care for patients both on a local and national level up to 18 years of age. Her areas of interest include Adolescent Rheumatology Transition Care as well as JIA, Down's arthropathy and Auto-Inflammatory syndromes.

Dr Bernadette Lynch

Dr Bernadette Lynch graduated from the Royal College of Surgeons in Ireland in 2003. She completed her higher specialist training in Rheumatology and General Medicine in 2013 having worked and studied in Dublin, Galway and London. She was awarded an MD from University College Dublin in 2011 for work on IL-22 and musculoskeletal ultrasound in Inflammatory Arthritis. She undertook a fellowship in Scleroderma and Vasculitis at the Royal Free Hospital Hampstead under Professor Chris Denton and Dr Aine Burns. During this time, Bernadette was part of the UK Scleroderma Study Group (UKSSG) which developed the national guidelines on the management of complications of Scleroderma. She took up her current appointment as Consultant Rheumatologist and General Physician in University Hospital Galway in 2015. Her principal clinical and academic interests are Scleroderma and Inflammatory Arthritis.

Dr Aine Gorman

Aine Gorman is a graduate of NUIG, completing her undergraduate studies in 2011 later undertaking basic specialist training at St James's Hospital. She entered Higher Specialist Training in Rheumatology in 2016.

Now representing the SpR group on the Board of ISR.

Dr Adrian Pendleton
Consultant Rheumatologist
Musgrave Park Hospital, Belfast

Dr Adrian Pendleton is a Consultant Rheumatologist and Clinical Lead for Rheumatology in the Belfast Health and Social Care Trust. Dr Adrian Pendleton trained in both Rheumatology and General Internal Medicine in Belfast and Nottingham. He was first appointed as a consultant Rheumatologist at the Queens Medical Centre, Nottingham University Hospitals before returning to the Belfast Trust Health and Social care Trust. Dr Pendleton is a Fellow of the Royal College of Physicians of Edinburgh and a Fellow of the Royal College of Physicians of Ireland and a Fellow of the British Society for Sport and Exercise Medicine (BASM). He is currently the Regional Specialty Advisor for Rheumatology with the Joint Royal College Physicians Training Board. Dr Pendleton has many research interests which include Early diagnosis and management of inflammatory arthritis, use of musculoskeletal ultrasound in Inflammatory arthritis, vasculitis and soft tissue injury.

Dr Bryan Whelan

Dr Bryan Whelan is a Consultant Rheumatologist in Our Lady's Hospital in Manorhmailton, Co Leitrim and an Honourary Senior Lecturer in Medicine in NUIG. He qualified from UCD in 2000 and completed BST in the Mater Hospital in Dublin. He completed SpR training in Rheumatology in CUH, the Mater Hospital and University College London. He has an MD and Masters Sports and Exercise Medicine from UCC and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine. He is currently a board member of Arthritis Ireland, the SUH Research and Education Foundation, a member of the Academic Committee of the FSEM and a member of the Advisory Committee for Human Medicines Clinical Trials Subcommittee of the HPRA. His current research interests include muscle disease, exercise in rheumatology and osteoarthritis.

Oliver Kelly, Nordic, Grainne O'Leary, Arthritis Ireland and Theresa Higgins, Nordic

Photos from ISR Spring Meeting 2018

Dr Sinead Harney

Professor Ashok Rai

Dr Paddy Barrett

Brenda McCarthy, Croom Hospital; Elaine Fitzgerald and Noreen Harrington, Manorhamilton

Grainne O'Leary, Arthritis Ireland and Anna Barrett Accord Healthcare

Dr Maurice Barry

Olive Kelly, Nordic, Deyrick Deane, MSD, Ross Shanley, MSD and Mark Gorman, MSD

Grainne O'Leary, Lisa Wallace and Brenda Daly, Janssen

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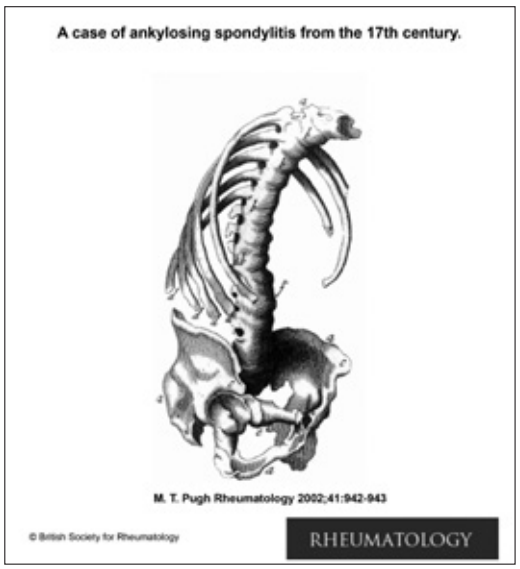
ABBREVIATED PRESCRIBING INFORMATION. ▼ COSENTYX 150 mg solution for injection in pre-filled pen. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** COSENTYX 150 mg solution for injection in pre-filled pen. **Therapeutic Indications:** The treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; the treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. **Dosage & Method of Administration:** *Plaque Psoriasis:* Recommended dose in adults is 300 mg given as two subcutaneous injections of 150 mg. Dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. *Ankylosing Spondylitis:* The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For all other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. For all of the above indications, available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 16 weeks. The safety and efficacy in children below the age of 18 years have not yet been established. **Contraindications:** Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis). **Warnings/Precautions:** *Infections:* Cosentyx has the potential to increase the risk of infections. Infections observed in clinical studies are mainly mild or moderate upper respiratory tract infections such as nasopharyngitis not requiring treatment discontinuation. Non serious mucocutaneous candida infections more frequently reported for secukinumab than placebo in psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, close monitoring and discontinue treatment until the infection resolves. Should not be given to patients with active tuberculosis. Anti tuberculosis therapy should be considered prior to initiation in patients with latent tuberculosis. *Crohn's disease:* Caution should be exercised when prescribing to patients with Crohn's disease as exacerbations of Crohn's disease, in some cases serious, were observed in clinical studies. Close monitoring of patients with Crohn's disease treated with Cosentyx. *Hypersensitivity reactions:* In clinical studies, rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx. If an anaphylactic or other serious allergic reactions occur, administration should be discontinued immediately and appropriate therapy initiated. *Latex-sensitive individuals:* The removable cap of the Cosentyx pre filled pen contains a derivative of natural rubber latex. *Vaccinations:* Live vaccines should not be given concurrently with Cosentyx. Patients may receive concurrent inactivated or non live vaccinations. *Concomitant immunosuppressive therapy:* Use in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. **Interactions:** Live vaccines should not be given concurrently with Cosentyx. In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP 3A4 substrate). No interaction seen when administered concomitantly with methotrexate (MTX) and/or corticosteroids. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. It is preferable to avoid the use of Cosentyx in pregnancy as there are no adequate data from the use of secukinumab in pregnant women. It is not known whether secukinumab is excreted in human milk. A decision on whether to discontinue breast feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. The effect of secukinumab on human fertility has not been evaluated. **Undesirable Effects:** *Very common (≥1/10);* Upper respiratory tract infections. *Common (≥1/100 to <1/10);* Oral herpes, rhinorrhoea, diarrhoea, urticaria *Uncommon (≥1/1,000 to <1/100);* Oral candidiasis, tinea pedis, otitis externa, neutropenia, conjunctivitis. *Rare (≥1/10,000 to <1/1,000);* Anaphylactic reactions. Please see Summary of Product Characteristics for further information on undesirable effects. **Legal Category:** POM. **Marketing Authorisation Holder:** Novartis Europharm Ltd, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland. **Marketing Authorisation Numbers:** EU/1/14/980/004-005. **Date of Revision of Abbreviated Prescribing Information:** April 2018. Full prescribing information is available upon request from: Novartis Ireland Limited, Vista Building, Elm Park Business Park, Elm Park, Dublin 4. Tel: 01-2204100 or at www.medicines.ie Detailed information on this product is also available on the website of the European Medicines Agency http://www.ema.europa.eu **References: 1.** Cosentyx Summary of Product Characteristics, April 2018. **2.** Mease PJ *et al.* Presented at the American College of Rheumatology 2016. Presentation number 961. **3.** Braun J *et al.* Ann Rheum Dis. 2016 Dec 13. pii: annrheumdis-2016-209730. doi: 10.1136/annrheumdis-2016-209730. **4.** Strand V, *et al.* Ann Rheum Dis. 2016;doi:10.1136/annrheumdis-2015-2090553. **5.** Novartis Data on File 2014. F2312_Patient assessment of pain through 24 weeks_Table 14.2-16.1.**6.** Novartis Data on File 2014. F2305_Total spinal pain through 24 weeks_Table 14. 2-12.1. **7.** Novartis Data on File 2014. F2310_Total spinal pain through 16 weeks_Table 14.2-12.1. **8.** Mease P *et al.* Arthritis Rheum 2015; 67 (S10): 2576: Oral presentation 2148 at the American College of Rheumatology (ACR), 9 November 2015, San Francisco, USA. **9.** van de Kerkhof P *et al.* J Am Acad Dermatol 2016; 75(1): 83-98. **10.** European Medicines Agency Public Assessment Report. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003729/WC500183131.pdf. *Patients received intravenous secukinumab (10 mg per kg of body weight) or matched placebo at weeks 0, 2, and 4, followed by subcutaneous secukinumab (150 mg or 75 mg) or matched placebo every 4 weeks starting at week 8. **Date of Preparation:** July 2018. IE02/COS16-CNF010d(1)b

NOVARTIS

ISR Bernard Connor Medal

Dylan McGagh
Award Winner 2018

Could patient-reported outcomes help to inform a holistic treat-to-target approach in rheumatology?



I was grateful to have the opportunity to experience rheumatology in some depth at an early stage of my medical school journey. While on a placement in March 2018, I spent 4 weeks shadowing clinical care nurses, consultants and registrars, which opened my horizons to the world of rheumatology. The naïve perception I harboured prior to my experience, and certainly one that is echoed in my many peers at a similar stage of medical school, is that of uncertainty as to the role of the rheumatology team. There was a consensus, certainly amongst students, that the role was limited to the management of joint conditions. I found this to be untrue. The underlying science behind the conditions was fascinating, and the systemic, extra-articular manifestations of the conditions were extensive, beyond previous appreciation. Having sat in on my first clinic, I was hooked. Without question, rheumatology struck me as a speciality which has diversity at its very core. The role of the rheumatology team in caring for these diverse patients opened my horizons to patient-centred care in practice, by placing a central emphasis on the patient's self-reported symptoms and difficulties in living with these chronic conditions.

The true diversity of clinical presentations, patient experiences and treatment regimens was apparent following this first morning spent in clinic. The first general clinic included patients with rheumatoid arthritis, ankylosing spondylitis, early onset osteoarthritis, CREST syndrome, fibromyalgia, psoriatic arthritis and gout. Perhaps what struck me most was the range of different approaches the clinician employed when communicating with this varied group of people. It appeared that these conditions could affect people at any stage in their life, from various juvenile arthritides to autoimmune conditions in patient's in their 9th decade and beyond. The spectrum of patients, based on this alone, impacts vastly on the clinical management.

The breadth of clinician-reported scoring tools echoed the range of clinical conditions on show. The composite names and acronyms of these tools were perplexing. Throughout the clinic, the rheumatologist utilised the BASDAI, the DAS-28 and the PsARC tools, amongst others, for appraising disease severity and comparing against previous visits to establish the course of their disease. At first exposure, their implementation felt unwieldy, the PsARC required some 68 joint counts and the visual analogue scales of pain and patient global asssessment, ranging from 1-100 were difficult to grasp for some patients in the context of improvement against their last visit. It seemed that these visual tools seemed vulnerable to cognitive biases, particularly anchoring bias where patients would react to analogies of severity which the clinician presented. Floor and ceiling effects, which are a reduced sensitivity of these tools to capture a full range of patients symptoms, have been reported as a major limitation of visual scales.

On further questioning, it was evident that a surrogate for disease severity was an essential component of the management of these patients, and procurement of further therapies was dependent on the levels of disease-activity over time. It was at this point where I first encountered the concept of treat-to-target. Much of medical school up to this point had been filled with learning various scientific and clinical concepts; however "T2T" had not yet reached the classrooms and study groups. I was initially intrigued by the idea, and took solace in its goal-based linearity. It seemed an efficient way of setting an objective and reaching a point of "remission" or "minimal disease activity", validated and proven to reduce the destructive sequelae of chronically active disease. The advent of effective and tolerable disease modifying drugs and biologic therapies has certainly made it a possibility to target remission, in a set of conditions, which one generation ago, had patients bed-bound and contorted with the destructive effects of chronic inflammation.

As my time with the team passed, it became apparent that there were certain anomalies to the measurement tools, and therefore opportunities for discordance between targets and disease activity. There were certain patients who had what appeared to be particularly active disease, with signs of acute inflammation and yet markers of disease were grossly normal. There were also several patients, who despite describing debilitating symptoms shaking their very daily existence, still displayed a stoicism in determining their VAS scores. In these patients, this discordance had the capacity to affect the overall scoring and potentially influence the downstream target. On these occasions, it took the vigilance, understanding and wisdom of the clinician to identify this dissociation and further delve into the symptoms the patient had been experiencing. Had this particularly clinician not been so incisive and invested in patient-centred care, it begs the question if the true targets of improving daily living could be met?

I was privileged to spend some time with some of these patients and ask further questions about their complex conditions. These individuals were forthcoming with their time and knowledge. What I saw as the most noteworthy feature of these conversations was the impact that the individual's conditions had on their daily well-being and sense of self, which was much more wide-ranging than their clinical values seemed to demonstrate. On the whole, patients do not describe goals of reducing disease activity, as per the scoring tools. It was evident that their goals encompassed desires to improve or preserve on their daily well-being and functioning, and this in itself is immensely subjective and unique to each patient.

One patient, who had been diagnosed with rheumatoid arthritis 40 years previously, and had undergone multiple corrective surgeries on her wrists and ankles and had been crippled by pain for nearly 3 decades, had the sole wish of maintaining stable

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Special warning and precautions for use include: Infections, tuberculosis, Hepatitis B virus (HBV) reactivation, malignancies and lymphoproliferative disorders, skin cancers, paediatric malignancy, chronic obstructive pulmonary disease (COPD), congestive heart failure, haematological reactions, neurological events, hypersensitivity, immunosuppression, autoimmunity, vaccinations, concomitant use with other biologics, surgery, activated partial thromboplastin time (aPTT) assay and elderly patients.

Adverse Effects: Common adverse-effects (≥1/100 to <1/10): Bacterial infections (including abscess) and viral infections (including herpes zoster, papillomavirus and influenza), eosinophilic disorders, leukopenia (including neutropenia, lymphopenia), headaches (including migraine), sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pyrexia, pain (any site), asthenia, pruritus (any site), injection site reactions. Consult SPC in relation to other side effects.

Dosing and administration: *Loading dose:* Recommended starting dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. *Maintenance dose:* In RA and PsA: The recommended dose is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dose of 400 mg every 4 weeks can be considered. In axSpA: The recommended dose is 200 mg every 2 weeks or 400 mg every 4 weeks.

RA, rheumatoid arthritis; PsA, psoriatic arthritis; axSpA, axial spondyloarthritis

CIMZIA® is indicated for the treatment of patients with: severe, active rheumatoid arthritis (RA) in combination with methotrexate (MTX) in adult patients when the response to disease modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. CIMZIA® can be given as monotherapy in RA in case of intolerance to MTX or when continued treatment with MTX is inappropriate. CIMZIA® is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs; Severe active axial spondyloarthritis (axSpA) comprising: adult patients with severe active ankylosing spondylitis (AS) who have have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs) and adult patients with severe active axial spondyloarthritis without radiographic evidence of AS (nr-axSpA) but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to NSAID; active psoriatic arthritis (PsA) in combination with MTX in adults when response to previous DMARD therapy has been inadequate. CIMZIA® can be given as monotherapy in PsA in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

***The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA® dose due to its elimination rate, but the need for treatment of the woman should also be taken into account. CIMZIA® should only be used during pregnancy if clinically needed. Data from more than 500 prospectively collected pregnancies exposed to CIMZIA® with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA®. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA® administration during pregnancy. CIMZIA® can be used during breastfeeding.**

Reference:
CIMZIA® Summary of product characteristics, December 2017.

UK/18CI0032 February 2018

POM

Further information is available from UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland.

Marketing Authorisation Number(s):
EU/1/09/544/001, EU/1/09/544/005

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disease and limiting the number of flares. She was still the sole carer for her son who had disabilities, and looking after his welfare was her purpose in life. There was another patient, with psoriatic arthritis, whose goal for treatment was improvement of their energy levels. They were debilitated by constant fatigue which had prevented them from functioning and they wanted to take a more active role in the care of their children. Another patient, with early-onset osteoarthritis, who had embraced the T2T approach and had set himself the task of climbing to Everest base camp within 18 months, a target which may have seemed distant in the context of his swollen, painful fingers and active disease. However, he struck me as someone who set himself targets in daily life, and by setting long-term objectives, could endeavour to reach some form of recovery. From these conversations, it was apparent to me that the concept of remission or recovery is patientspecific and varied from individual to individual. Some of the themes which arose from this time reflect qualitative research by an OMERACT-EULAR collaboration which integrated patients, clinicians and researchers to further understand core domains which constitute remission from a patient-perspective1,2. This working group found that reduced fatigue and pain duration and intensity, along with increased independence and ability to work were central components of perceived remission.

Although few people would argue with the value of patient-centred care across all disciplines of medicine, in rheumatology, placing an emphasis on patient-reported outcomes (PROs) as a core foundation of the patient journey is tangible and pragmatic, simply because of the effects rheumatological conditions can have on daily life. Compared to much more insidious, yet equally severe chronic conditions, such as diabetes and hypertension, the potential value which lies in detailed PROs in these patients is perhaps limited when compared to the pain, stiffness and fatigue associated with RA, AS and PsA. The consequences that these symptoms can have on a person's confidence, independence and functioning provides a unique opportunity to measure these factors and provide an objective evaluation on subjective inputs, ultimately guiding holistic recovery which is valued by those most important, the patient and their families and carers.

In the field of psychology, where patient perceptions and subjective experiences of a condition is a central figure in the patient-psychologist dynamic, there is some scope for understanding the application of patient-reported outcome measurement in medicine. Generally, psychologists separate appraisal tools into psychological testing and psychological assessment. Assessment is deemed a more detailed process and incorporates a clinical history and interview process while testing utilises formal tests such as questionnaires or checklists, often described as "norm-referenced" tests. That simply means the tests have been standardized so that testtakers are evaluated in a similar way, no matter where they live or who administers the test. A complete assessment process may incorporate the use of psychometric tests, akin to a diseasespecific patient-reported questionnaires in a full rheumatology clinic review, however, placing a sole focus on the use of these tools, without thorough assessment, may actually obstruct patient-centered care. In the context of medicine, the assessment, in the form of the clinical history, is a clinician's oldest instrument. This holistic approach to the patient assessment is comparable to the clinicians I have observed, whom placed a focal significance on the individual's subjective experience of their condition, supplementary to the use of cliniciancentered questionnaires such as the DAS-28 and the BASDAI. It could be argued that in settings where constraints are placed on the healthcare team, such as increased waiting times and staff shortages, that detailed exploration of the patient's perspective may be sacrificed.

For true targets to be reached in a holistic T2T approach placing the patient as the central participant, the patient's perceptions need to be integrated with current objective measures of disease activity. As I had the privilege of exploring, people with rheumatic conditions have fears and desires for treatment regimens which are integral to their sense of self. In order to truly treat these chronic and complex conditions, accounting for these individual factors, there is scope to utilise more detailed patient-reported outcome questionnaires, either on digital platforms while patients await their consultation or via a regular diary between consultations. If the tools we employ work effectively and barriers to their functionality are removed, there is an opportunity to bridge the gap between the clinical and the patient worlds, only elevating the value we place on the clinical history and human interaction.

References

1. van Tuyl, L. H. D. *et al.* The patient perspective on remission in rheumatoid arthritis: "You've got limits, but you're back to being you again". *Ann Rheum Dis* 74, 1004–1010 (2015).
2. van Tuyl, L. H. *et al*. Remission in Rheumatoid Arthritis: Working Toward Incorporation of the Patient Perspective at OMERACT 12. *J Rheumatol* 43, 203–207 (2016).

Dylan McGagh Bernard Connor Medal Winner

Dylan McGagh is a 3rd year Graduate Entry Medical student at Magdalen College, University of Oxford. He graduated from Trinity College, Dublin in 2016 with a Gold medal and 1st class honours degree in Human Health and Disease and went onto start his medical school studies in September of that year. His first exposure to rheumatology was during his final year at Trinity when he undertook a research project under the supervision of Dr Aisling Dunne of the School of Biochemistry and Professor Geraldine McCarthy. This project involved isolating microvesicles from synovial fluid of patients with osteoarthritis, and demonstrated a number of novel phenotypic and functional properties of these cell-derived vesicles. From this early interest, Dylan was able to get exposure to clinical rheumatology at the Nuffield Orthopaedic Centre in Oxford and Stoke Mandeville Hospital, Aylesbuy. He has a desire to pursue a career in Rheumatology, with a particular interest in maternal medicine also.

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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. *Older people:* 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, Toxic epidermal necrolysis and acute anaphylactic reaction/shock; do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. *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 of treating gout in these patients with febuxostat such use is not recommended. *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:* No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. *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. Where the combination cannot be avoided see SmPC for dosing instructions. *Rosiglitazone/CYP2C8 inhibitors:* No dosage adjustment required. *Theophylline:* No special caution advised for 80 mg febuxostat, no data available for 120 mg. *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/indometacin/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, haematocritic decrease, blood lactate dehydrogenase increased, blood potassium increase. Rare (0.1-0.01%): Pancytopenia, thrombocytopenia, agranulocytosis**, anaphylactic reaction**, drug hypersensitivity**, blurred vision, weight decrease, increase appetite, anorexia, nervousness, tinnitus, pancreatitis, mouth ulceration, hepatitis, jaundice**, liver injury**, Toxic epidermal necrolysis**, Stevens-Johnson Syndrome**, DRESS**, angioedema**, generalized rash (serious)**, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic**, rash erythematous, rash morbillifom, 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, blood creatine phosphokinase 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, 014, 020. **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 A96 T924 or may be found in the SmPC. **Last updated:** July 2018.

References: 1. Adenuric 80 mg SmPC. May 2018. **2.** Adenuric 120 mg SmPC. May 2018.

Date of item: July 2018
IR-ADEN-08-2018

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Dr Sarah Wade
Postdoctoral researcher, Molecular Rheumatology, Trinity College Dublin, Ireland.

Sarah is an Arthritis Ireland postdoctoral researcher in the Molecular Rheumatology research lab at Trinity College Dublin. She holds a 1st class Honours degree in Biomedical, Health and Life Sciences from University College Dublin. In 2014, Sarah was awarded an Irish Research Council (IRC) Ph.D fellowship, completed in 2017 under the supervision of Professor Ursula Fearon and Professor Douglas Veale. Sarah's research interests are in synovial inflammation, where she focuses on the characterization and functional analysis of synovial angiogenesis, inflammatory microenvironments, immune cells infiltration and cellular metabolism. In 2016, she was appointed newsletter editor and social media liaison for EMEUNET - a young rheumatology network for young clinicians and scientists in Europe - where her role is to highlight and disseminate basic research content in rheumatology.

(18A127)
DYSREGULATED MIR-125A PROMOTES JOINT ANGIOGENESIS THROUGH ALTERED BIOENERGETICS.

Author(s)
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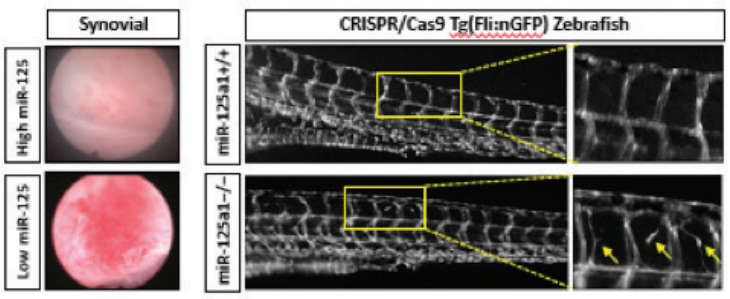
Introduction
Psoriatic arthritis (PsA) is characterised by an early vascular phase essential for pannus growth, immune responses and disease progression. Recently, numerous studies have highlighted the emerging importance of endothelial cell (EC) metabolism in disease.

Aims/Background
Herein, we propose microRNA, miR-125, modulates EC bioenergetics and orchestrates joint angiogenesis as characterised by ex-vivo associations, in-vitro assays and novel CRISPR/cas9 in-vivo zebrafish models.

Method
MiRNA levels were quantified in synovial tissue by RT-PCR and compared to macroscopic synovial vascularity and immunohistochemical analysis of angiogenic factors (FactorVIII/VEGF/ANG2). ECs (HMVEC) were transfected with anti-miR-125a for 24hr. Angiogenic mechanisms were quantified using tube formation assays, transwell matrigel chambers, wound repair and gene expression analysis. Real-time analysis of anti-125 treated ECs metabolism was assessed using the XF-24 Extracellular Flux Analyzer (Seahorse Bioscience). To determine if altered metabolism is observed ex vivo, metabolism markers (GAPDH/PKM2/GLUT1/ATP) were assessed by immunohistochemistry. In vivo, miR-125a CRISPR/Cas9-based knock-out zebrafish were generated and vascular development monitored. Finally, the therapeutic effect of blocking glycolysis using a small molecule, 3PO, which blocks PFKFB3, was assessed in miR-125a-/- ECs and zebrafish embryos.

Results
Synovial expression of miR-125 was significantly decreased in PsA versus OA synovial tissue, levels of which were associated with macroscopic and microscopic synovial vascularity. Decreased expression of miR-125a in HMVEC resulted in increased tube formation, invasion and migration properties. Inhibition of miR-125 promoted a metabolic shift towards glycolysis with parallel changes at the gene level. Ex vivo, increased vascular expression of glycolytic markers was observed in PsA versus OA synovial tissue. In vivo, miR-125a knockout zebrafish displayed increased vascular sprouting similar to the irregular nature of the vasculature within the PsA synovium. Finally, 3PO significantly inhibited anti-miR-125a-induced mechanism whilst normalising the vascular development of miR-125a-/- embryos.



Conclusions
Decreased expression of miR-125 in PsA synovium and in-vivo models was strongly associated pro-angiogenic mechanisms. Elevated glycolysis following miR-125 inhibition enabled ECs to meet the increased energy demands for new vessel formation. Correcting these miRNA deficiencies and their resulting metabolic shift, either by conventional pharmacological or as novel drug targets, may provide therapeutic benefit, especially in early disease.

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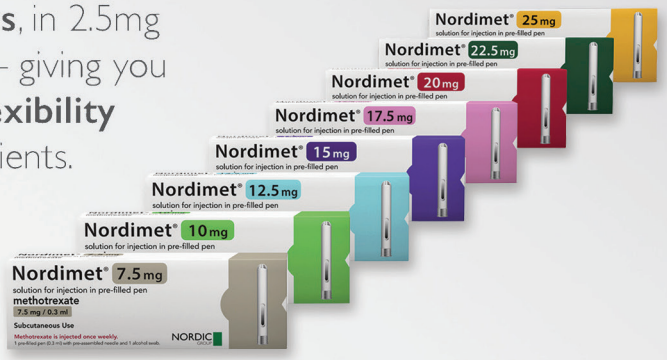

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Exanthema. Erythema. Pruritus. Uncommon: Pharyngitis. Pancytopenia. Precipitation of diabetes mellitus. Depression. Enteritis. Pancreatitis. Gastrointestinal ulceration and bleeding. Cirrhosis, Fibrosis and fatty degeneration of liver. Inflammation and ulceration of bladder. Renal impairment. Rare: Infection. Conjunctivitis. Sepsis. Allergic reactions. Anaphylactic shock. Hypogammaglobulinaemia. Visual disturbances. Pericarditis. Pericardial effusion. Pericardial tamponade. Thromboembolic events. Pulmonary fibrosis. Pneumocystis carinii pneumonia. Shortness of breath and bronchial asthma. Pleural effusion. Acute hepatitis. Renal failure. Anuria. Very rare: Lymphoma. Agranulocytosis. Severe courses of bone marrow depression. Acute aseptic meningitis. Convulsions. Paralysis. Impaired vision. Retinopathy. Haematemesis. Toxic megacolon. Hepatic failure. Stevens-Johnson syndrome. Toxic epidermal necrolysis. Not known: Eosinophilia. Encephalopathy/Leukoencephalopathy. **Legal classification:** POM. **MA numbers:** ***Nordimet:*** EU/1/16/1124/001 – 008. **Further information available from:** Nordic Pharma Ltd, Unit 3, Commerce Park, Brunel Road, Theale, Reading, United Kingdom. **Date of prescribing information:** January 2017. **Code for PI:** NOR/17/001i

Adverse events should be reported.
Reporting forms and information can be found at http://www.hpra.ie
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Date Of Preparation: April 2018
I/18/NOR002

NORDIC PHARMA

Oral Presentations
Thursday, 20 September 2018

Basic Science Presentations

Abstract No.	Name	Title of Paper	Time
18A137	Trudy McGarry	Rheumatoid arthritis peripheral CD14+ monocytes are hyper-inflammatory, hyper-glycolytic and retain a memory bias toward M1 macrophages	9.50
18A166	Emma Dorris	Genetics of Rare Disease: A novel familial RELA truncation associate with Behçet's-like Mucocuaneous Ulceration Syndrome	9.59
18A130	Charlene Foley	Comparison of B and T cell subsets, cytokine expression and synovial pathology in Down's Arthritis (DA) and Juvenile Idiopathic Arthritis (JIA)	10.07
18A168	Megan Hanlon	Distinct macrophage phenotype and bioenergetic profiles in Rheumatoid Arthritis	10.15

Clinical Presentations

Abstract No.	Name	Title of Paper	Time
18A201	Yousef Alammari	Urate Lowering Therapy (ULT) reduces non-specific foot pain in patients who fail to meet ACR/EULAR 2015 Gout Criteria; an effect predicted by Ultrasound and potential rational for re-classification	10.25
18A141	Gillian Fitzgerald	Lateral DXA more effective in detecting osteoporosis than conventional DXA in Axial Spondyloarthropathy	10.33
18A133	Daire O'Leary	Beyond NSAIDS: second-line therapeutic agents for chronic recurrent multifocal osteomyelitis	10.42
18A187	Wan Lin Ng	Risk of Obstructive Sleep Apnoea in Patients with Rheumatic Disease: A Prospective Cohort Study	10.51

Friday 21 September 2018

Oral Presentations - Case Reports

Abstract No.		Identify of Cases not to be disclosed prior to meeting. Audience Participation units available	Time
18A152	Case 1		9.15
18A184	Case 2		9.30
18A199	Case 3		9.45
18A155	Case 4		10.00

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INDICATION(S): Plaque psoriasis adults: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA.
Plaque psoriasis paediatrics: Moderate to severe plaque psoriasis in adolescent patients from 12 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
Psoriatic arthritis: Alone or in combination with methotrexate for treatment of active psoriatic arthritis in adult patients when response to previous non-biological diseasemodifying anti-rheumatic drug (DMARD) therapy has been inadequate.
Crohn's Disease: Treatment of adult patients with moderately to severely active Crohn's disease who had inadequate response with/lost response to/were intolerant to either conventional therapy or TNFα antagonist or have contraindications to such therapies.

DOSAGE & ADMINISTRATION: *Adults:* Under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis/psoriatic arthritis/Crohn's disease.
Psoriasis or psoriatic arthritis, Subcutaneous (s.c.) injection. Avoid areas with psoriasis. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients.
Plaque psoriasis, adults & elderly: Patients ≤ 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients).
Plaque psoriasis paediatrics (12 years and older): Patients <60 kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients ≥60 - ≤100kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients >100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks.
Psoriatic arthritis, adults & elderly: 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight >100 kg.
Consider discontinuation if no response after 28 weeks.
Crohn's Disease Initial single intravenous infusion dose based on body weight (260 mg or 390 mg or 520 mg) diluted in sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given; followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no response at 16 weeks. Immunomodulators and/or corticosteroids may be continued but consider reducing/discontinuing corticosteroids if responding to Stelara. If therapy interrupted, resume s.c. every 8 weeks if safe/effective.
Children: *<12 years* - Not recommended for psoriasis. *<18 years* - Not recommended for psoriatic arthritis and Crohn's disease. ***Renal & Hepatic impairment:*** Not studied.

CONTRAINDICATIONS: Hypersensitivity to product; clinically important, active infection.

SPECIAL WARNINGS & PRECAUTIONS: ***Infections:*** Potential to increase risk of infections and reactivate latent infections. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, closely monitor and STELARA should not be administered until infection resolves.
Malignancies: Potential to increase risk of malignancy. No studies in patients with history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment for non-melanoma skin cancer. ***Concomitant immunosuppressive therapy:*** Caution, including when changing immunosuppressivebiologic agents. ***Hypersensitivity reactions:*** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted and STELARA discontinued. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. ***Immunotherapy:*** Not known whether STELARA affects allergy immunotherapy. ***Serious skin conditions:*** Exfoliative dermatitis reported following treatment. Discontinue STELARA if drug reaction is suspected.

SIDE EFFECTS: ***Common:*** upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. ***Other side effects:*** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis, lower respiratory tract infection.
Studies show adverse events reported in ≥12 year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis.
Refer to SmPC for other side effects.

FERTILITY: The effect of ustekinumab has not been evaluated.

PREGNANCY: Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment.

LACTATION: Limited data in humans.

INTERACTIONS: ***In vitro,*** STELARA had no effect on CYP450 activities. ***Vaccinations:*** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines in patients receiving STELARA. ***Concomitant immunosuppressive therapy:*** Psoriasis: Safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. Psoriatic arthritis: concomitant MTX did not appear to affect STELARA. Crohn's disease: concomitant immunosupressive or corticosteroid therapy did not appear to affect STELARA.
Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
45 mg	1 x vial	EU/1/08/494/001
45 mg	1 x 0.5 ml pre-filled syringe	EU/1/08/494/003
90 mg	1 x 1.0 ml pre-filled syringe	EU/1/08/494/004
130 mg	1 x vial	EU/1/08/494/005

MARKETING AUTHORISATION HOLDER: JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.
FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.
Prescribing information last revised: 09/2017

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie Adverse events should also be reported to Janssen-Cilag Limited on +441494 567447 or at dsafety@its.jnj.com.

REFERENCES: 1. Coates LC et al. Arthritis Rheumatol 2016;68:1060-1071 **2.** Kavanaugh A et al. Arthritis Care Res (Hoboken) 2015;doi: 10.1002/acr.22645. **3.** Kimball AB et al. J Eur Acad Dermatol Venereol. 2013;27:1535-1545. **4.** Rich P et al. Br J Dermatol. 2014; 170:398-407. **5.** McInnes I et al. Lancet. 2013;382;9894:780-789. **6.** Ritchin C et al. Ann Rheum Dis. 2014;73:990-999. **7.** Stelara® Summary of Product Characteristics, available at www.medicines.ie

PHIR/STE/0718/0005 | Date of Preparation: July 2018

(18A137) ABSTRACT 1 ORAL PRESENTATION BASIC SCIENCE

Rheumatoid arthritis peripheral CD14+ monocytes are hyper-inflammatory, hyper-glycolytic and retain a memory bias toward M1 macrophages

Author(s)
Trudy McGarry[1], Megan Hanlon[2], Clare Cunningham[2], Douglas J Veale[1] and Ursula Fearon[2].
Department(s)/Institutions
1. Centre for Arthritis and Rheumatic Diseases, St. Vincent's University Hospital and University College Dublin. 2. Molecular Rheumatology, Trinity Biomedical Sciences Institute, Trinity College Dublin

Introduction
Myeloid cells with a monocyte/macrophages phenotype are present in large numbers in the rheumatoid arthritis (RA) joint, significantly contributing to disease.

Aims/Background
This study aimed to assess whether peripheral monocytes in RA are pre-programmed to become M1 pro-inflammatory macrophages.

Method
Blood was collected from healthy donors, at-risk individuals (Those with arthralgia, ACPA+/RF+, normal CRP and no evidence of synovitis) and established RA patients. CD14+ monocytes were isolated from peripheral blood mononuclear cells using a CD14 magnetic bead separation kit. Cells were stimulated with LPS (100ng/ml) for 3-24 hours and to assess the effects of STAT3 inhibition, cells were pre-treated with STATTIC (10μM) for 30mins. A Human Cytokine and Chemokine PCR array was carried out and those genes most differentially expression were further validated in a larger cohort of patients using RT-PCR. The metabolic profile of cells was analysed using Seahorse XFE Technology, which concomitantly analysis glycolysis and mitochondrial respiration in real-time. Gene and protein expression of key inflammatory and glycolytic markers was also carried out by RT-PCR, western blotting and ELISA.

Results
CD14+ RA monocytes are hyper-inflammatory upon stimulation, with significantly higher expression of IL-1β, TNFα, IL-6, IL-27, CXCL10 and CXCL11 compared to healthy controls, which is indicative of a M1-like pro-inflammatory phenotype. These hyper-inflammatory cells are highly glycolytic, with increased expression of HIF1α and PFKFB3, a key glycolytic enzyme. Both baseline glycolysis and the maximal glycolytic capacity are increased in RA CD14+ monocytes, with no changes observed in mitochondrial respiration. This hyper-inflammatory, hyper-glycolytic phenotype is mediated by STAT3, as selective STAT3 inhibition can significantly decrease M1-like cytokines and PFKFB3 expression. Finally, this pro-inflammatory phenotype in evident in CD14+ monocytes from arthralgia ACPA+/RF+ people at risk of developing disease, demonstrating that these processes may precede clinical manifestations in RA.

Conclusions
This study demonstrates the unique inflammatory and metabolic phenotype of RA monocytes, suggesting that peripheral CD14+ monocytes may be pre-programmed to become M1-like pro-inflammatory macrophages. In addition, the observation of this phenotype in at-risk individuals indicates that these features may precede clinical manifestations of RA and therefore could be useful as a biomarker for early diagnosis.

(18A166) ABSTRACT 2 ORAL PRESENTATION BASIC SCIENCE

Genetics of Rare Disease: A novel familial RELA truncation associates with Behçet's-like Mucocutaneous Ulceration Syndrome

Author(s)
Emma Dorris, Fahd Adeeb, Dylan Lawless, Eoin Cummins, Sinisa Savic, Sandy Fraser, Anthony G. Wilson
Department(s)/Institutions
UCD Centre for Arthritis Research University of Limerick The University of Leeds UCD School of Medicine Croom Orthopedic Hospital

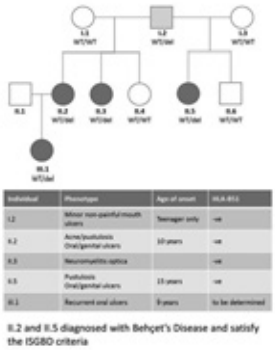
Introduction
Bechet's disease (BD) is a heterogeneous multifactorial auto-inflammatory condition characterized by recurrent episodes of oral and genital ulceration, uveitis and skin lesions, with less frequent involvement of the gastrointestinal tract, large blood vessels and central nervous system. The NF-κB pathway is a 'master-regulator' of immune and inflammatory signaling, with the ability to control the expression of key inflammatory genes and genes associated with apoptosis and proliferation.

Aims/Background
The aim of this study is to identify potentially causative mutations. The objective was to determine genotype-phenotype association with the aim of earlier and better disease suppression, preventing tissue damage and improving the quality of life of affected children.

Method
This study involved a 3-generation family with Behçet's-like mucocutaneous ulceration syndrome; primarily involving childhood-onset chronic oral and genital ulcers (figure 1). ISGBD criteria were used to diagnose Behçet's Disease (BD). DNA was isolated from PBMCs from affected patients and non-affected familial controls. DNA sequencing identified a cysteine deletion at position 1459 in RELA which segregated with the condition. Immunoblot analysis of RELA confirmed protein truncation. PBMCs were stimulated with TNF or IL1B and NFkB phosphorylation, apoptosis markers, translocation and transcriptional activation was measured relative to unstimulated controls.

Results
A heterozygous cysteine deletion at position 1459 in RELA was detected in affected individuals. This mutation is coding, inducing a frameshift His487ThrfsTer7, predicted to produce a truncated protein of 492 amino acids which would result in a ~6kDa smaller protein. This truncation was confirmed by immunoblot. Preliminary data indicates RelAHis487ThrfsTer7 heterozygotes have altered kinetics in inflammatory and apoptosis pathways in response to inflammatory stimulants.

Conclusions
This study gives novel information on both the genetic basis and biological mechanisms of inherited BD. Crucially, the His487ThrfsTer7 mutation interrupts the two C-terminal RELA transactivating domains. Our study supports several recently published studies that loss-of-function mutations in the NF-κB pathway are linked with the development of familial early-onset BD-like syndromes. Understanding both the genetic basis and biological mechanisms facilitates personalized medicines approaches that target the primary disease mediators, which result in earlier disease control and reduced tissue damage.



II.2 and II.5 diagnosed with Behçet's Disease and satisfy the ISGBD criteria

(18A130) ABSTRACT 3 ORAL PRESENTATION BASIC SCIENCE

Comparison of B and T cell subsets, cytokine expression and synovial pathology in Down's Arthritis (DA) and Juvenile Idiopathic Arthritis (JIA)

Author(s)
Charlene Foley[1], Achilleas Floudas[2], Mary Canavan[2], Monika Biniecka[2], Emma-Jane MacDermott[1], Orla G Killeen[1], Ronan Mullan[3] and Ursula Fearon[2]
Department(s)/Institutions
1 National Centre for Paediatric Rheumatology 2 Trinity Biomedical Sciences Institute 3 Tallaght Hospital

Introduction
A pathological feature of Down syndrome (DS) is dysregulation of the immune system. This almost certainly contributes to the high incidence of autoimmune diseases observed in this cohort. Previous work by our group suggests that the prevalence of Down's Arthritis (DA) is 18-21 fold greater than JIA. Children with DA often follow an erosive, polyarticular course of disease with small joint involvement observed in a significantly greater proportion ($p<0.01$) of children than expected in a typical JIA cohort. The DA clinical phenotype may be distinct from JIA, however little is known about the differences in synovial pathology or immunological regulation. Indeed no studies to date have examined these entities in DA.

Aims/Background
To examine B-cell subsets and T cell cytokine profiles; and characterise and compare the synovial membrane immunohistochemistry in children with DA and JIA.

Method
Multicolour flow-cytometry was used to analyse the phenotype of B-cells and T-cell cytokines in PBMCs from 40 children, n=10 per group; Healthy Control (HC), JIA, DS, DA. Cells were stained with the following panels;
B-cells (CD38, CD24, CD20, CD80, CD27, IgM, CD138, CD45, CD19, MHCclassII, BCMA, CD40, CD86, IgD);
T-cell cytokines analysed after 5hours PMA/Ionomycin stimulation (CD3, CD8, CD161, IFN-γ, TNF-α, IL-17a, GM-CSF).
Flow cytometry data was assessed by Flowjo software.
Synovial tissue was obtained through US-guided biopsy and analysed by immunohistochemistry for CD3, CD20, CD68, FVIII (DA n=3; JIA n=4).

Results
Flow cytometry analysis revealed that children with DA have a significantly lower number of circulating CD19+CD20+ B-cells when compared to children with JIA ($p<0.05$) and HC ($p<0.001$); however a greater proportion of memory B-cells (CD27+) when compared to children with DS ($p<0.05$).
IFN-γ and TNF-α production by CD8+/CD8- T-cells was greater in DA compared to both JIA (CD8+IFNγ+ $p<0.001$; CD8+TNFα+ $p<0.01$; CD8-IFNγ + $p<0.05$; CD8-TNFα $p<0.05$) and HC (CD8+IFNγ+ $p<0.05$; CD8+TNFα+ $p<0.05$; CD8-IFNγ+ $p<0.05$; CD8-TNFα $p<0.01$).
Examination of synovial tissue from children with DA demonstrated higher levels of CD3+cells, Macrophages ($p<0.05$), CD20+cells and FVIII.

Conclusions
There are significant differences in B-cell populations, T-cell cytokine production and immunohistochemical features of synovial tissue in children with DA and JIA. More work is required to verify these results.

(18A168) ABSTRACT 4 ORAL PRESENTATION BASIC SCIENCE

Distinct macrophage phenotype and bioenergetic profiles in Rheumatoid Arthritis

Author(s)
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Introduction
Synovial macrophages play a key role in RA disease progression, however, the diversity and plasticity of macrophage subsets and their metabolic profile within the joint has yet to be elucidated.

Aims/Background
To phenotype distinct macrophage subsets within the RA joint, and determine the metabolic, inflammatory and phagocytosis function of RA macrophages compared to healthy controls (HC).

Method
Synovial-tissue biopsies from RA, PsA and OA, obtained through arthroscopy, were digested to yield a single cell suspension. Biopsy suspensions and synovial fluid mononuclear cells were analysed using advanced flow-cytometry with the following antibody panel (CD40,-CD45,-CD64,-CD68,-CD163,-CD206,-CD253). CD14+ monocytes were sorted from RA and HC bloods and differentiated/ polarized into M1/M2 macrophages. Inflammatory (IL-8,-MCP-1,-IL-1b,-CCR5,-IRAK1,-OSM) and metabolic (HIF1a,-PFKFB3,-PKM2,-LDHA,-HK2) markers were measured by RT-PCR, and phagocytosis by OVA luciferase-yellow assays. Glycolysis (ECAR) and oxidative phosphorylation (OCR) were quantified by Seahorse -XFE- technology.

Results
RA synovial-tissue and fluid CD68+ macrophages displayed markers typical of both M1(CD40+CD253+) and M2(CD206+CD163+). A significant increase in frequency of CD68+ and CD64+ macrophages in synovial-tissue compared to fluid was observed ($p<0.05$), with significant increases in marker expression of CD40,CD163,CD206 ($p<0.07$). A spectrum of macrophage-subtypes within the inflamed joint was observed, with significant enrichment of a dominant double positive CD206+CD163+ macrophage-subtype in the synovial-tissue versus synovial fluid demonstrated ($p<0.05$). Increased frequency of CD206+CD163+ macrophages and higher expression of activation marker CD40 were demonstrated in RA synovial-tissue compared to PsA and OA. M1 macrophages demonstrate a pro-glycolytic phenotype with significant increases in HIF1a,-HK2,-PKM2,-and PFKB3, compared to M2, effects exacerbated in RA macrophages compared to HC. In parallel, using seahorse-technology RA M1 and M2 macrophages displayed higher ECAR and OCR profiles, in addition to an increased ECAR:OCR ratio compared to HC ($p<0.05$), evidence that RA macrophages switch to a glycolytic profile. This was paralleled by increased intracellular-cytokine expression of IL-1b,-IL-6 and TNFa and gene expression of IL-8,-IL-1b, OSM and MCP-1 ($p<0.05$). Finally, phagocytic ability of RA M1 was impaired compared to HC.

Conclusions
We have identified, for the first time, a dominant macrophages subtype enriched in RA synovial-tissue. Furthermore, RA M1/M2 have distinct metabolic profiles associated with differences in key inflammatory mediators and phagocytic function.

(18A201) ABSTRACT 5 ORAL PRESENTATION CLINICAL

Urate Lowering Therapy (ULT) reduces non-specific foot pain in patients who fail to meet ACR/EULAR 2015 Gout Criteria; an effect predicted by Ultrasound and potential rationale for re-classification.

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Introduction
The ACR/EULAR Criteria for gout require a prior history of acute attack involving a peripheral joint/bursa(1). The presence of chronic non-specific foot pain, which is insufficient for a gout diagnosis, may occur with hyperuricaemia(2).

Aims/Background
This case-control study evaluated urate deposition in hyperuricaemic individuals who do not fulfill gout criteria, and a potential role for ULT.

Method
Hyperuricaemic individuals with chronic foot pain, not fulfilling diagnostic gout criteria (n=16) were compared with asymptomatic hyperuricaemic controls (n=15). US of bilateral MTP1 and features of monosodium urate (MSU) crystal deposition including Double Contour (DC) sign, Tophus, or erosion were recorded. Cases only were treated with febuxostat 80mg for 3 months. Serum urate, 24hr and 7-Day VAS pain scales and the Manchester Foot Pain and Disability Index (MFPDI) were recorded.

Results
DC sign, Erosion and Tophus occured in 44%, 37% and 37% of cases respectively (Fig1). No US features of gout occurred in controls. Serum urate was higher in cases (449+19 µmol/L) vs controls (421+7.1;p=006). For cases, baseline 24-hr VAS (65+4.9) reduced at 1-month (41+6.6;P<0.001) and 3-month (32+7.4;P=0.001) of ULT. 7-day pain VAS (70+6.8) decreased at 1-month (43+7.1 P=0.001) and 3-months (37+8.3);P=0.001). MFPDI (25+2.1) decreased at 1-month (21+2.9;P=0.012) and 3-months (17+3;P=007). When grouped according to the presence (n=7) or absence (n=9) of DC sign, no differences were observed for baseline pain scores (Figure2). Following ULT therapy however, 24hr VAS pain scores were significantly lower in DC positive patients at 1-month (26+8.4 DC positive vs 52+8.1;P=0.05 DC negative) and 3-months (14.3+4.2 vs 49+10.1;P=0.017). 7-day VAS pain scores were significantly lower in DC positive patients at 1-month (27+7.6 vs 57+9;P=0.023) and 3-months (17.8+6.4 vs 56+11.6;P=0.026).

Conclusions
Ultrasound features of MSU crystal deposition are strongly associated with non-specific foot pain in hyperuricaemic patients, who do not otherwise fulfill the diagnostic criteria for gout. Treatment with ULT reduces non-specific foot pain to a greater extent in patients with US evidence of MSU crystal articular cartilage deposition. These findings suggest the ACR/EULAR 2015 criteria are insufficiently sensitive for early gout detection and should be changed to aid earlier treatment and long term control of this debilitating disease.

Figure

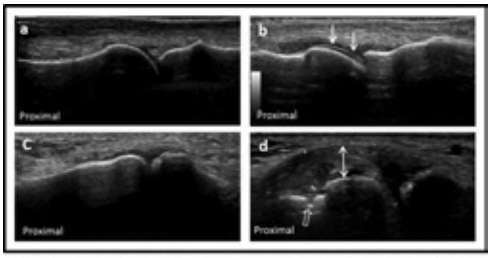

Fig 2. Ultrasound Features in Patients with Hyperuricemia. Dorsal longitudinal ultrasound of MTP1 in (a) isolated hyperuricaemia, (b) hyperuricaemia with non-specific foot pain. The presence of Double Contour sign due to articular cartilage MSU deposition is shown in (b) (solid arrows). (c) Medial longitudinal ultrasound of MTP1 in (c) isolated hyperuricaemia and (d) hyperuricaemia with non-specific foot pain. The presence of tophus (double headed arrow) and juxta-articular erosion (open arrow) over the medial surface of the 1st Metatarsal in (d) is shown. (Greyscale Images obtained using LogiqG9 at 15MHz).

Figure

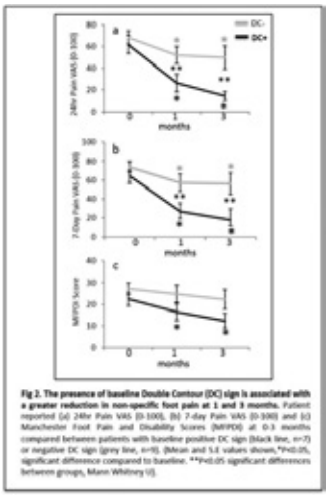

Fig 2. The presence of baseline Double Contour (DC) sign is associated with a greater reduction in non-specific foot pain at 1 and 3 months. Patient reported (a) 24hr Pain VAS (0-100), (b) 7-day Pain VAS (0-100) and (c) Manchester Foot Pain and Disability Scores (MFPDI) at 0-3 months compared between patients with baseline positive DC sign (black line, n=7) or negative DC sign (grey line, n=9). (Mean and S.E values shown, *P<0.05, significant difference compared to baseline. **P<0.05 significant differences between groups, Mann Whitney U).

(18A141) ABSTRACT 6 ORAL PRESENTATION CLINICAL

Lateral DXA More Effective in Detecting Osteoporosis than Conventional DXA in Axial Spondyloarthropathy

Author(s)
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Introduction
The consequences of osteoporosis are well outlined. In axial spondyloarthropathy (axSpA), osteoproliferation of the spine means posterioanterior (PA) dual-energy x-ray absorptiometry (DXA) can't discriminate between new bone formation and vertebral body, potentially overestimating BMD. Lateral DXA of the spine avoids spinal osteoproliferation and is an attractive option.

Aims/Background
The aim of this study is to compare lateral and PA DXA of the lumbar spine and determine patient variables that render conventional DXA unreliable.

Method
Patients fulfilling modified New York (mNY) or Assessment of Spondyloarthritis International Society (ASAS) criteria were consecutively recruited in this twin-centre cross-sectional study.

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Otezla® (apremilast) 30mg tablets

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Broad and sustained efficacy[1-3]

- Significant improvements vs placebo in a broad range of clinical outcomes, with responses that were sustained during 1 year of follow-up in psoriasis[1,2*] and 3 years in psoriatic arthritis[3]

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- OTEZLA is an oral therapy with no label requirement for pre-screening for tuberculosis or routine treatment-specific laboratory monitoring required[1]

The reassurance of a long-term safety and tolerability profile[4,5]

- In Phase 3 trials, the most common adverse events (AEs) were generally mild to moderate in severity[1]
- Long-term follow-up (≥3 years) indicated generally no increase in the incidence or severity of AEs[4,5]

Help your patients move forward with OTEZLA

For special warnings and precautions on psychiatric disorders, GI, severe renal impairment, and underweight patients, please refer to the OTEZLA Summary of Product Characteristics.

*Sustained efficacy was shown in patients who continued receiving OTEZLA after demonstrating a response at Week 32 (psoriasis; PASI-75).[2]

Prescribing Information: OTEZLA® (apremilast) 10mg, 20mg and 30mg film coated-tablets.
Refer to the Summary of Product Characteristics (SPC) before prescribing
Further information is available upon request
Presentation: 10mg, 20mg and 30mg film coated-tablets. **Indications**: Psoriatic arthritis: OTEZLA®, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Psoriasis: OTEZLA® 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 ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). **Dosage and administration**: Treatment with OTEZLA® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required per the following schedule: Day 1: 10mg in the AM; Day 2: 10mg in the AM and 10 mg in the PM; Day 3: 10mg in the AM and 20mg in the PM; Day 4: 20mg in the AM and 20mg in the PM; Day 5: 20mg in the AM and 30mg in the evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis. **Special populations**: Elderly patients: No dose adjustment is required for this patient population. Patients with renal impairment: No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of OTEZLA® should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that OTEZLA® is titrated using only the AM doses and the evening doses be skipped. Patients with hepatic impairment: No dose adjustment is necessary for patients with hepatic impairment Paediatric population: The safety and efficacy of OTEZLA® in children aged 0 to 17 years have not been established. No data is available. **Contraindications**: Hypersensitivity to the active substance(s) or to any of the excipients. OTEZLA® is contraindicated in pregnancy. Pregnancy should be excluded before treatment can be initiated. **Special warnings and precautions**: Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Severe diarrhoea, nausea, and vomiting associated with the use of Otezla has been reported. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older may be at a higher risk of complications. Discontinuation of treatment may be necessary. OTEZLA® is associated with an increased risk of psychiatric disorders such as insomnia and depression. Instances of suicidal ideation and behaviour, including suicide, have been observed in patients with or without history of depression. The risks and benefits of starting or continuing treatment with OTEZLA® should be carefully assessed if patients report previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products likely to cause psychiatric events is intended. Patients and caregivers should be instructed to notify the prescriber of any changes in behavior or mood and of any suicidal ideation. If patients suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with OTEZLA®. OTEZLA® should be dose reduced to 30mg once daily in patients with severe renal impairment. OTEZLA® may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. OTEZLA® should not be used during breast-feeding. No fertility data is available in humans. **Interactions**: Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of OTEZLA®, which may result in a loss of efficacy of OTEZLA®. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with OTEZLA® is not recommended. In clinical studies, OTEZLA® has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and OTEZLA®. OTEZLA® can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between OTEZLA® and methotrexate in psoriatic arthritis patients. OTEZLA® can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between OTEZLA® and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA® can be co-administered with oral contraceptives. **Side effects**: The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Very commonly reported adverse events are listed as: diarrhoea* and nausea*. Common adverse events are listed as: bronchitis, upper respiratory tract infection, nasopharyngitis*, decreased appetite*, insomnia, depression, migraine*, tension headache*, headache*, cough, vomiting*, dyspepsia, frequent bowel movements, upper abdominal pain*, gastroesophageal reflux disease, back pain*, fatigue. Prescribers should consult the summary of product characteristics in relation to other side-effects. Hypersensitivity* and risk of triggering suicide* have also been reported. *At least one of these adverse reactions was reported as serious **Legal category**: POM **Marketing authorisation numbers**: EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder**: Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB. **Date of preparation**: Jan 2018 **Approval code**: UK-I&I140098a(2)

Please report any suspected adverse reactions directly to the Health Products Regulatory Authority (HPRA) using the online forms at www.hpra.ie or the freepost reporting system
Adverse events should also be reported to Celgene Drug Safety
Tel: 1800 936 217 Fax: 1800 936 477

References:
1. OTEZLA (apremilast) 30 mg tablets. Summary of Product Characteristics. Celgene Europe Ltd. **2.** Papp K, et al. *J Am Acad Dermatol.* 2015;73(1):37–49. **3.** Kavanaugh A, et al. Poster presented at: the Annual Meeting of the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP), 6–11 November 2015; San Francisco, CA (#2843). **4.** Crowley J, et al. *J Am Acad Dermatol.* 2017;77(2):310-317. **5.** Mease PJ, et al. Poster presented at: the Annual European Congress of Rheumatology (European League Against Rheumatism [EULAR]), 8–11 June 2016; London, UK (#FRI0470). **6.** Torres T & Puig L. *Am J Clin Dermatol.* 2018;19(1):23-32.

Date of preparation: July 2018
UK-OTZ180020h

A detailed assessment of patients included demographics, clinical exam, laboratory assessment and validated measures of disease severity (BASDAI, ASDAS-CRP, BASMI, mSASSS). BMD of the spine was assessed using DXA in the lateral and PA projections. R software was used for statistical analysis.

Results

One hundred and ten patients were assessed, 100 of whom had paired AP and lateral DXAs: 76% (n=84) male, 92% Caucasian, 81% mNY criteria. Median (IQR) age was 52 (17) years, disease duration 23.5 (20) years, delay to diagnosis 7 (12) years, body mass index (BMI) 27.6 (6.3) kg/m2, BASDAI 3.9 (2.1-5.6), BASMI 4.1 (2.8-5.8), ASDAS-CRP 2.2 (1.5-3), mSASSS 8.5 (2-36).

Lateral spine BMD is significantly lower than PA BMD (mean difference between AP and lateral lumbar spine DXA of 0.337 g/cm2, 95% CI 0.3-0.37) and detects more cases of both osteopenia (27% versus 17%) and osteoporosis (16% versus 2%) at the spine ($p<0.01$).

The following variables correlate with a larger difference between the measurement of AP and lateral DXA: BASMI (r=0.54), disease duration (r=0.37), BMI (r=0.32), mSASSS (r=0.52).

In multiple regression analysis, a model with disease duration, BMI, BASMI and shorter time to diagnosis predicts a greater difference between AP and lateral BMD ($p<0.05$).

Conclusions

Lateral DXA detects more cases of osteoporosis than PA DXA, particularly in patients with higher BASMI and BMI and longer disease. Relying on AP DXA may miss low BMD in axSpA patients. Lateral DXA is a practical and alternative to PA DXA when measuring BMD in the spine of axSpA patients.

(18A133) ABSTRACT 7 **ORAL PRESENTATION CLINICAL**

Beyond NSAIDS : second-line therapeutic agents for chronic recurrent multifocal osteomyelitis

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Department(s)/Institutions

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Introduction

Chronic recurrent multifocal osteomyelitis (CRMO) is a rare autoinflammatory disease affecting bone. Untreated CRMO can result in complications such as vertebral compression fractures and leg length discrepancy. First line treatment is with non-steroidal anti-inflammatory drugs (NSAIDs) with a reported response rate of 50-80%. Limited data is available on the efficacy of second-line treatments which include methotrexate, bisphosphonates and biologic agents.

Aims/Background

To describe the experience of the National Centre for Paediatric Rheumatology (NCPR) treating currently attending CRMO patients with second-line agents.

Method

Retrospective chart review of current patients requiring second-line agents attending the National Centre for Paediatric Rheumatology. Persistent active disease was defined as persistent pain with tenderness/warmth or persistent bone oedema on MRI in at least one lesion site after >4 weeks treatment (CARRA consensus treatment guidelines). Response to treatment was defined as clinical and/or radiological improvement without complete resolution. Remission was defined as normal ESR, absence of clinically active lesions, resolution of marrow oedema on MRI and absence of new lesions on whole-body MRI (modified CARRA criteria for treatment failure).

Results

Clinical charts of 30 patients with CRMO were reviewed. Second-line treatment was required in 60%. The indications for second-line treatment were persistent active disease on NSAIDS or the presence of spinal lesions or cosmetically significant mandibular lesion.

A total of 19 patients received methotrexate, either alone (n=8) or in combination with a biologic agent (n=11). Three received pamidronate; none achieved remission and all subsequently received methotrexate +/- biologic. Of those who received methotrexate monotherapy, 1 is in remission on treatment, 1 remains in remission off treatment, 6 have responded but not achieved remission.

Of those on biologic combination therapy, 2 patients are in remission, 1 discontinued treatment due to a hypersensitivity reaction. The remaining patients improved but have yet to achieve remission.

Conclusions

Treatment with second-line agents has led to a symptomatic improvement in all patients.

Combination therapy of methotrexate and a biologic agent may be the most favourable option but randomised controlled trials with clearly defined response and remission criteria are required.

(18A187) ABSTRACT 8 **ORAL PRESENTATION CLINICAL**

Risk of Obstructive Sleep Apnoea in Patients with Rheumatic Disease: A Prospective Cohort Study

Author(s)

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Department(s)/Institutions

1 Department of Rheumatology, University Hospital Limerick 2 Department of Respiratory, University Hospital Limerick

Introduction

Sleep plays an important component in our lives and sleep abnormalities have been known to be linked with various rheumatic conditions.1,2 Obstructive sleep apnoea (OSA) could potentially affect the severity of rheumatic symptoms such as pain, fatigue and also influence the disease activity.

Aims/Background

This study aims to evaluate the risk of OSA in patients with rheumatic diseases in an Irish cohort.

Method

Patients with a diagnosis of a rheumatic disease were recruited from Rheumatology outpatients. These patients were asked to complete the Berlin Sleep Questionnaire(BSQ) to evaluate their level of risk for OSA. The Health Assessment Questionnaire(HAQ), Patient Global Assessment(PtGA) and the Physician Global Assessment(PhGA) were also completed.

Results

111 patients were recruited. Mean age was 52 years and 22(19.8%) were males. The most common diagnosis in our cohort was rheumatoid arthritis 54(45.4%), followed by spondyloarthritis 12(10.1%), psoriatic arthritis 11(9.2%), systemic lupus erythematosus 9(7.6%), Behçet's disease 7(5.9%), scleroderma 6(5.0%) and others 20(16.8%); with 8 patients having two diagnoses. Our cohort also completed the HAQ which demonstrated 98(88.3%) having mild to moderate disability and 13(11.7%) having moderate to severe disability. 39 out of 111 were noted to have a high risk for OSA based on the BSQ. In the high risk cohort, the mean PtGA score was 46.5 while PhGA score was 30.3, compared to the low risk cohort which

was 36.7 for PtGA and 24.9 for PhGA. 33(84.6%) patients in the high risk cohort had mild to moderate disability and 6(15.4%) had moderate to severe disability as compared to 64(88.9%) with mild to moderate disability and 8(11.1%) with moderate to severe disability in the low risk cohort.

Conclusions

This is the first prospective study in Ireland to evaluate the risk of OSA in patients with rheumatic diseases. 35.1% from our cohort were found to be at high risk for OSA and are due to undergo overnight pulse oximetry and polysomnography to objectively assess the presence or absence of OSA. The disease activity reported by both patient and physician along with the level of disability were greater in the high risk cohort. This suggests that OSA increases the likelihood of exacerbating rheumatic activities.

(18A101) ABSTRACT 9 **POSTER 1**

Monitoring of lipids in patients on tocilizumab following introduction of 'new subcutaneous tocilizumab progress chart'

Author(s)

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Introduction

Tocilizumab is a humanized monoclonal antibody that inhibits cytokine interleukin-6. The British Society for Rheumatology recommends lipid monitoring in patients receiving tocilizumab - fasting lipids at baseline and at 3 months into treatment.1

Aims/Background

We carried out an audit looking at lipid monitoring in patients on tocilizumab between August 2016 and February 2017. It demonstrated that even if patients were having their lipid profile checked the results (when high) were not always acted upon. We have therefore identified a need for 'new subcutaneous tocilizumab progress chart' with the reminder to check lipids.

Method

We looked at all patients newly commenced on subcutaneous tocilizumab between October 2017 and April 2018. Eight patients were identified and retrospective data collection from medical charts was performed.

Results

The 'new subcutaneous tocilizumab progress chart' was present in 75% of patients' medical notes. 75% of patients had fasting lipids checked at baseline. The introduction of 'new subcutaneous tocilizumab progress chart' has increased the number of patients who had their lipids checked at 2-3 months into treatment from 50% to 75%. Furthermore, 100% of patients who were identified to have high cholesterol levels had appropriate plan of action recorded in their notes. The audit has also identified that those patients who did not have the new progress chart used in their notes had neither baseline nor repeat lipid profile done.

Conclusions

In summary, introduction of the 'new subcutaneous tocilizumab progress chart' improved lipid monitoring and management in patients newly commenced on subcutaneous tocilizumab therapy.

References:

1. Malaviya AP., Ledingham J. et al. "The 2013 BSR and BHPR guideline for the use of intravenous tocilizumab in the treatment of adult patients with rheumatoid arthritis". Rheumatology 2014; 53:1344-1346

S/C TOCILIZUMAB PROGRESS CHART

Patient details: (Affix stickers/graph)

Consultant:

Date of 1st dose _____

Review Date	ESR	CRP	HAQ	DAS 28/4	TJC	SJC	Global Health (0-100)	Steroid Dose	Weight	LIPIDS				
										Total	LDL	HDL	Ratio	Management if applicable

(18A104) ABSRACT 10 **POSTER 2**

The Utility and Limitations of CRP, ESR and DAS28-CRP, in Appraising Synovial Inflammation in Rheumatoid Arthritis

Author(s)

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Department(s)/Institutions

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Introduction

Identifying and quantifying inflammatory disease activity in RA remains a challenge. Many studies have suggested that a large proportion of patients may have active inflammation, but normal inflammatory markers. Although various disease activity scores have been validated, most rely on biomarkers such as CRP and ESR.

Aims/Background

Since the synovium is the principal target of inflammation in RA, we studied the synovium at the microscopic level, and relate CRP, ESR and DAS28-CRP with histological features of synovial biopsies, including specific cellular infiltrate. In this study, we examine the utility and limitations of these biomarkers, as well as the DAS28-CRP in appraising disease activity in RA.

Method

223 consecutive rheumatoid arthritis reporting knee arthralgia underwent synovial sampling of the affected knee via needle arthroscopy. The synovium was examined by microscopy with H+E staining as well as immunohistochemistry, and related to the ESR, CRP and DAS28-CRP on samples taken immediately before arthroscopy.

Results

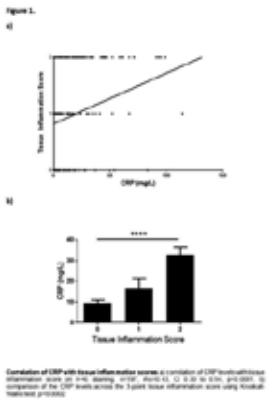
Although a statistically significant positive correlation was observed between CRP and the level of inflammation in the biopsy retrieved ($n = 197$, rho = 0.43, CI 0.30–0.54, $p < 0.0001$, figure 1), there was histological evidence of inflammation in the synovium in 49.4% of the patients who had a normal CRP (figure 2). A positive correlation was also observed between ESR and the level of inflammation in the biopsy retrieved ($n = 188$, rho = 0.29, CI 0.15–0.42 $p < 0.0001$). A statistically significant but weak positive correlation was observed between the DAS28-CRP and synovial inflammation ($n = 189$, rho = 0.23, CI 0.09–0.37, $p= 0.0011$). Only the CD19 infiltrate in the synovium correlated with serum CRP ($n = 70$, rho = 0.32, CI 0.08–0.52, $p = 0.0068$).

Conclusions

CRP has a moderately strong relationship with disease activity, but there are significant pitfalls in the use of this biomarker in RA, and therefore a need interpret CRP results judiciously. The results of this study underline the heterogeneity of RA, and the need to develop

improved panels of biomarkers, to better stratify RA, and to identify the cohort for whom inflammatory activity cannot be measured accurately with CRP.

Figure



Figure

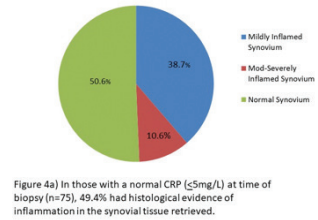


Figure 4a) In those with a normal CRP (≤5mg/L) at time of biopsy (n=75), 49.4% had histological evidence of inflammation in the synovial tissue retrieved.

(18A105) ABSTRACT 11

POSTER 3

Real Life Switching from Infliximab Innovator (Remicade) to Biosimilar (Inflectra) in Patients with Various Rheumatic Diseases: a 6-month Single-Centre Prospective Observational Study

Author(s)

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Introduction

Inflectra, biosimilar infliximab has been approved by the European Medicine Agency since September 2013 for all licensed indications of Remicade (innovator infliximab) having demonstrated similar pharmacokinetics, safety, and efficacy to those of innovator INX. Although Biosimilars can offer significant cost savings, there is a paucity of real-world data and guidelines regarding switching from innovator Remicade to Inflectra.

Aims/Background

The aim of this study was to explore the efficacy, safety, acceptance and retention rate of biosimilar CT-P13 after switching from Remicade, originator infliximab in patients with various rheumatic diseases.

Method

A proposal to switch was made to all patients attending our rheumatology infusion unit. Baseline demographics and clinical characteristics were obtained before switching to Inflectra (biosimilar). Disease activity and safety assessment were undertaken before and then every 12 weeks after switching. The retention rate of Inflectra switch patients was compared with a cohort of Inflectra naive (11 patients) and historic Remicade (31 patients) patients.

Results

: Thirty out of thirty-one patients {median (IQR) age 50 (18), 20F} with various rheumatic diseases (9 with diagnosis of AS, 6 with RA, 6 with Behcet disease, 3 with Enteropathic arthritis, 2 with psoriatic arthritis and 1 with JIA, Graves ophthalmopathy, juvenile dermatomyositis and undifferentiated inflammatory arthritis each) agreed to the switch. After 6 months of Inflectra, we could not find any statistical difference in term of mean values of PGA {33 (26.3) vs 35.3 (24) p=0.37}, BASDAI (3.12 (1.2) vs 2.98 (1.5) p=0.60} , SDAI {14.6 (16.5) vs 13.1 (10.4) p=0.65}, DAS28CRP {3.9 (1.6) vs 3.28 (1.0) p=0.85}, CRP {3.13 (4.2) vs 3.48 (4.8) p=0.09} , Behcet disease score {1.17 (1.3) vs 1.33 (2.16) p=0.77} and HAQ-DI {0.42 (0.45) vs 0.45 (0.47) p=0.18}. The retention rate on Inflectra switch was 86.7% as compared to 90.9% on Inflectra naive cohort and 100% for historic Remicade cohort.

Conclusions

These results demonstrate that is Inflectra is comparable to Remicade in efficacy and there are no new safety signals. Subjective symptoms were an important cause for a slightly lower retention rate in switch group and this we believe may be due to a degree of the nocebo effect.

Figure

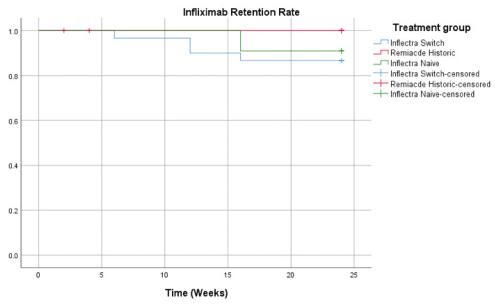
Table 1 Baseline characteristics of Inflectra switch and Inflectra naïve patients groups

Characteristics at inclusion	Inflectra switch population (n = 30)	Inflectra-naïve population (n = 11)
Age, years, mean (S.D.)	50 (12.2)	47.2 (15.2)
Female Sex	20 (66.7%)	6 (54.5%)
Disease duration mean(S.D.)	6.8 (2.9)	8 (5.2)
Weight, Kgs, mean (S.D.)	72.4 (10.5)	94.2 (30.9)
Height, centimeters, mean (S.D.)	166.6 (9.14)	165.9 (8.4)
BMI, kg/m², mean (S.D.)	26.1 (3.65)	34.5 (11.8)
Infliximab dose, mg/kg, median (range)	5 (3-8)	5
Infliximab infusion rhythm, median (range)	6 (4-12)	6 (6-8)
Duration of being on Infliximab before switch, months, median (range)	72 (24-192)	11 (2-26)
Concomitant csDMARDs, n (%)	16 (53.3%)	6 (54.5%)
Methotrexate, dose, mg, median (range)	15 (10-25)	15 (10-25)
Concomitant corticosteroids, n (%)	9 (30%)	6 (54.5)
Previously been on other bDMARDS, n (%)	19 (63.3%)	11 (100%)

Figure

Table 2 Comparison of various pre-switch and post switch disease activity measures

Parameter	Pre-switch	6 months Post switch	p-Value
PGA mean	33+26.3	35.3+24	0.369
BASDAI mean	3.12±1.2	2.98±1.5	0.60
ASDAS-CRP mean	1.7+0.57	1.67+ 0.67	0.90
SDAI mean	14.6± 16.5	13.1± 10.4	0.65
DAS28CRP mean	3.9+ 1.6	3.28+ 1.0	0.85
DAS28ESR mean	3.97± 2.04	3.49± 1.20	0.45
TJC median	5+6	3+ 8	0.67
SJC median	0+ 4	0+ 2	0.23
CRP mean	3.13± 4.2	3.47±4.8	0.096
ESR mean	13.7+11.9	12.47+7.99	0.41
BD activity Score mean	1.17±1.3	1.33±2.16	0.77
HAQ-DI mean	0.42+0.45	0.45+0.47	0.18



(18A107) ABSTRACT 12 POSTER 4

Rapid Response With Upadacitinib Treatment in Patients with Rheumatoid Arthritis and an Inadequate Response to csDMARDs or bDMARDs

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Introduction
Upadacitinib (UPA), a potent JAK inhibitor with preferential activity against JAK-1, demonstrated efficacy in patients (pts) with moderate to severe rheumatoid arthritis (RA) with an inadequate response (IR) to csDMARDs or bDMARDs in the SELECT-NEXT1 and SELECT-BEYOND2 trials, respectively.

Aims/Background
To investigate the speed of response to UPA across disease measures in csDMARD- and bDMARD-IR pts.

Method
661 pts in NEXT and 498 in BEYOND received UPA 15mg or UPA 30mg once daily (QD) or placebo (PBO) for 12 weeks (wks)1,2. Time to first achievement of clinically meaningful outcomes, including ACR20/50, DAS28-CRP≤3.2 and Low Disease Activity (LDA) measures of CDAI (≤10) and SDAI (≤11) was evaluated. The cumulative incidences of ACR20/50, DAS28-CRP ≤3.2 and LDA by CDAI and SDAI over 12 wks were estimated. Hazard ratios between UPA and PBO were obtained using Cox proportional hazards model with treatment group, corresponding baseline values and main stratification factors, without control for multiple comparisons. All analyses were based on observed data without imputation.

Results
Pts had a disease duration of 7 and 13 years in NEXT and BEYOND respectively.1,2 In BEYOND, pts were treatment-refractory as evidenced by 53% having received ≥2 prior bDMARDs2. Median times to achieve ACR20 were similar, irrespective of pt population, being 4 wks for UPA 15mg QD and 2-3 wks for UPA 30mg QD vs 12 wks on PBO (p<.001). In general, the median times to achieve ACR50, DAS28-CRP≤3.2 for UPA 15mg and 30mg QD were ~12 wks and ~8 wks for both csDMARD-IR and bDMARD-IR pts, whereas the median was not reached for pts on PBO during the first 12 wks (p< 0.001, Table 1). The median time to LDA by CDAI and SDAI was ~12 wks across UPA doses and populations, but was not reached for pts receiving PBO within that time. Pts receiving UPA were 2-4 times more likely to achieve clinical responses vs pts receiving PBO. In general, both UPA doses performed similarly across pt populations, with numerically quicker responses observed in pts receiving UPA 30mg vs UPA 15mg QD. Median times to achieve 20% and 50% improvements in tender and swollen joint counts were 1-2 wks and 2-4 wks respectively, for both UPA doses irrespective of pt population. Median times to achieve 20% improvements in morning stiffness duration and severity were approximately 2 wks in each of the UPA arms vs 4 wks on PBO (p< 0.001).

Conclusions
Pts receiving UPA at either 15mg or 30mg QD were more likely to achieve clinical responses at significantly earlier time points when compared with pts receiving PBO. Irrespective of being csDMARD-IR or bDMARD-IR, times to achieve various clinical responses were consistent between pt populations.

(18A108) ABSTRACT 13 POSTER 5

NSAIDs (Non Steroidal anti inflammatory drugs) prescription's practice in Rheumatology Department

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Introduction
The treatment of inflammatory Rheumatic conditions has revolutionized in the last 2 decades shifting from the conventional oral analgesic to potent Biologics. The main aim being targeting the synovitis, and preventing joint damage, and disability.

Aims/Background
NSAIDs are one of the commonly used, and an effective analgesic in treating inflammatory arthritis. The annual prescription figure is around 110 million, just in the USA. Despite, its efficacy, the limiting factor for its' use is the side effects, particularly peptic ulceration, and its complications, such as haemorrhage and perforation, renal injury and cardiovascular risk.
5_ 7 % of hospital admission are related to adverse effects of NSAIDs and among them, resulting from gastrointestinal, nervous system, and allergic reactions.

Method
A prospective study
- Age
- Sex
- Diagnosis
- taking NSAIDS or not ?
- Name of the NSAIDS.
- cardiac conditions
- renal disease
- Who prescribed the medication?

Results
Age n: 160
Below 65 : 134
Above 65 : 26

Age and NSAIDs

Below 65 Yes :57 , No :77
Above 65 Yes : 14, No: 14

Cardiac history , n :8
Patients with cardiac conditios :8
Cardiac history , Atrial fibrillation :2
IHD /PCI: 1
MI: 1
AVR :1
Patients with cardiac history and taking NSAIDs 7/8 (87.5%)
Name of NSAIDs taken Etoricoxib :3
Diclofenac : 3
Ibuprofen :1
Renal disease, n :3

Number of patients with renal disease 3
Renal disease CKD :3
Renal disease and NSAIDS 1/3 : 33.3
NSAIDs Diclofenac

NSAIDs prescribed by a Rheumatologist :43%
GP : 45%
Both :12%

Conclusions
The high risk group, being above 65 and having a cardiac history, were prescribed NSAIDs, which reflects the current prescribing practice which needs to be addressed, in order to minimise the NSAIDs related side effects in these patients

(18A109) ABSTRACT 14 **POSTER 6**

Effects Of Baricitinib On Patients Who Stop Methotrexate Monotherapy And Switch To Baricitinib Monotherapy

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Introduction
Baricitinib (BARI) is a reversible oral JAK inhibitor with selectivity for JAK1/JAK2 for active Rheumatoid Arthritis.
Aims/Background
Efficacy and safety were evaluated in pts from RA-BEGIN who switched from methotrexate (MTX) or the combination of BARI+MTX to BARI upon entering LTE study (RA-BEYOND).
Method
In RA-BEGIN, 588 pts were randomised to MTX, BARI monotherapy, or BARI+MTX. At wk 52, pts could enter the LTE; all pts received BARI 4 mg monotherapy. MTX could be added by investigator decision. 451 pts enrolled in LTE: 423 not rescued in RA-BEGIN. This post-hoc analysis evaluated efficacy of pts who continued BARI monotherapy compared to those in whom MTX was added before wk 24.
Results
200/423 (47%) remained on monotherapy at wk 24, and 223 pts started on MTX before wk 24. Most (193) initiated MTX within 4 wks of LTE start. Pts who had MTX added in the LTE had worse disease control upon entry and during the LTE. Through 24 wks, statistically significant improvement in disease state was observed in the MTX-to-BARI group regardless of whether or not MTX was added back. In the BARI-to-BARI monotherapy group, the addition of MTX led to lowered disease activity, which was statistically significant. No statistically significant changes in disease activity were observed in the pts who were switched from BARI+MTX to BARI monotherapy regardless of additional MTX. Exposure-adjusted incidence rates for total treatment-emergent adverse events were lowest in the MTX-to-BARI group. Clinically significant differences in SIE, SAEs, or AEs leading to drug discontinuation were not seen in any of the arms.
Conclusions
Switching from MTX to BARI, maintaining BARI monotherapy was associated with improvements in disease control during the initial 24 wks post-switch. Disease control did not significantly change after MTX withdrawal. Discontinuation of MTX in pts treated with combination during the index study was associated with maintenance of response. Pts who entered the LTE with suboptimal disease control after treatment with BARI monotherapy or who discontinued combination therapy may benefit from the addition of MTX. There were no differences in safety measures including serious events or led to drug discontinuation.

(18A110) ABSTRACT 15 **POSTER 7**

Effects of Baricitinib on Haematological Laboratory Parameters in Patients with Rheumatoid Arthritis

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Introduction
Baricitinib (BARI) is a reversible oral JAK inhibitor with selectivity for JAK1/JAK2 for active Rheumatoid Arthritis.
Aims/Background
Rheumatoid arthritis is associated with an increased neutrophil and platelet count, and decreased lymphocyte count.
Method
To summarise changes in absolute neutrophil counts (ANC), absolute lymphocyte counts (ALC), platelet counts, and haemoglobin (Hgb), and associated adverse events, with baricitinib (BARI [JAK1/2 inhibitor]) treatment. Data were pooled from completed Phase 1/2/3 studies and an extension study.
Results
BARI treatment was associated with a decrease in ANC and an increase in ALC and platelets, which stabilized and returned to baseline with prolonged treatment or treatment discontinuation. Neutropaenia (<1000 cells/mm3) was rare (<1%) and was not associated with higher risk of overall or serious infections. Lymphopaenia was associated with slightly higher rate of overall infections. Incidence of overall and serious infections in ALL BARI-RA set was 29.9 and 2.9 per 100 patient-years, respectively.
More BARI 4-mg (2.3%) as compared to placebo-treated (1.3%) patients had platelet count ≥600x109/L. In 6-study placebo-controlled set (0-24 weeks), 5 BARI 4-mg-treated patients (vs 0 placebo-treated) had "deep vein thrombosis" (DVT) and/or "pulmonary embolism" (PE). Incidence of overall and serious DVT/PE in ALL BARI-RA set remained low at 0.5 and 0.3 per 100 patient-years, respectively. The proportion of patients with high platelet levels (≥600x109/L) was comparable between patients with DVT/PE vs those without DVT/PE (at baseline: 0 vs 0.5%; post-baseline: 6.5% vs 3.3%).
With long-term BARI treatment, Hgb levels decreased transiently before returning to levels slightly higher than baseline at Week-52. Incidence of severe treatment-emergent shifts in Hgb (grade <3 to grade ≥3: <8 and ≥6.5 g/dL) was low across all treatment groups (<0.5%).
Conclusions
No associations were observed between ANC decrease and infections or thrombocytosis and DVT/PE. BARI treatment was

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NP-2714 Date of preparation: August 2017

not associated with an increased incidence of erythropaenia-related events or anaemia as compared to placebo. Few patients interrupted/discontinued BARI due to TE laboratory abnormalities.

(18A111) ABSTRACT 16 **POSTER 8**

Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 5.5 years: an Updated Integrated Safety Analysis

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Introduction
Baricitinib (bari), an oral, selective inhibitor of Janus kinase (JAK) 1 and JAK 2, is approved in the EU, US, and Japan for the treatment of moderately to severely active RA in adults. We further describe the drug's safety profile with updated data from an on-going long-term extension (LTE) study.

Aims/Background
We further describe the drug's safety profile with updated data from an on-going long-term extension (LTE) study.

Method
Long-term safety of once-daily bari was evaluated in "all-bari-RA" dataset [all active RA patients on bari from 8 randomized trials (4 Ph3, 3 Ph2, 1 Ph1b) and 1 LTE study (data up to 01-Sept-2016)]. PBO comparisons were evaluated up to Wk 24 in "PBO-4mg" dataset from 6 Ph2/3 trials, in which patients were randomized to bari 4mg, censoring at rescue or treatment switch. Dose responses were evaluated from 4 Ph2/3 trials, in which patients were randomized to 2 or 4mg and includes data from LTE ("2mg-4mg-extended" dataset) censoring at rescue or dose change (as-treated analysis). Because of latent period for malignancy, 2mg 4mg extended was analyzed without censoring for rescue or dose change. Incidence rates (IR) per 100 patient years (PY) were calculated.

Results
3492 patients received bari for 6637 total PY of exposure (>2400 PY increase from previous analysis); maximum exposure was 5.5 yrs. No differences were seen for bari 4mg vs PBO in AEs leading to permanent discontinuation, death, malignancy, serious infection, or MACE. Herpes zoster IR was significantly higher for bari 4mg vs PBO (IR 1.0 vs 4.3). Malignancy (excluding non-melanoma skin cancer) IR were 0.5 and 1.3 for 2mg and 4mg (as-treated analysis) and 0.7 and 0.9 (as-randomized analysis). IRs for aforementioned events and lymphoma (0.09), gastrointestinal perforation (0.05), and tuberculosis (0.15, all in endemic areas) in the current all-bari-RA were similar to previous reports. Less than 1% of patients discontinued due to abnormal lab results.

Conclusions
Baricitinib maintained a safety profile similar to previous reports1 and acceptable in the context of demonstrated efficacy.2,3

References:
1. Smolen JS et al. Ann Rheum Dis 2016:75(Suppl 2):243-4.
2. Taylor PC et al. NEJM 2017:376:652-62.
3. Genovese Mc et al. NEJM 2016:374:1243-52.

(18A112) ABSTRACT 17 **POSTER 9**

Safety Summary Results of Baricitinib Focusing on Serious Infections Events and Preselected Comorbidities

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Introduction
Baricitinib (BARI) is an oral selective JAK1/JAK2 inhibitor for the treatment of patients with Rheumatoid Arthritis (RA) with an acceptable safety profile.

Aims/Background
Objective is to evaluate the incidence rate (IR) of serious infection events (SIE) and selected comorbidities.

Method
Exposure adjusted IR of SIE were summarized in 6-study- and 4-study- PBO-controlled sets, 0-24 weeks (wks), plus in ALL-BARI-RA set (any BARI dose for ≤5years (Ph 1-3/LTE studies)). Potential risk factors for SIE were investigated in ALL-BARI-RA set using Cox models. Sensitivity analysis for comorbidities included patients (N=1683) from 5 studies (BARI 4mg/PBO) up to 16wks.

Results
The most frequent SIE observed in the ALL-BARI-RA-set (N=3492; 5133 patient-years (PY) of exposure [PYE]) were pneumonia, herpes zoster, urinary tract infection, and cellulitis (all <1%), 150 patients reported SIE (IR=2.9/100PY), and 2 patients with SIE died (IR=0.04/100PY). During wks0-24, similar SIE rates were observed in BARI 4mg (N=997;417PYE) and PBO (N=1070;403PYE) groups in the 6-study-set, and between BARI 2/4 mg (N=479;192PYE/N=479;194PYE) dose groups in the 4-study-set. Prior biologic use, advancing age, region of Asia (excluding Japan), abnormal body mass index (BMI), and corticosteroid use were identified as independent factors for SIE in the ALL-BARI-RA-set, and none differed significantly between BARI 4mg and PBO in the 6-study-set (data not shown).
The presence of selected comorbidities did not affect the incidence of treatment emergent adverse events (TEAEs), serious adverse events (SAE), discontinuations, or deaths caused by SAEs for BARI 4mg vs PBO. The most common TEAEs were nasopharyngitis and upper respiratory tract infection.

Conclusions
SIE incidence was similar between BARI- and PBO-and BARI

2mg/4mg treated RA patients up to wk24. No trends were noted for patients in each preselected comorbidity subgroup for increased risk of events after treatment with BARI 4mg compared with PBO up to wk16.

(18A113) ABSTRACT 18 **POSTER 10**

Durability, Maintenance and Effects of Dose Reduction Following Prolonged Treatment with Baricitinib

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Introduction
Baricitinib (BARI) is a reversible oral JAK inhibitor with selectivity for JAK1/JAK2 for active Rheumatoid Arthritis.
Aims/Background
It is clinically relevant to understand the durability and maintenance of response to baricitinib (BARI), a selective Janus kinase (JAK)1/JAK2 inhibitor, over prolonged use, and the dose tapering strategies available after achieving disease control.
Method
Upon completion of BARI Phase 3 originating studies (OS) (RA-BEGIN, RA-BEAM, RA-BUILD, and RA-BEACON), patients could enter the long term extension (LTE) study, RA-BEYOND. Durability of response was evaluated as proportion of patients achieving SDAI≤11 in the OS and through 96 weeks in the LTE. Maintenance of response was evaluated as proportion of patients who had responded to BARI at entry into LTE and maintained the response at Week 96. Within RA-BEYOND, patients who received BARI 4-mg for ≥15 months and who achieved sustained LDA (CDAI≤10) or remission (CDAI≤2.8) at 2 consecutive visits, were re-randomised in a blinded manner to continue BARI 4-mg or step down to 2-mg.
Results
Durability of response was evident as response rates were higher 96 weeks after entry into RA-BEYOND as compared to Week 12 of the OS. Most responders at entry into LTE maintained their response through Week 96 (data not shown).
Dose reduction to BARI 2-mg once daily (QD) resulted in small increases in disease activity up to Week 48, as compared to BARI 4-mg. CDAI≤10 rates at Week 48 were 68.2 for BARI 2-mg (vs 80.8 for 4-mg, p≤0.01]). By Week 48, a majority of patients (in both the groups) recaptured (data not shown) or maintained the state of LDA or remission.
Conclusions
Effectiveness of BARI, as measured by durability and maintenance of response, is maintained with prolonged therapy. In line with the observations from OS, 4-mg QD is the most efficacious dose. Dose tapering to 2-mg QD may be a reasonable consideration according to treatment goals and responses of an individual patient.

(18A114) ABSTRACT 19

POSTER 11

Vaccinations in Inflammatory arthritis patients

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Rheumatology Department Connolly Hospital Blanchardstown
Introduction
Patients with autoimmune inflammatory rheumatic diseases (AIIRD) are at increased risk of contracting infections. This risk is further increased by immunosuppressive disease modifying agents.(
Aims/Background
The vaccination status of patients should be assessed early in the course of work up for patients with AIIRD.Hepatitis A, B, Influenza, streptococcus pneumonia, Nisseria meningitides, Tetanus toxoid and human papilloma virus vaccinations' history should be taken. Efficacy is reduced by immunosuppressive medications. Preferentially vaccinations should be administered during stable disease to minimise flare ups and side effects. They can be given while while patients are on biologics but ideally before B cell depletion. Live attenuated ones should be avoided.
Objectives
The mortality rate of AIIRD patients dying from pulmonary infections is higher than the general population, and therefore EULAR recommends vaccinating these patients against Influenza and pneumococcal. The aim of the study was to assess how many of our inflammatory arthritis patients received vaccinations for these two agents.Hepatitis A and B vaccination is recommended in high risk groups only , and varicella zoster(VZ) for patients prior to Rituximab,as it cause reactivation of VZ.
Method
Aprospective study.
100 patients with AIIRD patients filled in a questionnaire on the day of their outpatient appointment. The following parameters were included.
- ID number
- Sex
- Age
- Diagnosis
- Oral DMARDS
- Biologics
- Vaccination received /not
- Name of the vaccination
- Year of vaccination
- Who recommended it? GP/rheumatologist

Results
Results table attached .
Conclusions
Though nearly half of the cohort receive vaccinations, most of them didn't receive both flue and pneumococcal vaccine and not annually either, which can be improved by better communication and advise at the outpatient visit.

Age Range	Frequency	Valid Percent
26 – 41 years	14	15.9
42 – 57 years	49	42
58 – 73 years	23	26.1
74 – 89 years	14	15.9
Total	**100**	**100**

Mean age was 55 year (age range 27 – 89 years)

Table 2: Diagnosis

Diagnosis	Frequency	Valid Percent
Rheumatoid Arthritis	45	45.9
Ankylosing Spondylitis	16	16.3
Psoriatic Arthritis	11	11.2
Inflammatory Arthritis	8	8.2
SLE	7	5.1
Rheumatoid Arthritis / Osteoarthritis	3	3.1
Juvenile Inflammatory Arthritis	1	1
Crohn's	1	1
PMR	1	1
Reactive arthritis	2	2
Sjogren's syndrome	1	1
Stills disease	2	2
Wegener's	2	2
Total	**100**	**100**

Table 3: DMARDS n:37

Medication	Frequency	Valid Percent
Methotrexate (MTX)	29	78.3
Leflunamide	2	5.4
Hydroxychloroquine (HCQ)	4	10.4
Sulfasalazine (SSZ)	2	5.4
Total	**37**	**100**

The majority of patients (52%, n = 51) were not on oral medication, while 11 were on non-steroidal anti-inflammatory drugs (NSAIDs).

Table 4: Biologic Drugs

Drug	Frequency	Valid Percent
Etanercept	23	38.3
Adalimumab	17	28.3
Infliximab	7	11.7
Rituximab	4	6.7
Certalizumab	3	5
Secukinumab	3	5
Abatacept	2	3
Golimumab	1	1.3
Stelara	1	1.3
Total	**61**	**100**

62% of the patients were on Biologics

Table 5: Name of vaccine V's year of vaccination

	Year							
Name	Annually	2017	2016	2015	2010	10 years ago	34 years ago	Total
Flu	14	7	10	4	1	1	1	38
Flu + Pneumococcal	1	1	5	1	1	–	–	9
Total	**15**	**8**	**15**	**5**	**2**	**1**	**1**	**47**

(18A115) ABSTRACT 20 POSTER 12

Early recognition of people at high risk of osteoporotic hip fractures and indication of primary and secondary prevention.

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Introduction
Osteoporosis is commonest bone disease affecting over 200 million people worldwide. In Ireland there are 18000 osteoporotic fractures annually costing an estimated 653 million euro to healthcare system. By early recognition and treatment, incidence of fractures can be reduced which can cut short economic burden on HSE.

Aims/Background
1. Early identification of osteoporosis and risk of hip fractures in elderly people
2. To determine what percentage of patients are on Primary Prevention and had hip fracture.
3. To find how many patients are offered Secondary Prevention while in Ortho Rehabilitation ward without benefit of fracture liaison services.

Method
There were 31 sequential patients included in the study who had hip fracture and met criteria of Osteoporosis and they were transferred for Rehabilitation to south Infirmary Victoria University Hospital after hip replacement in acute orthopedic unit at CUH. A detailed questionnaire was filled from patients including risk factors to calculate their pre-fracture FRAX Scores to meet criteria for osteoporosis and treatment. The Audit study started in March 2018 and ended by end of April 2018.

Results
The data was collected from 31 patients (n=31). Out of 31 there were 22 females and 9 males(F:M=22:9) . There were 29 patients above 65yrs age (93.5%).Out of 31 patients there were 30(97%) who had Pre-Fracture FRAX Score >3% (10 yrs risk of hip fracture) requiring treatment. Out of 30, only 6 patients (20%) were on primary prevention. After hip fracture, only 6 (20%) out of 30 were on treatment in Ortho Rehabilitation ward. 16% of patients had low BMI <18.5.

Conclusions
All women 65years and older, men >75 years should be assessed for risk factors for osteoporosis and probability of hip fracture in 10 yrs time using FRAX Score tool to determine indication for treatment which can save elderly population from morbidity and mortality related with fractures and reducing economic burden on healthcare system. This study further reinforces the need for proper fracture liaison services.

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Presentation Olumiant 2 mg film-coated tablet contains 2 mg of baricitinib. Olumiant 2 mg tablet is a light pink, 9.0 x 7.5 mm oblong tablets, debossed with "Lilly" on one side and "2" on the other. Olumiant 4 mg film-coated tablet contains 4 mg of baricitinib. Olumiant 4 mg tablet is a medium pink, 8.5 mm round tablets, debossed with "Lilly" on one side and "4" on the other. **Uses** Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate. **Dosage and Administration** Treatment should be initiated by physicians experienced in the diagnosis and treatment of rheumatoid arthritis. Posology The recommended dose of Olumiant is 4 mg once daily. A dose of 2 mg once daily is appropriate for patients such as those aged ≥ 75 years and may be appropriate for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily may also be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) less than 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) less than 1 x 10^9 cells/L, or who have a haemoglobin value less than 8 g/dL. Treatment may be initiated once values have improved above these limits. *Renal impairment:* The recommended dose is 2 mg once daily in patients with creatinine clearance between 30 and 60 mL/min. Olumiant is not recommended for use in patients with creatinine clearance < 30 mL/min (see the SmPC for full information). *Hepatic impairment:* No dose adjustment is required in patients with mild or moderate hepatic impairment. Olumiant is not recommended for use in patients with severe hepatic impairment (see the SmPC for full information). *Co-administration with OAT3 inhibitors:* The recommended dose is 2 mg once daily in patients taking Organic Anion Transporter 3 (OAT3) inhibitors with a strong inhibition potential, such as probenecid (see the SmPC for full information). No clinical pharmacology study has been conducted with OAT3 inhibitors with less inhibition potential. The prodrug leflunomide rapidly converts to teriflunomide which is a weak OAT3 inhibitor and therefore may lead to an increase in baricitinib exposure. Since dedicated interaction studies have not been conducted, caution should be used when leflunomide or teriflunomide are given concomitantly with baricitinib (see the SmPC for full information on Interaction with other medicinal products and other forms of interaction). *Elderly:* Clinical experience in patients ≥ 75 years is very limited and in these patients a starting dose of 2 mg is appropriate. *Paediatric population:* The safety and efficacy of Olumiant in children and adolescents aged 0 to 18 years have not yet been established. No data are available. Method of administration Oral use: Olumiant is to be taken once daily with or without food and may be taken at any time of the day. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. Pregnancy: Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking Olumiant the parents should be informed of the potential risk to the foetus. **Warnings and Special Precautions** Infections: Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo (see the SmPC for full information). In treatment naïve patients, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections (see the SmPC for full information). If an infection develops, the patient should be monitored carefully and Olumiant therapy should be temporarily interrupted if the patient is not responding to standard therapy. Olumiant treatment should not be resumed until the infection resolves. *Tuberculosis:* Patients should be screened for tuberculosis (TB) before starting Olumiant therapy. Olumiant should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of Olumiant in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L, Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L and haemoglobin < 8 g/dL were reported in less than 1 % of patients in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management (see section 4.2 of the SmPC for further information). The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies (see the SmPC for full information). Herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional DMARDs. If a patient develops herpes zoster, Olumiant treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, Olumiant therapy is not recommended. Prior to initiating Olumiant, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib compared to placebo (see the SmPC for full information). Elevations in LDL cholesterol decreased to pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of Olumiant therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined. Hepatic transaminase elevations: Increases in alanine transaminase (ALT) and aspartate transaminase (AST) to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in less than 1 % of patients in clinical trials. In treatment-naïve patients, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy (see the SmPC for full information). If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, Olumiant should be temporarily interrupted until this diagnosis is excluded. Malignancy: The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Venous Thromboembolism: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Olumiant should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, Olumiant treatment should be temporarily interrupted and patients should be evaluated promptly, followed by appropriate treatment. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biologic DMARDs or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. Data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations (see the SmPC for full information). **Interactions** See the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, Pregnancy, and Lactation** *Pregnancy:* There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity (see the SmPC for full information). Baricitinib was teratogenic in rats and rabbits Olumiant is contraindicated during pregnancy. *Breast-feeding:* It is unknown whether baricitinib/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of baricitinib in milk. A decision must be made whether to discontinue breast-feeding or to discontinue Olumiant therapy. *Fertility:* The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines** Olumiant has no or negligible influence on the ability to drive and use machines. **Undesirable Effects** *Summary of the safety profile:* The most commonly reported adverse drug reactions occurring in ≥ 2 % of patients treated with Olumiant monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6 %), upper respiratory tract infections (14.7 %) and nausea (2.8 %). Infections reported with Olumiant treatment included Herpes zoster. *Very common (≥ 1/10):* Upper respiratory tract infection, Hypercholesterolaemia, *Common (≥ 1/100 to < 1/10):* Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Thrombocytosis > 600 x 109 cells/L, Nausea, ALT increased ≥ 3 x ULN. *Uncommon (≥ 1/1,000 to < 1/100):* Neutropaenia < 1 x 109 cells/L, Hypertriglyceridaemia, AST increased ≥ 3 x ULN, Creatine phosphokinase increased > 5 x ULN. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* **United Kingdom:** http://www.medicines.org.uk/emc/, or **Ireland:** http://www.medicines.ie/. **Legal Category** POM **Marketing Authorisation Numbers and Holder** EU/1/16/1170/002, EU/1/16/1170/010, EU/1/16/1170/014, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets, £2,416.68 per pack of 84 x 4 mg film-coated tablets. *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review:** January 2018 **Further information is available from** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: **UK:** + 44-(0) 1256 315000, **Ireland:** + 353-(0) 1 661 4377, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk; www.lilly.ie.

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Adverse events and product complaints should also be reported to Lilly: please call **Lilly UK** on **01256 315 000**, or **Lilly Ireland** on **01 664 0446**.

References: 1. Olumiant (baricitinib) tablets. Summary of product Characteristics. Eli Lilly and Company Ltd.

(18A116) ABSTRACT 21 POSTER 13

Study of Inpatient Prescription of Oral Bisphosphonates

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Introduction
Due to the unique bioavailability characteristics of oral bisphosphonates their absorption can be affected by modifiable factors on medicine kardex while an inpatient in hospital. By addressing these unique prescription issues, bisphosphonate absorption can be improved with a subsequent improvement in bone densitometry readings.

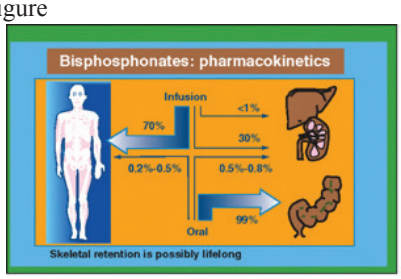
Aims/Background
Bisphosphonates are poorly absorbed orally (less than 1 percent of the dose) and must be taken on an empty stomach for maximal absorption. Bioavailability may be seriously impaired by ingestion with liquids other than plain water, such as mineral water, coffee, or juice; by retained gastric contents, as with insufficient fasting time or gastroparesis; or by eating or drinking too soon afterwards. Aims of the improvement project were to Investigate what proportion of bisphosphonate were prescribed and taken according to current best practice guidelines, in inpatient population Musgrave Park Hospital.

Method
Data was collected via combination of patient questionnaire and inpatient Kardex prescriptions studied at random. Patients that were studied had wide range of co-morbidities and prescription indications. The patient population was from current inpatients in Ward 3A Musgrave Park Hospital Belfast (Tertiary Rheumatology Centre), along with Meadowlands wards 2 and 3 (Inpatient fracture rehabilitation wards for Belfast Trust area). Data was collected between March and April 2018. Information obtained from questionnaire included data such as type of bisphosphonate take, timing of dose, was bisphosphonate taken on empty stomach, and did the patient remain upright for 30mins after. We decided to focus on these questions as it is part of current best practice guidelines with regards to bisphosphonate prescriptions.

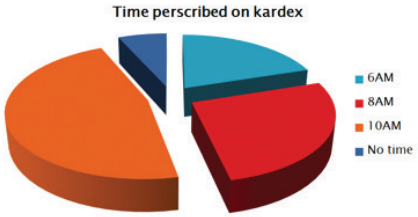
Results
Our study revealed that more than half of inpatients (55%) had oral bisphosphonate prescribed along with other medications and not the recommended 30mins before other medications. The most frequently occurring time for bisphosphonate to be prescribed was 10am (47% of inpatients) which incidentally correlates with the morning drug round and is after the breakfast distribution on the wards. None of the kardexes studied had written instructions about how to take drug.

Conclusions
Improvement of bisphosphonate prescription as hospital inpatient can lead to subsequent improvement in bioavailability and absorption of oral bisphosphonate.

Figure



Figure



(18A117) ABSTRACT 22 POSTER 14

Comparison of the Bioavailability of a Single Dose of Certolizumab Pegol Injected by Pre-Filled Syringe or by Electro-Mechanical Auto-Injection e-Device: a Phase 1, Open-Label, Randomised, Parallel Gr

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Introduction
When administered subcutaneously (SC) using a pre-filled syringe (PFS), the anti-TNF certolizumab pegol (CZP) has a half-life of ~14 days and good bioavailability (~80%) at all tested doses. A reusable electro-mechanical auto-injection device (e-Device), ava®, was recently approved in the EU, providing an alternative SC-delivered CZP option in addition to the PFS and autoinjector device (AutoClicks®).

Aims/Background
To determine if a single 200mg CZP dose is bioequivalent when delivered SC by PFS or e-Device, and to assess the safety and tolerability of both administration methods.

Method
NCT02806219 was a phase 1, open-label, randomised, parallel group, single-centre bioequivalence study. Healthy volunteers were randomised 1:1 to receive 200mg CZP via a PFS or e-Device. Primary outcomes were maximum CZP plasma concentration (Cmax), area under the plasma concentration vs time curve (AUC), and AUC from baseline (BL) to final data point (AUC(0-t)). At BL (Day 1), volunteers received a single 200mg CZP dose. CZP plasma concentrations were measured on Day 1 prior to CZP administration, at 12 hours (h) post-dose, and on Days 2–7, 10, 14, 21, 28, 42, 56, and 70. Safety and tolerability were assessed using the safety set (all receiving a CZP dose) via reported treatment-emergent adverse events (TEAEs), serious AEs, and adverse device events (ADEs: AEs considered by the investigator to be related to/caused by the device). An injection site pain visual analog scale (VAS; 0–100mm) was completed post-injection (0h) and 1h post-injection.

Results
100 healthy volunteers were randomised to PFS (n=50) or e-Device (n=50). The mean plasma CZP concentration vs time profiles for the e-Device and PFS were comparable. Point estimates and 90% confidence intervals (CIs) for test/reference geometric mean ratios in Cmax and AUC were contained within bioequivalence limits of 80–125% (Table 1). Both administration methods were equally well tolerated; all reported TEAEs were mild or moderate, with no ADEs or injection site reaction TEAEs. Mean VAS pain scores were low at 0h (PFS: 10.7 [SD 14.3], e-Device: 18.0 [24.4]) and 1h (1.4 [2.9] vs 2.7 [7.0]).

Conclusions
CZP 200mg doses were bioequivalent whether administered by PFS or e-Device. The SC-delivered CZP injections were well tolerated when using either method.

Figure

Table: Results of the bioequivalence analysis comparing the PFS and e-Device

	Reference		Test		Test/Reference		
	CZP 200mg PFS		CZP 200mg e-Device				ANCOVA CV (%)
	n	Geometric LS Mean (95% CI)	n	Geometric LS Mean (95% CI)	Point estimate	90% CI	
C_{max} (µg/mL)	48	28.8 (27.1, 30.5)	50	28.7 (27.1, 30.4)	1.00	0.93, 1.07	20.6
AUC_{0-t} (µg·d/mL)	47	670.8 (623.7, 721.5)	50	668.7 (623.1, 717.7)	1.00	0.92, 1.09	25.6
AUC (µg·d/mL)	45	701.8 (653.3, 754.0)	49	688.6 (643.0, 737.6)	0.98	0.90, 1.07	24.6

PK-PPS. ANCOVA: analysis of covariance; AUC: area under the curve; AUC_{0-t}: AUC from baseline to final data point; CI: confidence interval; C_{max}: maximum plasma concentration; CV: coefficient of variation; d: day; CZP: certolizumab pegol; LS: least squares; PFS: pre-filled syringe; PK-PPS: pharmacokinetic per-protocol set.

(18A118) ABSTRACT 23 **POSTER 15**

Pregnancy Outcomes and Disease Activity in Women with Axial Spondyloarthritis: A Systematic Literature Review

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Introduction
Women with axial spondyloarthritis (axSpA) are often affected by the disease during their reproductive years, but reports on disease activity and pregnancy outcomes in these patients (pts) are sparse. In women with ankylosing spondylitis (AS), also currently termed as radiographic axSpA, a higher risk of disease activity flares and prevalence of adverse pregnancy outcomes have been reported vs healthy controls; however, in non-radiographic (nr)-axSpA pts, such data are virtually non-existent.

Aims/Background
To review available evidence on the relationship between axSpA disease activity and pregnancy, including foetal outcomes.

Method
A systematic literature review was conducted in October 2017 by searching EMBASE, MEDLINE®, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects. Publications were systematically screened for English language articles on observational studies of axSpA pts reporting pregnancy outcomes or disease activity during pregnancy. Studies utilising agents contraindicated in pregnancy were excluded. Supplementary searches of selected, 2016–17 conference proceedings and bibliographies of relevant review articles were also conducted.

Results
2216 publications were reviewed, with 20 publications on 15 unique studies meeting the inclusion criteria. When utilising verified disease activity measurement instruments, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) or Ankylosing Spondylitis Disease Activity Score C-Reactive Protein (ASDAS-CRP), 5 studies (3 prospective, 2 retrospective) reported active disease (as described by individual studies; Table) both during pregnancy and postpartum in most pts. Pregnancy outcomes in axSpA pts were compared with healthy controls in 6 studies (3 retrospective, 2 prospective, 1 case-control), the 3 largest of which (including 1 prospective) revealed higher risk or odds of preterm births in axSpA pts. Higher rates or risk of low birth weight/small-for-gestational-age neonates were shown in pts vs controls in 2/5 studies reporting such outcomes. Stillbirths, miscarriages or foetal loss/abortion occurred at similar rates in both populations.

Conclusions
Robust, prospective data on disease activity during pregnancies of women with axSpA are limited. Within the samples reported here, available data suggest that there may be a small increase in pre-term births; no signal for increased pregnancy loss was detected. Further research is needed to investigate relationships between maternal disease activity and pregnancy outcomes in axSpA.

Figure

Table: Maternal disease activity and pregnancy outcomes in axSpA patients

Maternal axSpA disease activity during pregnancy and postpartum				
Study	**Population[a]**	**Instrument**	**Activity during pregnancy[b]**	**Activity postpartum[b]**
Ursin 2017[c][d]	axSpA: 181/168	BASDAI	'Stable, low disease activity' (2nd trimester: BASDAI=3.97)	'Stable, low disease activity' (6 weeks pp: BASDAI=3.46)
Förger 2009[e]	AS[f]: 10	BASDAI	'Moderate disease activity'	'Stable' (2/10) 'Increased by 50%' (8/10)
Förger 2005[e]	AS[f]: 10	BASDAI	'Clinical improvement' (4/10) 'Remained active' (6/10)	*Not reported*
van den Brandt 2017[e]	axSpA[g]: 37	ASDAS-CRP	'Persistent high activity'[h]	'Persistent high activity'[h]
Timur 2016[d]	AS[f]: 20	ASDAS-CRP	'Decreased score' (14/20) 'Unchanged score' (6/20)	'Decreased score' (2/20) 'Unchanged score' (3/20) 'Increased score' (15/20)

Pregnancy outcomes of axSpA patients and healthy controls			
Study	**Populations[a]**	**Incidence per pregnancies vs controls (p value)**	
Fang 2017[c][d]	AS: 2492 Controls: 2,347,847	**Preterm birth:** 148/2492 vs 106,014/2,347,847 (aOR[i]: 1.18 [1.00–1.38],[j] <0.05) **Birth weight <2500 g:** 173/2492 vs 151,048/2,347,847 (aOR[i]: 1.06 [0.91–1.22], NS[j]) **SGA:** 221/2492 vs 227,984/2,347,847 (aOR[i]: 0.97 [0.85–1.11], NS) **Stillbirth:** 17/2492 vs 17,346/2,347,847 (aOR[i]: 0.81 [0.50–1.30], NS)	
Förger 2017[c][e]	axSpA: 78/70 Controls: 70	**Preterm birth:** 'higher risk' **SGA:** 'higher risk'	
Park 2017[c][d]	AS: 27/20 Controls: 108	**Preterm birth:** *Data not reported* (NS) **Low birth weight:** 22.2% vs 8.3% (0.024)	**Foetal loss:** 0/27 vs 0/108 (NS)
Timur 2016[d]	AS[f]: 20 Controls: 40	**Preterm birth:** 3/20 vs 3/40 (0.390) **Birth weight <2500 g:** 5/20 vs 3/40 (0.150)	**Abortion:** 0.2±0.4 vs 0.2±0.4 (1.000)
Jakobsson 2016[k]	AS[f]: 199 Controls: 477	**Preterm birth:** 22/199 vs 21/477 (aOR[i]: 2.62 [1.27–5.39] for untreated patients; 1.79 [0.55–5.82], NS for NSAID-treated patients)	**SGA:** 5/199 vs 6/477 (aOR[i]: 1.34 [0.37–4.85], NS for untreated patients; 4.47 [0.96–20.8], NS for NSAID-treated patients)
Ostensen and Husby 1983[e]	AS[f]: 13 Controls: 31	**Preterm birth:** 1/13 vs 0/31 **Miscarriage:** 0/13 vs 1/31	**Stillbirth:** 0/13 vs 1/31

[a] Pregnancies/Women (if not equal); [b] Cases per total pregnancies (n/N); [c] Congress abstract; [d] Retrospective data; [e] Prospective data; [f] modified New York criteria; [g] ASAS classification criteria; [h] ASDAS-CRP: 2.1–≤3.5; [i] aOR [95% confidence interval]; [j] Crude odds ratio significant at 1.19 (1.03-1.38); [k] Case-control study; [l] ICD-10: M45. aOR: adjusted odds ratio; AS: ankylosing spondylitis; ASDAS-CRP: ankylosing spondylitis disease activity score C-reactive protein; axSpA: axial spondyloarthritis; BASDAI: Bath ankylosing spondylitis disease activity index; NS: not significant; NSAID: non-steroidal anti-inflammatory drug; pp: postpartum; SGA: small-for-gestational-age.

(18A119) ABSTRACT 24 **POSTER 16**

An audit into the use of Hydroxychloroquine

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Department(s)/Institutions
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Introduction
The use of Hydroxychloroquine/ Plaquenil (PLQ) in rheumatoid arthritis and connective tissue diseases is long established and evidence based practice. Retinopathy with changes in pigmentation and visual field defects can occur with prolonged use, but appears to be uncommon if the recommended daily dose is not exceeded.

A Boston team developed an iOS App, DoseChecker, to provide a tool for rapid comparison of Actual Body Weight (ABW) and Ideal Body Weight (IBW) hydroxychloroquine dose calculations for a patient at the point of care.

Aims/Background

Our primary aim was to review the prescriptions of PLQ within the Rheumatology department, using the DoseChecker app and to modify the prescriptions if indicated.

A secondary objective was to evaluate effectiveness in communicating/documenting advice regarding annual eye-checks in patients on PLQ.

Method

Patients commencing on PLQ and patients currently prescribed PLQ were included in analysis. Data was collected using the attached form (Figure 1). Data obtained included, but was not limited to, diagnosis, age, weight, height, duration of use, current dose regimen, estimated cumulative dose, whether the current regimen was correct when consulting DoseChecker app, newly advised regimen if applicable and documented eye check within the last year.

Results

28 patients already using PLQ were included in the analysis, as well as 3 new start patients. The average age of patient included was 55 years. 27 patients had Rheumatoid Arthritis, 2 Sjogren's, 1 SLE and 1 MCTD (Figure 2). The median duration of use was 4.5 years, with the longest prescription 16.5 years. 4/28 patients had an incorrect dose regimen when checked against the DoseChecker app. The median difference in weekly dosing in those that required correction was 325mg. 6/28 patients had a documented eye check-up advised within the last 12 months. Using the DoseChecker app, 2/3 new start patients on PLQ had their prescription changed from the presumed 200mg bd, leading to a median difference in the weekly dose of 600mg.

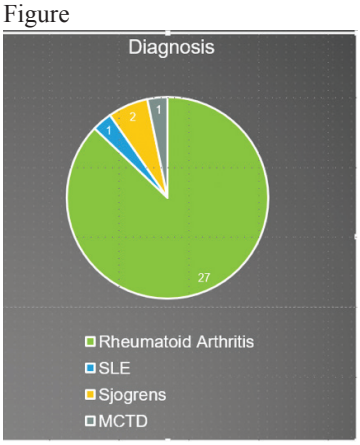
Conclusions

The use of the DoseChecker app has led to the amendment of 14% of current PLQ prescriptions and 67% of new prescriptions in this audit. Improvement in documentation pertaining to eye checks is required.

Figure

Patients previously commenced on PLQ	
Health and Care Number	
DOB	
Age	
Diagnosis	
Weight	
Height	
Duration of PLQ use (Years and Months)	
Current Dose Regimen and initiation dose regimen if different	
Estimated Cumulative Dose	
Eye Check Documented at review within last year	
Ophthalmology vs Optician performed	
Is the dose regimen correct when compared to the calculator?	
Advised dose regimen if wrong	
Is this based on IBW or ABW?	
Difference in the weekly dose	
If duration exceeds 7 years has there been documented advice since then about both the role of PLQ in their treatment and ongoing risk of retinal toxicity?	

Figure



(18A120) ABSTRACT 25 **POSTER 17**

Awareness of perioperative medication management of rheumatologic patients undergoing elective surgery amongst surgeons and anaesthetists

Author(s)

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Introduction

Rheumatologic patients may be on a number of medications which act as immunological suppressants. This can be of concern in those patients undergoing surgery due to risk of local or systemic infection postoperatively. Guidelines and principles exist recommending the best time to stop medications pre-op and restart post-op if indicated.

Aims/Background

We sought to assess awareness of recommendations amongst surgeons and anaesthetists.

Method

Questionnaire on awareness of guidelines for DMARDs, Biologics, SLE-specific medications(in non-severe SLE) for elective procedures only. All grades included(SHO/Registrar/Consultant); general surgery, orthopaedics, ENT, urology, anaesthetics. For each medication group, we asked where the subject seeks guidance and if they would stop preop and when+restart postop and when(assuming uncomplicated postop course). Answers based on ACR recommendations.

Results

22 subjects were surveyed: 4 consultants, 11 registrars and 7 senior house officers. For DMARDs, a majority of participants(33.33%) said they would seek rheumatology advice. 9/22(40.90%) stated correctly that they would not hold DMARDs preop. Of all participants, only 8.33% were correct across the biologic agents category for when to stop preop. The majority answer(41.66%) was that the participant did not know when to stop the biologic agents preop. The majority answer for restart time 10/22(45.45%) was correct in that the biologic agents would be restarted 2 weeks postop. For SLE specific medications, 46.66% stated they would seek rheumatology advice. 12/22(54.54%) selected correctly that they would stop SLE medications preop but only 6/12 selected correctly that they would do so 1 week preop. 5/22(22.72%) selected correctly that they would restart at 2 weeks post op.

Conclusions

There is a lack of knowledge around the recommended cessation and recommencement of rheumatologic medications in the perioperative period. 25% of candidates stated they would use local guidelines to

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Dosage and Administration: *Adults with rheumatoid arthritis*: Recommended initial dose is 7.5mg of methotrexate once weekly, administered subcutaneously. May be increased gradually by 2.5mg per week. Weekly dose of 25mg should not be exceeded. Doses exceeding 20mg/week are associated with significant increase in toxicity. Response to treatment expected after approximately 4 – 8 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. *Children and adolescents below 16 years with polyarthritic forms of juvenile idiopathic arthritis*: Children with body surface area below 0.75m^2 can not be treated with this product. Recommended dose 10 - 15mg/m^2 body surface area (BSA)/once weekly by subcutaneous injection. Weekly dosage may be increased to 20mg/m^2 body surface area/once weekly. Increase monitoring frequency if dose increased. Refer patients to rheumatology specialist in the treatment of children/adolescents. Use in children < 3 years of age not recommended. *Psoriasis vulgaris and psoriatic arthritis*: Administer test dose of 5 – 10mg parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. Recommended initial dose 7.5mg once weekly subcutaneously. Increase dose gradually. Do not exceed weekly dose of 25mg. Doses exceeding 20mg per week are associated with significant increase in toxicity. Response to treatment expected after approximately 2 – 6 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. Increase dose as necessary but do not exceed maximum recommended weekly dose of 25mg. Exceptionally a higher dose might be clinically justified, but should not exceed a maximum weekly dose of 30mg. *Crohn's Disease*: Induction treatment 25mg/week subcutaneously. Response to treatment expected after approximately 8 to 12 weeks. Maintenance treatment 15mg/week subcutaneously. *Renal impairment*: Use with caution. *Hepatic impairment*: Use with great caution, if at all, in patients with significant current or previous liver disease, especially if due to alcohol. If bilirubin is > 5mg/dl (85.5 µmol/l), methotrexate is contraindicated. *Elderly patients*: Consider dose reduction. *Third distribution space (pleural effusions, ascites)*: Half-life can be prolonged, dose reduction or discontinuation may be required. **Contraindications:** Hypersensitivity. Severe liver impairment. Alcohol abuse. Severe renal impairment (creatinine clearance less than 20 ml/min). Pre-existing blood dyscrasias. Serious, acute or chronic infections. Ulcers of oral cavity and known active gastrointestinal ulcer disease. Pregnancy, breast-feeding. Concurrent vaccination with live vaccines.

Warnings and Precautions: Clearly inform patients that therapy should be administered **once a week**, not every day. Supervise patients so that signs of possible toxic effects or adverse reactions are detected and evaluated with minimal delay. Treatment should be initiated and supervised by physicians with knowledge and experience in use of antimetabolite therapy. Possibility of severe/fatal toxic reactions, patients should be fully informed by physician of risks and recommended safety measures. Use in children under 3 is not recommended. *Before beginning or reinstituting treatment*: Complete blood count with differential and platelets, liver enzymes, bilirubin, serum albumin, chest x-ray and renal function tests. If clinically indicated, exclude tuberculosis and hepatitis. *During therapy (at least once a month during the first six months and every three months thereafter)*: Examine mouth and throat for mucosal changes. Complete blood count with differential and platelets. Profound drop in white-cell or platelet counts indicates immediate withdrawal of treatment and appropriate supportive therapy. Advise patients to report signs and symptoms of infection. Monitor patients taking haematotoxic medicinal products (e.g. leflunomide) closely with blood count and platelets. Liver function tests: Do not start treatment if abnormality of liver function tests or liver biopsy present. Stop treatment if abnormalities develop. Treatment may be recommenced if liver function returns to normal. Evaluate need for liver biopsy in psoriasis therapy. Temporary increases in transaminases have been reported. Consider dose reduction or discontinuation in the case of a constant increase in liver-related enzymes. Additional hepatotoxic medicinal products should not be taken unless clearly necessary and consumption of alcohol should be avoided. Monitor liver enzymes closely in patients taking other hepatotoxic products. The same should be taken into account with the simultaneous administration of haematoxic products. Monitor renal function. Where renal function may be compromised (e.g. the elderly), monitor more frequently particularly when concomitant medicinal products affect the elimination of methotrexate, cause kidney damage or can lead to impairment of blood formation. Dehydration may also intensity methotrexate toxicity. Respiratory system: Be alert for symptoms of lung function impairment. Pulmonary effects require quick diagnosis and discontinuation of methotrexate. Pulmonary symptoms (especially dry non-productive cough) or a non-specific pneumonitis occurring during methotrexate therapy may be indicative of a potentially dangerous lesion and require interruption of treatment and careful investigation. Acute or chronic interstitial pneumonitis, often associated with blood eosinophilia may occur and deaths have been reported. This lesion can occur at all dosages. Methotrexate may impair response to vaccination and affect result of immunological tests. Particular caution needed in presence of inactive, chronic infections (e.g. herpes zoster, tuberculosis, hepatitis B or C). Vaccination using live vaccines must not be performed. Malignant lymphomas may occur in which case therapy must be discontinued. Concomitant administration of folate antagonists has been reported to cause acute megaloblastic pancytopenia. Radiation induced dermatitis and sun-burn can reappear (recall-reaction). Psoriatic lesions can exacerbate during UV-irradiation and simultaneous administration of methotrexate. Methotrexate elimination is reduced in patients with a third distribution space (ascites, pleural effusions) requiring careful monitoring for toxicity and dose reduction or discontinuation of methotrexate. Pleural effusions and ascites should be drained prior to initiation of methotrexate. Diarrhoea and ulcerative stomatitis require interruption of therapy. Products containing folic acid, folinic acid or derivatives may decrease effectiveness. Treatment of psoriasis with methotrexate should be restricted to severe recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and only when diagnosis established by biopsy and/or after dermatological consultation. Encephalopathy / Leukoencephalopathy have been reported in oncologic patients. The absence of pregnancy should be confirmed before methotrexate is administered. Contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free". Methotrexate has minor or moderate influence on ability to drive and use machines. **Interactions:** Regular alcohol consumption or concomitant use with other hepatoxic products or retinoids increases the probability of hepatoxic effects. Patients taking hepatoxic or haemotoxic medicinal products should be carefully monitored. Oral antibiotics may interfere with enterohepatic circulation. Antibiotics can reduce renal clearance of methotrexate. Concurrent use with medicinal products with high plasma proteins binding can lead to increased toxicity. Use with probenecid, weak organic acids, pyrazoles and non-steroidal anti-inflammatory agents may result in increased toxicity. Concomitant use with medicinal products with adverse reactions on the bone marrow may result in pronounced impairment of blood formation. Administration of products which cause folate deficiency can lead to increased toxicity. Products containing folic acid or folinic acid may decrease effectiveness of methotrexate. Concomitant use with sulphasalazine can increase efficacy of methotrexate. Combination with mercaptopurine may require dose adjustment. Concomitant administration of proton-pump inhibitors can result in interactions. May decrease clearance of theophylline. Excessive consumption of caffeine or theophylline-containing beverages should be avoided. **Pregnancy and Lactation:** Contraindicated in pregnancy and lactation. Women getting pregnant during therapy should receive medical counselling about risk of adverse reactions for the child. Effective contraception is required during treatment and for at least 6 months thereafter. Women who wish to become pregnant should consult a genetic counselling centre. Men should seek advice about sperm preservation before starting therapy. **Adverse events include: Adverse events which could be considered serious include:** *Common:* Leukopenia, pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia, *Uncommon*: Pancytopenia, precipitation of diabetes mellitus, cirrhosis, fibrosis and fatty degeneration of the liver, renal impairment, *Rare*: Pericarditis, pericardial effusion, pulmonary fibrosis, gastrointestinal ulcers, acute hepatitis, renal failure, anuria, anaphylactic shock, allergic vasculitis, conjunctivitis, sepsis, hypogammoglobulinaemia. *Very rare*: Lymphoma, agranulocytosis, convulsions, paralysis, retinopathy, haematemesis, toxic megacolon, hepatic failure, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome). *Frequency unknown:* Leukoencephalopthy. **Other Very Common adverse events:** Stomatitis, dyspepsia, nausea, loss of appetite, elevated transaminases. **Other Common adverse events**: Anaemia, thrombopenia, headache, tiredness, drowsiness, oral ulcers, diarrhoea, exanthema, erythema, pruritus. See SPC for details of other adverse events. **Shelf Life:** 24 months. **Pack size:** 7.5mg/0.15ml; 10mg/0.2ml; 15mg/0.3ml; 20mg/0.4ml; 25mg/0.5ml. **Marketing Authorisation Holder (MAH):** Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom. **MA Number:** PA 1390/099/002, 003, 005, 007, 009. **Legal Category:** POM. Full prescribing information including the SPC, is available on request from Actavis Ireland Ltd, a subsidiary of Accord Healthcare Ltd, Euro House, Little Island, Co. Cork, Tel: 021-4619040 or www.accord-healthcare.ie/products. Adverse reactions can be reported to Medical Information at Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com or Tel: +44(0)1271385257. **Date of Generation of API:** January 2018 UK&IE/MET/0001/01-18

Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie), or by e-mailing medsafety@hpra.ie. Adverse events should also be reported to Medical Information via email: medinfo@accord-healthcare.com or tel: 0044 (0)1271 385257.

Actavis Ireland, Euro House, Euro Business Park, Little Island, Cork, T45 K857. Phone: 021 461 90 40

References: 1. Monthly Index of Medical Specialties (MIMS) www.mims.ie online, February 2018

Date of Preparation: April 2018 UK&IE/MET/0012/04-18

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aid decision making, however, none exist. While most candidates answered incorrectly across all questions, a significant portion also answered outright that they did not know the answer for the biologic agents, highlighting a need for education. Better awareness of guidelines may lead to better perioperative management and mitigate the risks and complications related to these medications in surgical patients. Information at a ward level/local guidelines may provide this.

(18A122) ABSTRACT 26 **POSTER 18**

Psoriatic Arthritis – An Audit to ascertain how quality of service can be improved in Patients with PsA

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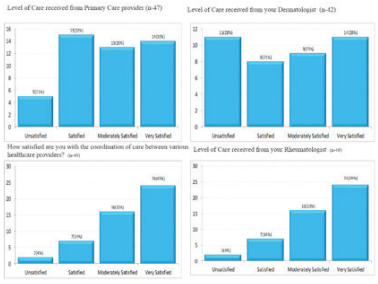
Introduction
Services for Psoriatic Arthritis patients are few in number in comparison to those suffering from Rheumatoid Arthritis. There has been so much focus on improving quality of services within the NHS this area needed to be addressed. The lead Consultant approached me and suggested an audit of services for Psoriatic Arthritis patients.
Aims/Background
To identify aspects of care we could potentially improve for PsA patients.
To identify if there are trends between co-morbidities and Psychological aspects of PsA and to propose a Quality improvement project to address PsA needs.
Method
Questionnaires were given to a random fifty-one patients with a diagnosis of Psoriatic Arthritis. Data was then collated by the Audit department and then presented at the monthly team audit meeting to present findings.
Results
50% of PsA patient's quality of life was moderately affected and 14% having an extreme effect on their quality of life.
20% found lack of sleep very significant and 29% moderately significant.
78% of patients wanted more education about complementary and alternative disease management strategies (exercise, stress reduction, dietary modification)
37% wanted more family/friend involvement in their care.
37% patients had depression, 24% obesity and 8% with hypertension and diabetes.
Conclusions
From the audit, it was found that 40% of Psoriatic patients would see their Specialist Nurse most often for the management of their care. This would be a prime opportunity to incorporate the WILD 5 Wellness programme, which improves mental wellness, social connectedness, conquers insomnia, tames depression and encourages exercise. Each of these interventions, which would aim to improve Psoriatic patient's quality of life and physical health.
Figure



(18A123) ABSTRACT 27 **POSTER 19**

Uptake of Pneumococcal and Influenza Vaccination in Patients Receiving Biological Dmards In Ireland

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Department(s)/Institutions
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Introduction
Biological disease-modifying antirheumatic drugs (bDMARDs) have made significant positive outcomes in the lives of patients with rheumatic disease.[1] Studies have shown that pneumococcal vaccination is cost effective while influenza vaccination significantly prevents morbidity and mortality in the elderly and in patients with chronic disease.[1]
Aims/Background
To evaluate the pneumococcal and influenza vaccination status in patients receiving bDMARDs.
Method
Patients on bDMARDs attending the rheumatology infusion unit were asked about their vaccination status on pneumococcal and influenza. The patients' current bDMARD and reasons for not having vaccination were recorded.
Results
Mean age of 92 patients were 53.2years. 30(32.6%) patients received both vaccines, and 39(42.4%) had neither. Of the 18(19.6%) patients age >65 years, 5(27.8%) received influenza vaccination alone and 8(44.4%) received both. Patients who did not receive vaccinations were given an educational booklet. 48(52.2%)on rituximab, 37(40.2%) on infliximab, 6(6.5%) on tocilizumab and 1(1.1%) was on abatacept. Of the 61(66.3%) patients who did not receive the pneumococcal vaccine, 44(72.1%) were unaware of its availability, 6(9.8%) were not interested, 4(6.6%) were afraid of the side effects, 4(6.6%) declined vaccination and 3(4.9%) were unaware it was recommended. 40(43.5%) who did not receive the influenza vaccine stated that they were either unaware(45%), not interested(25%), declined vaccination(10%), forgotten(5%), unaware it was recommended(5%) and afraid of the side effects(2.5%). 3(7.5%) had previous bad experiences from influenza vaccination.
Conclusions
This is the first study in Ireland on vaccination uptake in patients on bDMARDS. Patients on immunosuppressants are recommended to have these vaccinations, preferably before commencing on immunosuppressants.[2] The vaccination rate in our cohort was less than satisfactory. Hence, primary care physicians and the rheumatology team should take active roles in increasing awareness amongst patients on pneumococcal and influenza vaccination.

(18A124) ABSTRACT 28 **POSTER 20**

The Effects of Behçet's Disease Flare-ups On Mood: The Midwest of Ireland Study

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Introduction
Behçet's disease (BD) is a chronic inflammatory disorder that the aetiology remains poorly understood but can be debilitating to patients. The course of the disease is hard to predict and may cause

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[CLINICAL PARTICULARS] 1) Rheumatoid arthritis Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in: adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate. Adult patients with severe, active and progressive disease not previously treated with methotrexate 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. 2) Ankylosing spondylitis Remsima is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy. 3) Adult Crohn's disease Remsima is indicated for treatment of moderately to severely, active Crohn's disease, in adult 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.

Treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). 4) Ulcerative colitis Remsima is indicated for treatment of moderately to severely 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. 5) Psoriatic arthritis Remsima is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. Remsima should be administered in combination with methotrexate or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated. Infliximab has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. 6) Psoriasis Remsima is indicated for treatment of moderate to severe 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.

[Posology and method of administration] During Remsima treatment, other concomitant therapies, e.g. corticosteroids and immunosuppressants should be optimised.[1]

Rheumatoid arthritis 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. Remsima must be given concomitantly with methotrexate. Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. If a patient has an inadequate response or loses response after this period, consideration may be given to increase the dose step-wise by approximately 1.5 mg/kg, up to a maximum of 7.5 mg/kg every 8 weeks. Alternatively, administration of 3 mg/kg as often as every 4 weeks may be considered. If adequate response is achieved, patients should be continued on the selected dose or dose frequency. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment or after dose adjustment. 2) Ankylosing spondylitis 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 by 6 weeks (i.e. after 2 doses), no additional treatment with infliximab should be given. 3) Crohn's Disease ① Moderately to severely active Crohn's disease: 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 with infliximab should be given. Available data do not support further infliximab treatment, in patients not responding within 6 weeks of the initial infusion. In responding patients, the alternative strategies for continued treatment are: -Maintenance: Additional infusion of 5 mg/kg at 6 weeks after the initial dose, followed by infusions every 8 weeks or Re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. ② Fistulising, active Crohn's disease 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after the first infusion. If a patient does not respond after 3 doses, no additional treatment with infliximab should be given. In responding patients, the alternative strategies for continued treatment are: -Maintenance: Additional infusions of 5 mg/kg every 8 weeks or Re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur followed by infusions of 5 mg/kg every 8 weeks. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. In Crohn's disease, experience with re-administration if signs and symptoms of disease recur is limited and comparative data on the benefit/risk of the alternative strategies for continued treatment are lacking. 4) Ulcerative colitis 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. Available data suggest that the clinical response is usually achieved within 14 weeks of treatment, i.e. three doses. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. 5) Psoriatic arthritis 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. 6) Psoriasis 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 shows no response after 14 weeks (i.e. after 4 doses), no additional treatment with infliximab should be given. Re-administration for Crohn's disease and rheumatoid arthritis if the signs and symptoms of disease recur, infliximab can be re-administered within 16 weeks following the last infusion. In clinical studies, delayed hypersensitivity reactions have been uncommon and have occurred after infliximab-free intervals of less than 1 year (see sections 4.4 and 4.8). The safety and efficacy of re-administration after an infliximab-free interval of more than 16 weeks has not been established. This applies to both Crohn's disease patients and rheumatoid arthritis patients.

Re-administration for ulcerative colitis the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for ankylosing spondylitis the safety and efficacy of re-administration, other than every 6 to 8 weeks, has not been established. Re-administration for psoriatic arthritis the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for psoriasis limited experience from re-treatment with one single infliximab dose in psoriasis 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 re-treatment following disease flare by a re-induction regimen suggests a higher incidence of infusion reactions, including serious ones, when compared to 8-weekly maintenance treatment. **[Contraindications]** Patients with ① history of hypersensitivity to infliximab, to other murine proteins, or to any of the excipients ② tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections ③ moderate or severe heart failure (NYHA class III/IV)

Remsima™ Infliximab

Ref.) 1. Ann Rheum Dis 2012;71(Suppl3);111. 2. Ann Rheum Dis 2012;71(Suppl3):359

heavy psychological burden to those affected.

Aims/Background

The aim of the study is to evaluate the effect of disease flare on the mood of BD patients.

Method

25 patients satisfying the International Study Group for Behçet's Disease (ISGBD) diagnostic criteria were recruited from a regional rheumatology centre. Telephone interviews were performed to assess the level, significance and severity of patients' mood during disease flare.

Patients were asked to rate between 0-10 to reflect their mood (0-1=very poor, 2-3=bad, 4-6=fair, 7-8=good, 9-10=excellent). Patients were then requested to list the reasons contributing to the final mood score.

Results

The median age was 40 years with an interquartile range of 27(29-56). 16(64%) females and 9(36%) males. 13(52%) patients rated their mood to be less than 7 with some listing more than one reason for their low mood: the most common was BD flare-ups (69.23%), followed by other health reasons (46.15%), family issues (38.46%) and problems at work (23.08%). 15 (60%) had disease flare within the past six months. Of those, 11(73.33%) had oral ulcers, followed by arthralgia (53.33%), genital ulcers (33.33%), fatigue (26.67%), intestinal involvement (13.33%) and skin involvement (6.67%). 4 (16%) were currently on antidepressant medication.

Conclusions

This study demonstrates that disease flare in BD causes significant distress to patients. Therefore it of utmost important to consider both the physical and mental wellbeing of patients when managing this group of patients.

(18A125) ABSTRACT 29 **POSTER 21**

Are Exacerbations of Behçet's Disease (BD) Related to The Menstrual Cycle?: The Relationship Between Menstruation and Disease Flare In A Northern European BD Cohort

Author(s)

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Introduction

Behçet's disease (BD) is most commonly diagnosed during the reproductive years. Studies have shown that progesterone and oestrogen tend to exhibit anti-inflammatory activity.[1] The precipitous decline of progestogen at the onset of menstruation and after delivery with evidence of disease flare during this period among BD patients in a Korean study has led to the belief that exacerbation may be likely related to the abrupt progesterone withdrawal.[2] The epidemiological characteristics reflect a possible association of BD and female sex hormones.

Aims/Background

We aim to determine the relationship of Behçet's disease flare-ups and menstrual cycle.

Method

A total of 16 female patients fulfilling the International Study Group for Behçet's Disease (ISGBD) criteria were recruited from a regional rheumatology centre. Telephone interviews were performed to evaluate relationship between the occurrence of BD flare-ups and the menstrual cycle.

Results

The median age was 39 years with interquartile range (IQR) of 14.75 and the median age of menarche was 13 years with IQR of 2. 4(25%) women were menopausal.

7(43.75%) of the patients experienced exacerbation of BD related to menstruation. The types of disease flare were oral aphthosis (85.71%), arthralgia (57.14%), genital ulcerations (42.86%), lethargy (42.86%), skin manifestations (14.29%) and headache (14.29%).7 patients (43.75%) were on contraception, 6 of which contained progesterone.

Of the 9 patients who did not experienced exacerbation during menstruation, 4 were on progesterone containing contraceptives. 9(56.25%) had previous pregnancies; 2 patients had an episode of miscarriage and 1 had a stillbirth.

Conclusions

This study demonstrates that the female sex hormones play a major role in the disease activity of BD. Detailed studies in a larger cohort should be performed to further confirm the relationship.

(18A126) ABSTRACT 30 **POSTER 22**

Targeting cellular metabolism in CD4-stimulated synovial fibroblasts reduces inflammation and joint degradation in rheumatoid arthritis

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Introduction

Rheumatoid arthritis (RA) is a chronic autoimmune disease characterised by synovial tissue proliferation and degradation of articular cartilage. Activated synovial fibroblasts proliferate and express matrix-degrading proteases and pro-inflammatory cytokines, which contribute to cartilage and joint destruction. Moreover, synoviocyte activation correlates with infiltration of inflammatory lymphocytes and monocytes.

Aims/Background

To characterise the functional relationship linking fibroblasts and T lymphocytes in this complex microenvironment, we established an in-vitro model to examine the outcomes of co-culturing activated human CD4 T cells with RA synovial fibroblast cells (SFC) and subsequently altered a range of cellular metabolic pathways to identify key molecular players in joint inflammation.

Method

Anti-CD3/28-stimulated CD4 T cells from healthy human donors were co-cultured with SFC derived from arthroscopy biopsies of RA patients for 5 days. Supernatants were harvested and assayed for cytokine production by ELISA, while the cells were examined for proliferation, adhesion molecules, RANK ligand and glucose transporter, GLUT1, by flow cytometry. Furthermore, SFC were cultured with conditioned medium from stimulated healthy CD4 T cells and manipulated using metabolic manipulators AICAR and 2-DG and analysed by Seahorse assay and for invasion across a matrigel membrane by microscopy.

Results

We found that CD4 T cells induced increased levels of adhesion molecules in SFC, independent of cell contact. Furthermore, CD4 T cells promoted pro-inflammatory cytokine secretion and

invasiveness in these SFC. Interestingly, AICAR and 2-DG inhibited invasiveness while reducing the levels of adhesion molecules and IL-8. Seahorse flux analysis showed that T cells enhanced glycolysis, while concomitantly reducing oxidative phosphorylation in SFC, which was reversed by the addition of AICAR or 2-DG. Thus by targeting specific metabolic pathways, these inflammatory responses could be reversed.

Conclusions

Our results show that CD4 T cells work mutually with fibroblasts to create an inflammatory microenvironment which directly contributes to joint destruction through pro-inflammatory mediators, as well as a switch from oxidative phosphorylation to glycolysis. Therapeutic altering of these metabolic pathways using compounds that reduce inflammation, could have potential clinical implications for RA treatment.

(18A128)ABSTRACT 31

POSTER 23

Tofacitinib Impairs Monocyte-Derived Dendritic Cell Differentiation In Rheumatoid Arthritis And Psoriatic Arthritis

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Introduction

Tofacitinib (Pfizer) is an oral Janus kinase inhibitor, recently approved for the treatment of rheumatoid arthritis (RA) and psoriatic arthritis (PsA). Its effect on dendritic cells development and function remains still to be elucidated. Monocyte-derived dendritic cells (Mo-DC) are a subset of inflammatory DC derived from circulating monocytes and have a key role in inflammation and infection.

Aims/Background

To evaluate the effect of Tofacitinib on the ability of monocyte from RA and PsA patients to differentiate into dendritic cells, an important step in innate immunity.

Method

Monocytes were isolated from blood of healthy donor (HC), RA and PsA patients by magnetic separation and plated in presence/absence of GM-CSF/IL-4 cocktail for 7 days. Tofacitinib (1μM or DMSO as control) was added 15 minute prior to cytokine stimulation. CD209 and CD14 were evaluated by flow cytometry in the CD11c+ population. Dendritic cell uptake of soluble antigens by non-specific macropinocytosis (using Lucifer Yellow), and receptor-mediated endocytosis (using DQ Ovalbumin) were evaluated. Western blot analysis was utilized for analysis of NOX2, NOX5 and actin protein expression on the total cell lysate. Finally, the frequency of CD209 cells was evaluated by flow cytometry in both peripheral blood (PBMC) and synovial fluid (SFMC) mononuclear cells from RA and PsA patients.

Results

Mo-DC differentiation in RA and PsA patients was inhibited by Tofacitinib, as shown by reduced CD209 marker expression, paralleled by an increase of CD14 marker expression. The decreased differentiation ability was translated into a function impairment of phagocytic ability, as observed by the decreased uptake of both DQ Ovalbumin (receptor-mediated endocytosis) and Lucifer Yellow (macropinocytosis).

Tofacitinib decreased NOX5 and increased NOX2 protein expression in Mo-DC in both PsA and RA Mo-DC. Finally, we identified the CD209 population in PBMC cells from RA and PsA patients, and we observed an increased frequency of this population at the site of inflammation in SFMC cells from PsA and RA patients.

Conclusions

Together, these observations suggest a novel mechanism of action of Tofacitinib in RA and PsA, by inhibiting Mo-DC development, which may alter migration of DC to the joint and subsequent activation of the immune response.

(18A129) ABSTRACT 32

POSTER 24

The Association Between Biologic Exposure and Diagnosis of Lymphoma, A Case Series and Review of the Literature.

Author(s)

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Introduction

In the modern era the routine use of biologic agents in the treatment of inflammatory diseases has been an important medical advancement, with great outcomes and improvement in quality of life for patients. However these medicines are associated with rare but serious adverse events. The question of an association between use of biologics and the development of lymphoma has been suggested. Here we review a series of eight patients from The Adelaide and Meath Hospital, Tallaght (AMNCH) that developed lymphomas post immunosuppressive therapy.

Aims/Background

We conducted a review of the literature on the association of biologic therapy and development of lymphomas.

Method

A list was compiled of patients who had attended the haematology department in AMNCH for treatment of lymphomas with a history of biologic drug exposure (Tumour necrosis factor inhibitors (Anti-TNF), Interleukin-6 inhibitors (IL-6) etc). A chart review and brief outline of each case was completed. The PubMed database was searched for articles regarding biologic agents and lymphomas and the relevant papers reviewed.

Results

Clinical detail of seven patients that underwent treatment for lymphoma with prior biologic exposure in the AMNCH catchment area was available. In the case series four had a diagnosis of rheumatoid arthritis (RA) one ankylosing spondylitis, one crohns and one hydradenitis suppurativa. Five had previously been treated with adalimumab, two with etanercept and one with golimumab. Four of the patients went on to develop diffuse large B cell lymphoma (DLBCL), two Hodgkins Lymphoma, one large T cell granular lymphocytosis. The overwhelming evidence from the literature review, including a Cochrane review of 163 RCTs with 50,010 participants and 46 extension studies with 11,954 participants states that although biologic therapy is associated with adverse effects there is no link between their use and development of lymphoma. Indeed the pathophysiology of inflammatory conditions such as RA, crohns etc predisposes to malignancy.

Conclusions

Our case series details information on seven patients that developed different subtypes of lymphoma post biologic therapy. On review of the literature to date there is no evidence that biologics cause lymphoma, rather inflammatory activity. These are relatively new medications and long term data and registries are required.

(18A131) ABSTRACT 33 POSTER 25

A Comparison between a point of care uric acid testing meter and the standard laboratory serum uricase method.

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Introduction
Gout is a common and increasing cause of acute and chronic arthritis; responsible for significant use of resources due to hospital admissions for acute attacks.
Sustained low levels of serum uric acid (SUA) is a key factor in lowering flare ups of gout. 1
Laboratories in hospitals use the most common method for identifying SUA, this is based on the use of the enzyme uricase. 2
A point of care (POC) test meter that provides reliable and instant SUA could potentially improve patient care through more frequent SUA monitoring. Such a device could allow rapid adjustments to drug therapy and enable SUA targets to be reached an maintained as recommended by international guidelines. 3
Aims/Background
We aimed to compare the precision and accuracy of a commercially available POC test meter to the standard accredited uricase laboratory assay that is commonly used in practice to determine SUA.
Method
A commercially available uric acid POC (Humasens Plus) was used. Patients attending the rheumatology clinic had serum uric acid tested by the standard laboratory uricase method, and each patient had 2 finger prick blood samples taken and SUA measured using the POC. A single batch of manufecturer test strips were used.
SUA results from the lab uricase method and from the POC for each patient were then compared.
Results
11 patients were recruited and had SUA measured via the lab uricase method. A total number of 22 finger prick test samples were obtained from 11 patients.
The HumaSens meter had a high coefficient of varation CV of 64.1%. There was no instance where the HumaSens meter provided SUA that was in concordance with the laboratory uricase test.
Only one patient had the same reading on their 2 separate finger pricks using the POC (9.1%).
Conclusions
The HumaSens was overall easy to use. However it demonstrated a high CV of 64.1% which is not acceptable and would not allow for reliable SUA monitoring. Therefore we do not recommend using this POC in the management of gout.

Figure

(18A132) ABSTRACT 34 POSTER 26

Evaluation of the activity of the Rheumatology department in-patient consult service in a tertiary hospital

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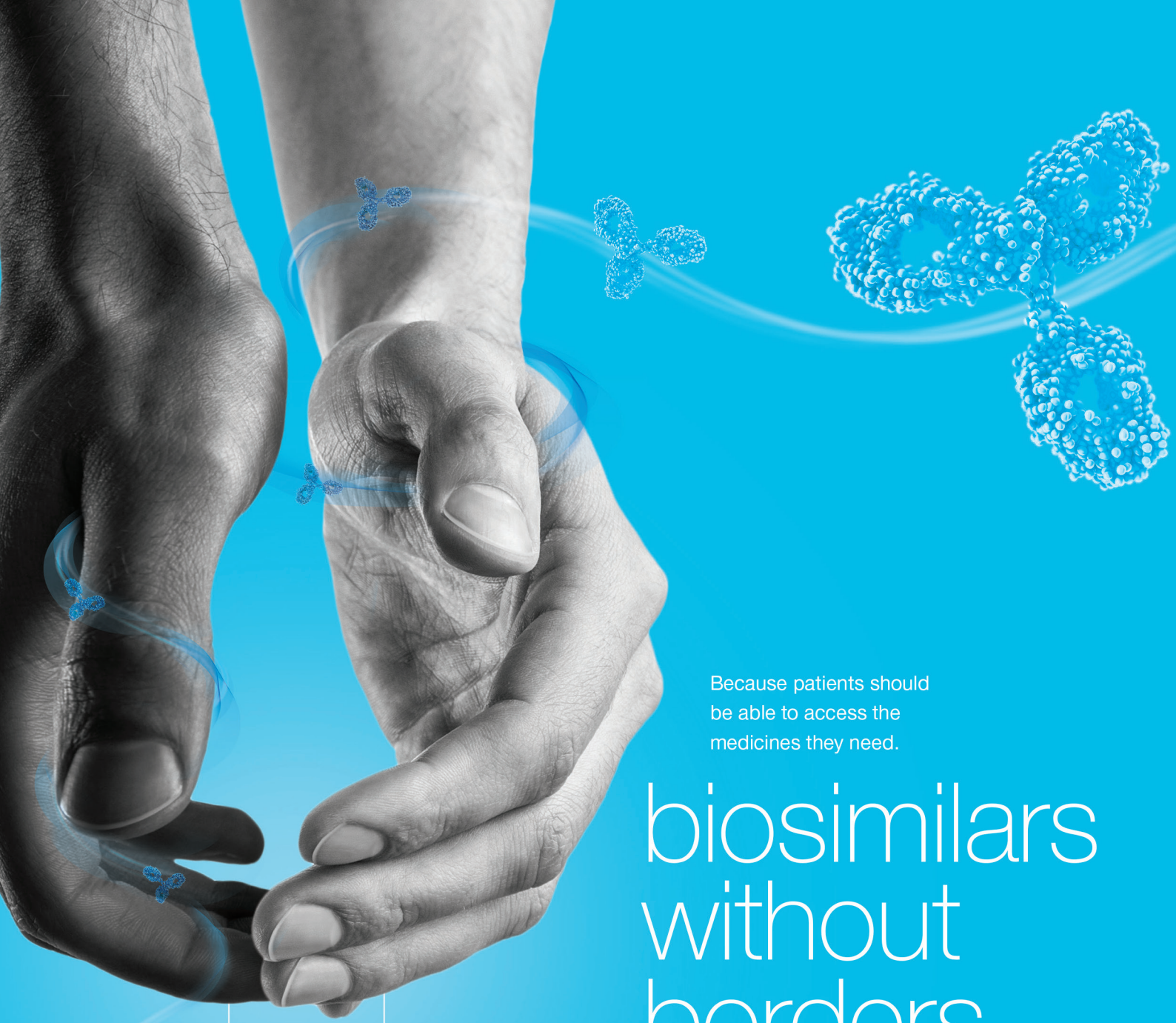
Introduction
Aside from running a busy outpatient department and participating in hospital medical on-call, Rheumatologists provide an inpatient consult service for referrals ranging from routine to urgent to emergency.
Aims/Background
The aims of our study were
1) To retrospectively assess the number, nature and demographic data of inpatient rheumatology consultations over a period of 2 months
2) To identify the final rheumatologic diagnosis made by the consult team
3) To examine the documentation of the final rheumatologic diagnosis in patients' electronic discharge summaries (EDS).
Method
Consults are requested by other specialties via an electronic system; the Patient Administration System (PAS).
Consecutive referrals seen by the inpatient consult service from July 1st 2017 to August 31st were recorded on an excel spreadsheet in the Rheumatology shared drive.
The cases were reviewed and the following were recorded: patient's demographic information, reason for Rheumatology referral, final rheumatologic/musculoskeletal diagnosis, patients offered follow-up in rheumatology outpatient upon discharge, treatment advised, number of patients who required a repeat consult.
The patients' EDS were also reviewed and documentation of a rheumatology consult taking place during their inpatient stay and the rheumatologic diagnosis made were recorded.
Results
65 patients were recorded in the excel spreadsheet over the 2 month period in 2017; of whom 35 were males and 30 were females with a mean age of 54 years old (age ranged from 18 to 90 years).
A repeat consult was requested on 10% of the above total number of patients during this period of 2 months.The top 5 reasons for referrals in descending order were as follows: crystal induced arthritis (n=17, 26%), polyarthritis in patients with either known or newly diagnosed inflammatory arthritis (n=7, 11%), osteoarthritis (n=5, 7.7%), advise regarding immunosuppressant therapy in patients with underlying rheumatologic conditions (n=5, 7.7%) and finally osteoporosis and advise regarding bone protection (n=4, 6.2%).
10 patients received intra-articular joint aspiration +/- steroid injections.
More than half of the patients seen on consult were offered a Rheumatology outpatient follow-up upon discharge from the hospital (n= 35, 54%).
75% of discharge summaries (n=49) correctly identified that a rheumatology consult took place during the patients' stay in hospital and 63% of discharge summaries (n=41) had the rheumatologic diagnosis recorded.
Conclusions
The rheumatology inpatient consult service has become busier over the years. This review reflects the variety of rheumatic diseases seen on consult, it also highlights that the most common referral is crystal-induced arthritis.
Gout and pseudogout are conditions commonly encountered in



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primary care setting and perhaps further education regarding the management of these conditions may be required amongst other specialties.
The consult service helped other specialties to establish or confirm the diagnosis and a treatment plan put in place and over 50% of patients were offered follow-up.
Only 63% of patients had their underlying musculoskeletal/ rheumatologic condition recorded in their discharge summaries. While this has slightly improved compared to the previous figure of 59.6% quoted in an audit in 2016, there is further room for improvement. This has potential impact when patients are discharged back to their primary care physicians and also is likely to affect hospital reimbursement.
This needs to be highlighted to junior doctors responsible for writing discharge summaries and further work is needed to educate on the importance of accurately documenting diagnoses on discharge summaries.

(18A134) ABSTRACT 35 **POSTER 27**

Audit on Screening, Management and Follow Up of Low Bone Density in Patients with Inflammatory Arthritis

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Introduction
Guidelines are lacking on the screening and management of low bone mineral density (BMD) in patients with inflammatory arthritis (IA), who are at high risk of compromised BMD because of the disease, steroid usage and other risk factors. There is also individual variability regarding follow up imaging.
Aims/Background
To audit the screening and management of low BMD in IA within a Rheumatology Rehabilitation Unit.
Method
Patients admitted from 14th Aug to 31st Dec 2017 were enrolled in the audit after informed consent. Parameters analysed included screening for low BMD since diagnosis, appropriateness of medications, education on lifestyle and exercises, repeat DEXA interval and the type of scanner. Data was collected by review of medical record, face-to-face and telephonic interviews. It was analysed with SPSS.
Results
A total of 50 (45 females, 5 males) patients were included. 11 patients had no DEXA planned since diagnosis and 1 was awaiting. 18 patients did not have FRAX screening. 8 patients had DEXA within 2 years of diagnosis. Out of those who had the DEXA, 5 never had a repeat scan and only in 15, it was repeated within 5 years. 20 had the DEXA scan on the same machine. 5 patients had osteoporosis on scan out of which 4 were on bone protection. 19 patients had osteopenia out of which 18 were on calcium and vit D supplementation. 34 out of 50 stated they did not receive education on bone health and DEXA scanning during admission. 18/50 did not receive life style advice and 3/50 were unfamiliar with weight bearing excerices.
Conclusions
Timely and regular assessment of fracture risk is essential in patients with IA . Our audit indicates that there is lack of clarity on best practice in the timing of assesment of bone density after diagnosis and subsequent follow up. It also showed that majority of those with low bone density were on the appropriate bone protection. Follow up DEXA was performed on the same machine for all the patients. There should be more focus on educating patients about the screening process and its significance.

(18A135) ABSTRACT 36 **POSTER 28**

The role of cellular metabolism in Rheumatoid and Psoriatic Arthritis

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Introduction
While Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA) share common features such as synovial hyperplasia, cartilage degradation and subchondral bone remodelling, their distinct differences, which aid their diagnosis, may account for the varying responses to specific treatments. Increased proliferation and angiogenesis transforms the synovium into an aggressive, tumour-like "pannus" which contributes to disease pathogenesis. Hypoxia, resulting from dysregulated angiogenesis, can cause cells to switch from mitochondrial respiration to anaerobic glycolysis in order to meet the cellular energy demand. The RA synovium is more hyperplastic and invasive than that of PsA, while a more abnormal vasculature is observed in the PsA synovium and correlates with a reduction in tissue pO2 levels.
Aims/Background
The aim of this study was to compare the metabolic profiles of RA and PsA synovial fibroblast cells (SFC) and to determine whether there is a correlation between dysregulated metabolism, cell function and disease pathogenesis.
Method
The metabolic profile of RA and PsA SFC was analysed using the XF96 Extracellular Flux Analyzer. Gene expression was determined by quantitative-PCR. SFC migration and invasion were observed by microscopy following wound-scratch and transwell invasion assays.
Results
RA SFC displayed increased migratory capacity and invasiveness compared to PsA SFC. Expression of IL-6, IL-8 and the glycolytic markers, GLUT1/3, HK2, PKM1/2, PDK2 and LDHA is higher in RA SFC compared to PsA SFC. PsA SFC have a higher oxygen consumption rate (OCR), extracellular acidification rate (ECAR) and ECAR:OCR ratio than RA SFC.
Conclusions
Consistent with clinical observations, RA SFC have a greater migratory and invasive capacity than PsA SFC. Interestingly, despite the lower expression of glycolytic markers, PsA SFC display increased glycolysis compared to RA SFC and have a more glycolytic phenotype as indicated by a higher ECAR:OCR ratio. This may be due to the more hypoxic joint microenvironment. Further investigation is required to determine the precise role of metabolism in specific pathogenic processes.

(18A138) ABSTRACT 37 **POSTER 29**

Synovial Phenotype is Associated With Patient Biometrics in Inflammatory Arthritis

Author(s)
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Department(s)/Institutions
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Prescribing Information

Humira (adalimumab) 20mg and 40mg solution for injection in pre-filled syringe, Humira 40mg solution for injection in pre-filled pen, Humira 40mg/0.8ml solution for injection (vial) and Humira 80mg solution for injection in pre-filled pen. Refer to Summary of Product Characteristics (SmPC) for full information. Presentation and method of administration: Each single dose 0.2 ml pre-filled syringe contains 20 mg of adalimumab for subcutaneous injection. Each single dose 0.4 ml pre-filled pen, 0.4 ml pre-filled syringe or 0.8 ml vial contains 40mg of adalimumab for subcutaneous injection. Each single dose 0.8 ml pre-filled pen contains 80 mg of adalimumab for subcutaneous injection. **Indications and Dosage:** Humira 20mg pre-filled syringe, Humira 40 mg vial and Humira 80 mg pen are only approved for use in specific indications with a therapeutic requirement, **please refer to SmPCs for full information**. Humira treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Humira is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Humira. 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. **Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. Dosage: 40 mg single dose every other week (EOW). Concomitant MTX should be continued. In monotherapy, patients may require 40 mg every week or 80mg EOW if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction of Humira after discontinuation for 70 days or longer gave same magnitudes of clinical response and similar safety profile as before dose interruption. **Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX, for active pJIA, with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Dosage: 10 kg to <30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response or intolerance to, conventional therapy. Dosage: 15 kg to < 30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW. **Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. Dosage: adults: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and / or MRI), and an inadequate response to, or intolerance to nonsteroidal anti-inflammatory drugs. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriasis (Ps), adults:** For moderate to severe chronic plaque psoriasis in candidates for systemic therapy. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Beyond 16 weeks, patients with inadequate response can increase dosage to 40 mg every week or 80mg EOW (refer to SmPC). If adequate response is achieved with 40mg every week or 80mg EOW, dosage may subsequently be reduced to 40 mg every other week. **Psoriasis, paediatrics 4 years and above:** For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate. Dosage: 15 kg to < 30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If ≥ 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. **Hidradenitis suppurativa (HS), adults and adolescents from 12 years of age:** For active moderate to severe HS (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. Dosage: HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80mg EOW. Reintroduction after treatment interruption: 40 mg every week or 80 mg EOW. Dosage: HS, adolescents from 12 years and ≥30 kg: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. If there is inadequate response to 40 mg EOW, an increase in dosage to 40 mg every week or 80mg EOW may be considered. Treatment interruption: Humira may be re-introduced as appropriate. Adults and adolescents from 12 years of age: Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Evaluate periodically the benefit and risk of continued long-term treatment. **Crohn's disease (CD), adults:** For moderately to severely active CD with who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, intolerance to or medical contraindications for such therapies. Dosage: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosage to 40 mg every week or 80mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Paediatric Crohn's disease (CD), 6 years and above:** For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator. Dosage: < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW. If insufficient response, consider an increase in dosage to 20 mg every week. If ≥ 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). Dosage: Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosage to 40 mg every week or 80mg EOW. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time. **Uveitis, adults:** For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Humira. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Paediatric Uveitis, 2 years and above:** For chronic non-infectious anterior uveitis with inadequate response or intolerance to conventional therapy, or in whom conventional therapy is inappropriate. Dosage: < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Optional 80 mg loading

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- Active and progressive **psoriatic arthritis** in adults when the response to previous disease-modifying anti rheumatic drug therapy has been inadequate.
- 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.

dose one week prior to start of maintenance therapy. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Contraindications:** Hypersensitivity to the active substance or any of the excipients (see SmPC). Active tuberculosis (TB) or other severe infections such as sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV). **Warnings and precautions:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal products. ***Infections:*** Patients taking TNF-antagonists are more susceptible to serious infections especially if impaired lung function. Monitor for infections, including TB, before, during and for 4 months after treatment. Do not initiate treatment with an active infection, until it is controlled. Consider risk/benefit prior to treatment in patients exposed to high risk of TB or who have travelled in areas of high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications. ***Serious infections:*** Serious infections, including those with hospitalisation or death reported in patients receiving treatment. ***TB:*** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated) reported. Screen all patients before therapy initiation for active or latent TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If active TB is diagnosed Humira therapy must not be initiated. If latent TB is suspected, consult a physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Humira. Despite prophylaxis TB reactivation has occurred on Humira. ***Other opportunistic infections:*** Opportunistic infections observed in patients receiving Humira. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. ***Hepatitis B Reactivation:*** Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult with a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs stop treatment and initiate appropriate anti-viral and supportive treatment. ***Neurological events:*** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurological evaluation should be performed in patients with non-infectious intermediate uveitis before therapy initiation and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders ***Allergic reactions:*** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction, stop Humira immediately and initiate appropriate therapy. ***Malignancies and lymphoproliferative disorders:*** A possible risk of malignancy, including lymphoma and leukaemia, in all patients including paediatric patients, treated with TNF antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non-melanoma skin cancer prior to and during treatment, caution in COPD patients, and in patients with increased risk of malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Humira (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC, history of dysplasia or colon carcinoma to be screened for dysplasia before and during treatment. ***Haematologic reactions:*** Adverse events of the haematologic system reported with Humira. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment. ***Vaccinations:*** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to Humira treatment ***Congestive heart failure:*** See contraindications. Caution is advised in mild heart failure (NYHA class I/II). Discontinue treatment for new or worsening symptoms of congestive heart failure. ***Autoimmune processes:*** Autoimmune antibodies may form with Humira. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. ***Surgery:*** Consider the long half-life of Humira for planned surgical procedures. Closely monitor for infections. ***Small bowel obstruction:*** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture requiring surgical treatment. ***Elderly:*** Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients. **Interactions:** Antibody formation was lower when Humira was given together with MTX in comparison with use as monotherapy. Combination of Humira with other biologic DMARDS (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Not recommended during pregnancy. Women of childbearing potential should use adequate contraception and continue its use for at least five months after the last Humira treatment. No administration of live vaccines to infants exposed to Humira in utero for 5 months following mother's last Humira treatment during pregnancy. Women must not breast-feed for at least five months after the last Humira treatment. **Adverse Reactions:** Very common ≥ 1/10: Respiratory tract Infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (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). **Serious, including fatal, adverse reactions have been reported**. including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome.

Prescribers should consult the SmPC for the complete list of reported side effects. Legal Category: POM. **Marketing Authorisation Numbers:** EU/1/03/256/022, EU/1/03/256/013, EU/1/03/256/017, EU/1/03/256/001, EU/1/03/256/021. **Further information:** available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24. **HCPs are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Date of revision of PI:** April 2018, PI/256/022

Abbreviations: CRP: C-reactive protein.

*21 years refers to clinical trial and post marketing experience since 2003 in rheumatoid arthritis.

References: 1. Burmester GR, Mease P, Dijkmans BAC, et al. Adalimumab safety and mortality rates from global clinical trials of six immune-mediated inflammatory diseases. Ann Rheum Dis 2009;68(12):1863–9. **2.** Humira® 40 mg solution for injection in pre-filled pen and syringe, Summary of Product Characteristics, available at www.medicines.ie.

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Introduction

The potential importance of altered body composition in the development of and disease course in inflammatory arthritis is increasingly being recognised. Body composition in different types of inflammatory arthritis and its influence on synovial pathology remains to be fully characterised.

Aims/Background

To evaluate body composition in seropositive and seronegative rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients and assess associations with disease characteristics and baseline synovial arthroscopic findings.

Method

We performed a prospective observational study of consecutive inflammatory arthritis patients seen in outpatient clinics. Demographic and clinical characteristics were collected on all patients. Synovial biopsy was performed by needle arthroscopy, and macroscopic and histologic features recorded. The degree of synovitis and vascularity were recorded on a 0–100-mm visual analog scale, and chondropathy on a semi-quantitative scale from 0-3. Mann-Whitney U test was used to compare groups. Spearman's Rank Correlation Coefficient was used to assess for associations between biometrics and demographic and clinical markers. GraphPad Prism Version 7 and IBM SPSS Statistics Version 24 were used for data analysis.

Results

We included 58 patients, 32 with seropositive RA, 10 with seronegative RA, and 16 with PsA. 37 (64%) were female. Mean (SD) age was 52.8 (13.9) years. Mean (SD) BMI was 29.7 (6.3) kg/m2, waist circumference was 94.4 (20.3) cm, and hip circumference 104.3 (21) cm. Full demographic and clinical details are shown in Table 1. Seronegative RA patients had significantly increased BMI (p=0.033) and waist circumference (p=0.017), but not hip circumference (p=0.248) compared to seropositive RA patients. PsA patients had significantly increased BMI (p<0.0001), waist circumference (p=0.001), and hip circumference (p<0.001) compared to seropositive but not seronegative RA patients. There was a significant correlation between waist circumference and both synovitis (r=0.31, p=0.018) and vascularity (r=0.34. p=0.010) at arthroscopy. BMI and hip circumference did not correlate with arthroscopic findings.

Conclusions

Different types of inflammatory arthritis have distinct body composition profiles. Waist circumference, but not other biometrics, correlates with baseline synovial inflammation and vascularity.

Figure

	Seropositive RA	Seronegative RA	PsA
Female, n (%)	18 (56.3)	7 (70)	12 (75)
Age, mean (SD), years	55.9 (14.6)	46.7 (15.8)	50.6 (9.6)
Rheumatoid Factor+, n (%)	31 (96.9)	0 (0)	3 (18.8)
ACPA+, n (%)	24 (75)	0 (0)	2 (12.5)
BMI, mean (SD), kg/m^2	26.9 (4.8)	31.9 (7.1)	34.0 (5.8)
Waist circumference, mean (SD), cm	86.4 (20.4)	101.3 (16.3)	105.9 (15.4)
Hip circumference, mean (SD), cm	98.4 (23.9)	105.8 (16.4)	115.4 (11.1)
CRP, mean (SD), mg/L	12.8 (17.8)	18.6 (27.1)	7.5 (6.0)
ESR, mean (SD), mm/hr	28.2 (24.5)	18.9 (19.7)	17.5 (8.8)
Swollen Joint Count, mean (SD)	4.1 (5.0)	2.4 (3.1)	3.2 (6.1)
Tender Joint Count, mean (SD)	6.2 (6.8)	7.5 (7.5)	4.4 (7.1)
VAS general health, mean (SD), mm	49.1 (31.0)	51.3 (21.3)	49.1 (25.2)
DAS28-CRP, mean (SD)	3.91 (1.54)	3.98 (0.94)	3.6 (1.4)
Synovitis, mean (SD), mm	65.3 (20.3)	60.0 (14.1)	75.0 (12.6)
Vascularity, mean (SD), mm	62.5 (19.8)	58.0 (17.5)	75.0 (13.2)
Chondropathy, mean (SD)	1.6 (0.7)	1.4 (0.6)	1.5 (0.7)

RA, rheumatoid arthritis; PsA, psoriatic arthritis; ACPA, anti-citrullinated protein antibody; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate

(18A139) ABSTRACT 38 POSTER 30

Increased Invasive Capacity and Metabolic Activity in Synovial Fibroblasts from Children with Downs Arthropathy Compared to Juvenile Idiopathic Arthritis

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Introduction

Downs Arthropathy (DA) is an inflammatory joint condition affecting children with Down syndrome, which is under-recognised, has a delayed diagnoses, resulting in chronic disability. Our clinical research showed an increased risk of arthritis in children with Down syndrome, with the prevalence in Ireland for DA 18-21 times greater than Juvenile idiopathic Arthritis (JIA). Furthermore children with DA had more erosive joint damage compared to JIA. This observed increase in erosive disease suggests that DA synovial fibroblasts (SFC) have a more invasive phenotype, however to date little is known about the underlying mechanisms that drive disease pathogenesis in DA.

Aims/Background

The aim of the present study is to compare the function of primary synovial fibroblasts from children with DA vs JIA.

Method

Synovial tissue biopsies were obtained from children with DA and JIA and assessed histologically for levels of vascularity, lining layer hyperplasia and sub-lining inflammation. Primary synovial fibroblasts were isolated from both DA and JIA and functional comparisons performed at passage 3. DASFC and JIASFC migration was assessed by wound repair scratch assays. Biocoat Matrigel™ Invasion Chambers were used to assess DASFC and JIASFC invasiveness. DASFC and JIASFC bioenergetic activity was assessed using the XFe96-Flux-analyser.

Results

Synovial tissue analysis demonstrated a marked increase in synovial lining layer hyperplasia in DA vs JIA, with a median lining layer thickness score of 6(3-9) in DA vs 3(2-4) JIA, suggesting a more invasive pannus in DA compared to JIA. An increase in the migration of DASFC compared to JIASFC was observed, an effect paralled by a significant increase in the invasive capacity of DASFC vs JIASFC. Metabolic activity was markedly different in DASFC vs JIASFC, with DASFC displaying increased basal metabolic activity compared to JIASFC.

Conclusions

This is the first study to demonstrate differences in synovial pathology of children with DA vs JIA, demonstrating a marked increase in the invasive layer of DA synovium compared to JIA. This was paralleled by a significant increase in the migratory, invasive and bioenergetic profile of DASFC vs JIASFC, a phenotype that may contribute to the increased erosive disease observed in DA compared to JIA.

(18A140) ABSTRACT 39 POSTER 31

A retrospective cohort study of IgG-4 Related Disease in Irish patients

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Introduction
Immunoglobulin (Ig) G4-related disease (IgG4RD) is a novel clinical entity characterized by elevated serum IgG4 concentration and tumefaction or tissue infiltration by IgG4-positive plasma cells.
Aims/Background
To describe the clinical presentations, laboratory features, imaging manifestations, histopathologic characteristics and treatments in a cohort of 38 patients with IgG4RD.
Method
A retrospective study was performed at St. Vincent's University Hospital. Clinical, laboratory, imaging and histopathologic data was retrieved from electronic records. All data were assessed using SPSS 24.0.
Results
Median age was 59 years with M:F ratio= 2.2:1. 24 (63.2%) patients were between 25-65 years), 14 (36.8%) were >65 years. 23 (60.5%) patients fulfilled the Comprehensive Diagnostic Criteria for IgG4RD as 'definite', whereas 5 (13.2%) patients fulfilled 'probable' diagnoses and 10 (26.3%) patients fall in 'possible' category. GI manifestations (followed by pancreatic) were the most frequent clinical presentation. 23 (60.5%) patients presented with single organ involvement;pancreas was the most frequently involved organ (17/38, (44.7%)). 55.3% had a serum IgG4 level above 135mg/dL. Lymphoplasmacytic infiltration was the commonest histopathologic pattern reported in 29 (76.3%) specimens. 25 (65.8%) patients had received steroid therapy and 19 (50.0%) had a good response. 11 (28.9%) patients received immunomodulatory agents including Rituximab (n=4), Azathioprine (n=7), and Mycophenolate mofetil (n=4). Overall, 28 (73.7%) patients had complete remission with treatment.
Conclusions
IgG4RD is a rare entity in Ireland and an inadequately understood condition overall. Further research is required to better understand the pathophysiology, clinical course and optimal treatment for IgG4RD.

(18A142) ABSTRACT 40 POSTER 32

Higher Serum Uric Acid Levels Protect Against Osteoporosis in Patients With Axial Spondyloarthropathy

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Introduction
Serum urate (SUA) is a risk factor for metabolic disease, such as hypertension. SUA also has an antioxidant effect, protecting against diseases with high oxidative stress. Osteoporosis is characterised by high oxidative stress levels, mediated through increased osteoclastic activity. Antioxidants may have protective properties against bone loss. Literature examining SUA and its impact on bone mineral density (BMD) in axial spondyloarthropathy (axSpA) is limited.
Aims/Background
Aim: examine the relationship between SUA and BMD in a well-characterised axSpA cohort.
Method
Patients fulfilling modified New York (mNY) or Assessment of SpondyloArthritis International Society (ASAS) criteria were consecutively recruited from 2 centres in this cross-sectional study. Patients underwent a detailed assessment: demographics, disease-related variables (validated measures of disease activity included BASDAI, ASDAS-CRP, BASMI), clinical examination, laboratory parameters (routine bloods, SUA, CRP, vitamin D). BMD was assessed using dual-energy x-ray absorptiometry of the lumbar spine and hip (total hip and femoral neck). SUA >360 µmol/L was considered high. Analysis was performed using SPSS.
Results
In total, 107 patients were included: 76% male, median (IQR) age 51.5 (17.8) years, disease duration 23.5 (20.4) years. Median BMI was 27.6 (6.5) kg/m^2 (31% obese). Low BMD was present in 38.5% of the cohort. Median (IQR) SUA in the cohort was 312 (119) µmol/L. SUA >360 µmol/L was present in 34% (n=36). More men than women had high SUA (94% v 5.6%, p<0.01). BMI was higher in those patients with SUA above 360 µmol/L than patients with normal levels (mean difference 4.2 kg/m^2, 95% CI 2.1-6.3).
SUA correlated positively (p<0.01) with BMD at the spine (r=0.3) and total hip (r=0.3). Patients with a high SUA had significantly less osteopenia or osteoporosis (19%) than patients with a normal SUA (46%) (OR 3.5, 95% CI 1.4-9.3).
In univariate logistic regression analysis, low SUA and low BMI were associated with low BMD. After correcting for obesity, patients with high SUA remained independently associated with normal BMD compared to those patients with a normal SUA (OR 3.4, 95% CI 1.2-9.6).
Conclusions
High SUA levels are independently associated with normal BMD, suggesting a protective effect of SUA against osteoporosis in axSpA patients.

(18A143) ABSTRACT 41 POSTER 33

Quantitative Ultrasound of the Calcaneus Has a Role to Play in Detecting Low Bone Mineral Density in Axial Spondyloarthropathy Patients

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Introduction
Dual energy x-ray absorptiometry (DXA) is gold standard for detecting osteoporosis. Quantitative ultrasound (QUS) of the calcaneus measures 3 parameters of bone: speed of sound (SOS), broadband ultrasound attenuation (BUA) and stiffness index (SI; composite of SOS and BUA) and can predict fragility fractures in postmenopausal women. QUS is cheap, portable and doesn't use any

ionising radiation. Few studies have investigated the use of QUS in axial spondyloarthropathy (axSpA).

Aims/Background

To investigate relationships between DXA and QUS in axSpA.

Method

Patients fulfilling modified New York (mNY) or Assessment of SpondyloArthritis International Society (ASAS) criteria were in this twin-centre cross-sectional study. DXA assessed BMD at the spine, hip and radius. QUS of the calcaneus generated SOS, BUA and SI. Patients had a detailed assessment that included demographics, clinical exam, laboratory assessment and validated measures of disease severity. SPSS was used for statistical analysis.

Results

Baseline characteristics of the cohort: n=107, 76% male, median (IQR) age 51.5 (17.8) years, disease duration 23.5 (20.4) years. Fragility fracture prevalence was 6%.

Using DXA and WHO criteria, 16.3% had osteoporosis, 41.3% of the cohort had osteopenia and 42.3% had normal BMD. Using QUS, 2.9% of the cohort had osteoporosis, 33.7% had osteopenia and 63.5% had normal BMD. Sensitivity of the QUS was 72% in detecting low BMD, specificity was 51%, positive predictive value was 71% and negative predictive value was 53%.

There was no difference in QUS parameters in the fractured versus non-fractured group; however fragility fractures occurred uncommonly in this cohort.

QUS parameter BUA correlated significantly ($p<0.05$) with all DXA sites (spine r=0.39, femoral neck r=0.33, total hip r=0.37, radius r=0.34), as did SI (spine r=0.32, femoral neck r=0.36, total hip r=0.35, total forearm r=0.37). There was no correlation between SOS and DXA measurements.

In multivariate regression, when controlling for age, gender and BMI, BUA and SI remained independent predictors of BMD at all DXA sites.

Conclusions

Quantitative ultrasound of the heel is independently associated with DXA measurements of BMD. More research is needed to determine association with fracture risk. QUS is a promising tool which may be incorporated in assessment for low BMD in axSpA.

(18A144) ABSTRACT 42 **POSTER 34**

Predicting Syndesmophyte Formation in Axial Spondyloarthropathy

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Introduction

Axial spondyloarthropathy (axSpA) is an inflammatory arthritis, which can result in syndesmophytes (new bone formation) and complete ankylosis of the spine. The pathogenesis of syndesmophytes is incompletely understood. Presence of baseline syndesmophytes predict further syndesmophytes, but other predictive factors have been difficult to define. The impact of extra-articular manifestations (EAMs) on syndesmophyte formation is unclear.

Aims/Background

1. Assess the burden of radiographic disease in axSpA
2. Determine variables associated with syndesmophytes, specifically investigating the effect of EAMs.

Method

A cross-sectional study of AxSpA patients was performed, comprising standardised clinical assessment and structured interviews. Lateral x-rays of the lumbar and cervical spine were performed to quantify syndesmophytes using a validated score (mSASSS) ranging from 0-72, with higher numbers indicating a higher burden. BASRI-hip was used to determine hip involvement, assessed on x-ray of pelvis.

Results

One hundred and four patients with axSpA were included: 78.8% (n=82) male, 98.1% (n=102) Caucasian, average (SD) age 50.8 (12) years, average disease duration 25 (13) years, EAM prevalence 29.1% (n=30). Uveitis was the most prevalent EAM (29%), followed by inflammatory bowel disease (IBD) (18.4%) and psoriasis (17.5%). Median (IQR) mSASSS was 9.5 (33.8), 10.6% (n=11) of patients had an mSASSS of 0 and 7.7% (n=8) had a bamboo spine. Increasing mSASSS correlated significantly ($p<0.05$) with increasing age (rho=0.6), longer disease duration (rho=0.5), rising BASMI (rho=0.8), higher BASFI (rho=0.4) and higher HAQ (rho=0.3). Patients with moderate or severe hip disease, as measured by BASRI, were more likely to have a higher mSASSS score (OR 3.8, 95% CI 1.5-9.3).

Patients with hypertension had higher median mSASSS score than patients without (25.4 v 7, $p<0.01$). Gender, HLA-B27 status, smoking, hypercholesterolaemia, ischaemic heart disease and diabetes had no impact on mSASSS.

The presence or absence of uveitis, psoriasis or IBD had no effect on syndesmophyte formation. Equally, peripheral arthritis had no effect.

Conclusions

In keeping with previous literature, higher mSASSS was associated with more severe disease. However, in contrast to other published studies, gender had no effect on the severity of mSASSS in our cohort. EAMs did not affect the mSASSS score, but worse hip disease did. It remains a challenge to predict which patients will develop syndesmophytes.

(18A145) ABSTRACT 43 **POSTER 35**

High Unemployment Rates in Irish patients with Ankylosing Spondylitis

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on behalf of the ASRI Steering Committee University Hospital Waterford & St James's Hospital

Introduction

Previous registry studies have noted increased rates of unemployment in patients with ankylosing spondylitis (AS)(1-2). With improved treatment options and earlier detection of AS, it was anticipated that this would no longer be true.

Aims/Background

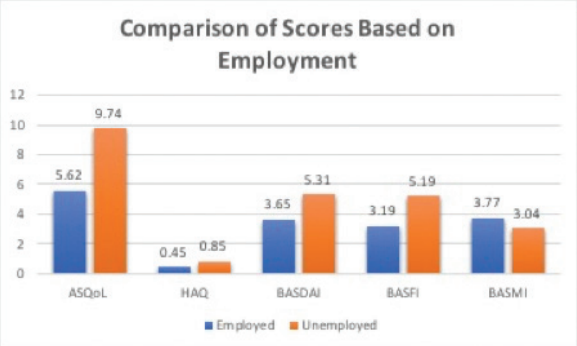
The Ankylosing Spondylitis Registry of Ireland (ASRI) is a source of epidemiological data on AS patients in Ireland. The aim of this study was to examine unemployment rates in this population and possible links with disease activity, function and quality of life.

Method

An analysis of the current patient population of the ASRI was performed using IBM SPSS Statistics version 25. Comparison of the mean ASQoL, HAQ, BASDAI, BASFI and BASMI scores were carried out between the employed versus the unemployed. An independent two tailed t test and a Mann Whitney U test was then carried out to determine significance. Further analysis was then done on age and disease duration.

Results
At the time of analysis 734 patients were enrolled. The mean age was 45.02, with 77% males and 23% female, mean duration of disease 18 years (means: ASQoL 6.57, HAQ 0.54, BASDAI 4.02, BASFI 3.63, BASFI 3.58). Unemployment rate in the ASRI population was 23%, which is noticeably higher than the national unemployment of 6%(3). Those patients were also noted to have higher ASQoL (9.74 versus 5.62), HAQ (0.85 versus 0.45), BASDAI (5.31 versus 3.65), and BASFI scores (5.19 versus 3.19)(figure 1). The difference between these means was statistically significant ($p<0.05$) across all 4 measures. However, BASMI scores were significantly lower in the unemployed (3.75 versus 3.04). No statistically significant difference was detected between genders. The distribution of age and disease duration was determined to be equal between the groups.
Conclusions
There is a higher prevalence of unemployment in the AS population as compared to the general population of Ireland. Unemployed AS patients tend to have decreased quality of life, poorer level of function, and higher levels of disease activity. Further research is needed to determine causation between level of disease activity and employment.

Figure



(18A147) ABSTRACT 44 **POSTER 36**

Comparison of Incidence of Adverse Events in Oral versus Injectable Methotrexate Therapy

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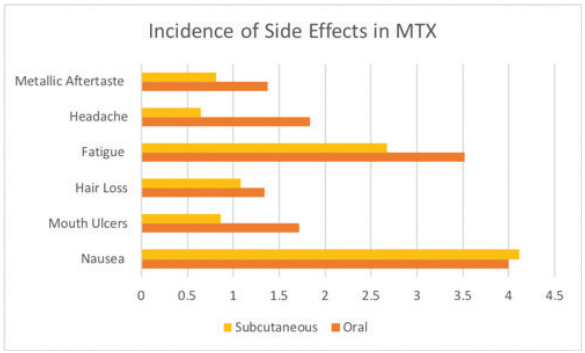
Introduction
Methotrexate(MTX) is one of the most commonly used disease modifying anti-rheumatic drugs (DMARD) currently in use. Its efficacy and safety has been well documented over the years in numerous autoimmune mediated inflammatory conditions. The 2015 American College of Rheumatology(ACR) guidelines on the management of rheumatoid arthritis recommend methotrexate as the preferred DMARD when initiating treatment. The incidence of side effects can limit use of MTX and in some cases require discontinuation. Subcutaneous MTX has been previously proposed as an option to circumvent this issue.
Aims/Background
To compare patient experiences and side effect profile with MTX in tablet form and as a subcutaneous injection in our patient population.
Method
An opt-in survey was carried out on all patients on Methotrexate attending the Rheumatology Outpatient Clinics and Infusion Room in University Hospital Waterford during a two-month period. The survey was constructed of ten questions which included duration of treatment, MTX dosage, MTX route (oral vs s/c) along with the frequency and severity of adverse effects. These were evaluated under the headings of nausea, mouth ulcers, hair loss, fatigue, headaches and metallic aftertaste. In patients experiencing adverse effects answers were recorded as a value between 1 to 10 to reflect frequency and severity. In total 49 patients participated in the survey and are included in the below calculations.
Results
In the studied population, 34 patients were on oral MTX while 18 patients were on subcutaneous MTX. The average duration of therapy on oral MTX was 161.9 months versus 36.4 months on subcutaneous. The incidence and severity of all studied side effects was found to be lower in patients on subcutaneous MTX, except for nausea which was high across both patient groups(figure 1).
Conclusions
The audit has shown that subcutanous methotrexate is overall better tolerated in our clinical practice. At present it is reserved for patients with issues tolerating oral MTX, this review would propose considering subcutaneous MTX as first line in certain patient populations.

Figure



(18A148) ABSTRACT 45 **POSTER 37**

Secukinumab Improves Abnormal Liver Blood Tests in Spondyloarthritis

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Department of Rheumatology, St. Vincent's University Hospital and St. James's Hospital
Introduction
We monitor for abnormal liver bloods tests in patients treated with biologic agents due to concern over drug induced adverse events. Patients with spondyloarthritis (SpA) frequently have other causes for abnormal liver blood tests including alcohol intake, NSAIDs, and particularly non-alcoholic fatty liver disease (NAFLD).
Aims/Background
This was a prospective observational study serially evaluating liver blood tests in consecutive SpA patients with abnormal baseline liver blood tests commencing secukinumab.
Method
Patients with known liver disease with an aetiology other than NAFLD were excluded. Demographic and clinical details were collected on all patients. The primary outcome was the change in alanine aminotransferase (ALT) before secukinumab and 3 months following secukinumab commencement. Wilcoxon Signed Rank

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Rare: pulmonary fibrosis, pneumocystis carinii pneumonia, shortness of breath and bronchial asthma, pleural effusion.***Blood and lymphatic system*** *disorders:* **Common:** Leukopenia, anaemia, thrombopenia. **Uncommon:** pancytopenia, **Very rare:** agranulocytosis, severe courses of bone marrow depression. ***Renal and urinary disorders:*** **uncommon:** Inflammation and ulceration of the urinary bladder renal impairment, disturbed micturition. **Rare:** renal failure, oliguria, anuria, electrolyte disturbances. ***Reproductive system and breast disorders:*** **Uncommon:** Inflammation and ulceration of the vagina **Very rare**: Loss of libido, impotence, gynaecomastia, oligospermia, impaired menstruation, vaginal discharge. ***Musculoskeletal and connective tissue disorders:*** **uncommon:** Arthralgia, myalgia, osteoporosis. ***Neoplasms benign malignant and unspecified (incl. cysts and polyps):*** Very rare: Reports of individual cases of lymphoma which subsided in a number of cases once treatment with methotrexate had been discontinued. **Overdose:** Calcium folinate is the specific antidote for neutralising the toxic undesirable effects of methotrexate. **Legal classification:** POM. **Marketing Authorisation Holder:** Medac Gesellschaft fur Klinische Spezialpraparate MbH, Theaterstr.6,22880 Wedel, Germany. **Marketing authorisation number:** PA 623/14/1. **Date of Revision of PI:** February 2017. **MARKETED IN IRELAND BY: FANNIN LTD, FANNIN HOUSE, LEOPARDSTOWN, DUBLIN 18.**

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Test was used to compare groups as the data was non-parametric. P values <0.05 were assumed as statistically significant throughout.

Results

25 patients (13 psoriatic arthritis (PsA), 12 ankylosing spondylitis (AS)) commenced secukinumab in our institution during the study period. 9 of the 25 (7 PsA, 2 AS) had abnormal baseline ALT and were included in the current study. There was a significant reduction in ALT in SpA patients following secukinumab treatment, median (IQR) 53 (47, 63) vs 42 (28, 50) u/L, p=0.021. PsA patients had a significant reduction in ALT following secukinumab treatment, median (IQR) 53 (50, 64) vs 42 (30, 49) u/L, p=0.018. 3 patients (33%) with increased ALT normalised during the study. There was no significant change in other liver blood tests between the groups.

Conclusions

Secukinumab use was associated with significant improvement in previously abnormal liver blood tests in SpA patients. Secukinumab may represent an attractive treatment option in SpA given the high frequency of liver blood test abnormalities in this patient group.

(18A149) ABSTRACT 46 **POSTER 38**

Arthroscopic Synovitis and Vascularity and C-reactive Protein Predict the Future Development of Rheumatoid Arthritis in Patients with Seropositive Arthralgia.

Author(s)

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Department(s)/Institutions

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Introduction

Arthralgia in patients who are seropositive for rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPA) is a precursor to rheumatoid arthritis (RA) in some but not all patients. The factors which influence progression and outcomes in these patients remain to be fully defined.

Aims/Background

To evaluate outcome and prognostic factors in a consecutive cohort of patients with seropositive arthralgia undergoing arthroscopy.

Method

We performed a prospective study of consecutive patients with seropositive arthralgia presenting to our outpatient clinic who underwent arthroscopy. All patients were seropositive for RF and/or ACPA. Demographic and clinical characteristics were collected on all patients. Synovial biopsy was performed by needle arthroscopy, and macroscopic and histologic features recorded. The degree of synovitis and vascularity were recorded on a 0–100-mm visual analog scale, and chondropathy on a semi-quantitative scale from 0-3. Diagnosis at last follow-up was recorded in all patients. Mann-Whitney U test was used to compare groups. Spearman's Rank Correlation Coefficient was used to assess for associations with outcomes.

Results

33 patients were recruited. Mean (SD) age was 54 (12) years. 22 (67%) were female. 27 (82%) were positive for RF and 30 (91%) for ACPA with 24 (73%) dual positive. Mean (SD) follow-up was 29 (10) months. Baseline characteristics are shown in Table 1. Final diagnosis was RA in 24 (73%), psoriatic arthritis in 2 (6%), connective tissue disease in 1 (3%), calcium pyrophosphate arthritis in 1 (3%), and remained seropositive arthralgia in 5 (15%). Baseline CRP was significantly higher in patients who developed rheumatoid arthritis than those who remained seropositive arthralgia, mean (SD) 9.63 (16.63) vs 1.40 (0.55) mg/dL (p=0.005). Macroscopic synovitis and vascularity at arthroscopy were both significantly higher in those who developed RA than in those who remained as seropositive arthralgia, mean (SD) 60 (25) vs 28 (13) mm (p=0.009) and mean (SD) 56 (26) vs 26 (13) mm (p=0.012) respectively. Baseline DAS28-CRP, tender joint count, swollen joint count, and patient global assessment were not different between the groups. All patients who had plasma cells or lymphoid aggregates on baseline synovial biopsy progressed to RA over the course of the study.

Conclusions

Most but not all patients with seropositive arthralgia develop RA. Elevated baseline CRP and macroscopic synovitis and vascularity scores at arthroscopy predict the future development of RA.

Figure

Characteristic	
Age, years	54 (12)
Sex, female, n (%)	22 (67%)
Tender Joint Count	3 (6)
Swollen Joint Count	0 (0)
C Reactive Protein (mg/dL)	7.67 (15.21)
Erythrocyte Sedimentation Rate (mm/hr)	21 (19)
Patient Global Assessment (mm)	47 (28)
DAS28-CRP	3.42 (1.34)
Arthroscopic synovitis (mm)	56 (26)
Arthroscopic vascularity (mm)	53 (26)

Table 1 Baseline Characteristics of 33 Patients with Seropositive Arthralgia. Data expressed as mean (SD) unless otherwise specified.

(18A150) ABSTRACT 47 **POSTER 39**

Long-term outcome of rituximab in rheumatoid arthritis: real world experience

Author(s)

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Introduction

Rituximab is an effective treatment for rheumatoid arthritis (RA). Data on long-term outcomes following rituximab treatment are limited.

Aims/Background

To evaluate the long-term efficacy of, and identify predictors of response to, rituximab in our centre.

Method

We conducted an observational study of RA patients treated with rituximab from 2003-2016. Demographic and clinical characteristics, including response to treatment, were assessed with tender joint count, swollen joint count, ESR, and CRP. Arthroscopy was performed in patients where clinically indicated. Univariate and multivariable logistic regression models were established to evaluate baseline predictors of treatment response. Remission was defined

as DAS28-CRP <2.6 or meeting the 2011 ACR/EULAR remission criteria.

Results
114 RA patients were treated with rituximab. Baseline characteristics of patients are shown in Table 1. 34 were receiving rituximab monotherapy, 80 were receiving combination therapy with a csDMARD. At last follow-up median (IQR) duration of rituximab treatment was 3.1 (1.8, 6.1) years. 68 (60%) patients maintained remission, 14 (12%) were primary non-responders (7% RF-, 50% ACPA-, 7% RF-ACPA-), 25 (22%) secondary non-responders (24% RF-, 40% ACPA-, 12% RF-ACPA-), and 7 (6%) stopped rituximab due to adverse events (3 hypersensitivity reactions, 2 recurrent LRTIs, 1 neutropenia, 1 severe herpes zoster). Of the 68 patients in remission, 26 (38%) were on rituximab monotherapy and 42 (62%) were receiving combination therapy with a csDMARD. Of the 39 biologic naïve patients, 24 (62%) were in remission and 15 (38%) were not; rituximab achieved equally good outcomes in patients who had previously failed a biologic. Outcomes are shown in Table 2. No significant baseline predictors of treatment response were identified using logistic regression modelling. In the 44 patients who had an arthroscopy, baseline ESR (p=0.312), CRP (p=0.590), patient global assessment (p=0.934), DAS28-CRP (p=1), TJC (p=0.750), SJC (p=0.848), macroscopic synovitis (p=0.490), macroscopic vascularity (p=0.936), and histologic inflammation (p=0.146) did not predict response to rituximab.
Conclusions
Rituximab is an effective long-term treatment, with 60% remission, for many of our RA patients, including those who have previously failed a biologic. In this cohort, no baseline demographic, clinical, or serological characteristics accurately predict response to rituximab.

Figure

Table 1: Baseline characteristics of 114 rituximab treated patients

N=114	
Age, years, mean (+-SD)	62 (+-13)
Female, n (%)	83 (73)
Disease duration, years, median (IQR)	13.5 (7, 24.3)
Previous csDMARDs, median (IQR)	1 (0, 2)
Previous bDMARDs, median (IQR)	1 (0, 2)
Serology, n (%)	
RF+	97 (85%)
ACPA+	73 (64%)
RF+ACPA+	67 (59%)
RF-ACPA-	13 (11%)

csDMARD, conventional synthetic disease modifying anti-rheumatic drug; bDMARD, biologic disease modifying anti-rheumatic drug; RF, rheumatoid factor; ACPA, anti-citrullinated protein antibody

Figure

Table 2: Outcome of 114 rituximab treated patients at last follow-up

N=114	
Remission, n (%)	68 (60%)
Primary non-responders, n (%)	14 (12%)
Secondary non-responders, n (%)	25 (22%)
Stopped due to Adverse Events, n(%)	7 (6%)
Rituximab monotherapy, n (%)	34 (30%)
csDMARD combination therapy, n (%)	80 (70%)

(18A153) ABSTRACT 48 **POSTER 40**

Clinical Audit of Hydroxychloroquine Dosing and Toxicity Screening in Rheumatology Patients

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Introduction
Hydroxychloroquine (HCQ) is used widely in treating various long-term inflammatory disorders of the joints and skin. HCQ has an excellent safety profile, however, some patients taking HCQ can develop hydroxychloroquine retinopathy resulting in permanent loss of vision. Recent publications have shown that HCQ associated retinal toxicity is not as rare as previously thought, with prevalence in a large demographic study reported at 7.5%. The risk of toxicity was greatly dependent on dosage and duration of use. The American Academy of Ophthalmology and the Royal College of Ophthalmologists have recently revised their guidelines with regard to screening and dosage recommendations to reflect this new evidence.
Aims/Background
We wished to assess HCQ prescribing and retinal toxicity monitoring practices in our department
Method
A clinical audit was conducted in the rheumatology department of St James's Hospital. Audit standards were based on the Royal College of Ophthalmologists recommendations. Best practice standards included appropriate weight-based dosing of HCQ, baseline visual exam, and appropriate monitoring for retinal toxicity. We audited **using a standardised screening form.**
Results
23 patients were recruited, 89.4% were female with a mean age of 48 years. Patients were on HCQ for a mean duration of 5.8 years and 74% were aware of the associated adverse effects of HCQ. Regarding dosing, 87% were on an appropriate dose of HCQ and 48% had their weight recorded. Regarding retinal toxicity screening, 56.5% had an eye screen at some stage during treatment. However, 47.8% had been on therapy for greater than five years of which, 45% had undergone an eye screen within the prior 12 months. Taking this into consideration, 43.5% of the sample met current screening recommendations for ocular toxicity.
Conclusions
This study highlights that current guidelines for appropriately dosing HCQ and monitoring for retinopathy are not being met. The current system can be improved and the next step is to develop a combined institutional protocol for HCQ screening.

(18A154) ABSTRACT 49 **POSTER 41**

RItuximab Use in Northern Ireland

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Introduction
Rituximab is a commonly used biologic therapy in rheumatology for a variety of pathologies. This retrospective study examining key demographics of the patient population in Northern Ireland currently

receiving riuximab.

Aims/Background

The aim was to review the electronic care record of all patients currently receiving rituximab according to the biologic database held within the Belfast Trust. Once data had been collected this would be compared to the recommendations in current NICE guidelines. This should then identify areas for development.

Method

A snapshot of the database was taken in March 2018. The electronic care record of each patient registered on the database as currently receiving rituximab was reviewed and data entered into an annonymous spreadsheet. This included gender, age, diagnosis, previous biologic therapy and DMARD therapy. Data was then analysed in Microsoft Excel.

Results

242 patients included identified, of these 179 were currently receiving rituximab. The most common indication was seropositive rheumatoid arthritis, accounting for 73% of patients. 13 cases had no serological definition of arthritis. 39% of patients were not on a DMARD. However, 57% of patients had been on methotrexate prior to commencing rituximab. In total, only 28 patients had never had methotrexate. The most common biologic used prior to switch to rituximab was adalimumab. In the population identified by the database but not currently receiving rituximab the most common reason for cesation was inefficacy. DAS28 was infrequently recorded. Use of mabthera or truxima (the two formulations of rituximab currently used) was not clearly defined.

Conclusions

Rituximab is used for a variety of rheumatological conditions within Northern Ireland. As recommended by NICE methotrexate was used as DMARD therapy prior to or alongisde biologic therapy unless contraindicated. Poor documentation of DAS 28 scores made efficacy difficult to assess. Improvement of the database and data recording at point of care is required to improve information available for further research, particularly with the introduction of biosimilars.

(18A156) ABSTRACT 50 **POSTER 42**

Assessment of immunomodulatory impact of multipotential stromal cells (MSCs) on monocytes in healthy controls and in patients with rheumatoid arthritis.

Author(s)

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Introduction

Multipotential stromal cells (MSCs) possess the capacity for multilineage differentiation and are used for their applications in bone and cartilage regeneration. MSCs have been shown to possess immunoregulatory properties, acting on both adaptive and innate immune cells, including monocytes. Consequently, MSCs have has been proposed as a therapy for autoimmune diseases, including rheumatoid arthritis (RA).

Aims/Background

To study the immunomodulatory effects of MSCs, and their conditioned media, on RA monocytes using a whole blood co-culture assay, thereby approaching a physiologically relevant setting.

Method

All experiments were performed using the IP006 clonal MSC cell line, conforming to ISCT phenotypic criteria for MSCs. For detection of intracellular TNF and IL-6 pro-inflammatory cytokine release by activated monocytes, whole blood from healthy control (HC) donors, early RA and established RA patients was stimulated with 1ng/ml lipopolysaccharide (LPS) and treated with Brefeldin A for 6 hours at 37oC. Subsequently, intracellular staining, using antibodies against TNF and IL-6 was carried out and analysed by flow cytometry. For the co-culture experiments 8x106 MSCs or 1.6 ml of MSC conditioned media (MSC-CM) were added to 0.2ml of the whole blood. The early RA patient cohort was treatment naïve, whereas the established RA cohort was multidrug resistant (failed to respond to 2 DMARDs and 2 Biologics).

Results

In HC blood, the addition of MSCs inhibited intracellular TNF and IL-6 expression in LPS-activated monocytes, by 1.6-fold and 2.1-fold, respectively. Greater inhibition of both TNF and IL-6 was observed, when MSC-CM was used instead of MSCs (TNF- 2.1-fold, n=13 and IL-6- 3.2-fold, n=19). Thus, for treatment of cytokine production by patients with early RA, bloods were treated with MSC-CM. This resulted in statistically significant inhibition of TNF ($p<0.001$) and IL-6 ($p<0.0001$) levels in activated monocytes (n=17), by 1.4-fold and 2.5-fold, respectively. The most potent immunosuppressive effects of IP006 MSC-CM were found in bloods from patients with established multidrug resistant disease. IP006 MSC-CM treatment inhibited production of TNF, by 3-fold ($p<0.0001$), and IL-6, by 2-fold ($p< 0.01$).

Conclusions

Both MSCs and MSC-CM displayed potent immunosuppressive effects on monocytes in health and RA, thereby providing evidence for a non-cell contact mechanism and supporting MSC-based therapies for RA.

(18A157) ABSTRACT 51 **POSTER 43**

A Single Center Experience with the Health Beacon Reporting System: A follow up one year review

Author(s)

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Introduction

Medication compliance has been shown to have significant effects on disease control, and quality of life in patients with inflammatory arthritis as well as healthcare costs. Monitoring compliance can be both difficult and labour intensive.

Aims/Background

The AbbVie Care Health Beacon Reporting System (HBRS) monitors the frequency of medication use via subcutaneous pen disposal. Our department had previously noted lower than anticipated compliance rates. This follow up is to examine the change in rates and issues identified with prolonged use.

Method

A retrospective review was completed on all UHW patients on Adalimumab currently utilising the HBRS (n=45). Compliance rates were categorised as excellent (81-100%), good (66-80%) or poor (<65%). Patients with a compliance rating of 0% were contacted . This analysis was compared to an earlier analysis done one year ago, shortly after the initiation of the HBRS.

Results

The 45 patients studied had confirmed diagnoses of ankylosing

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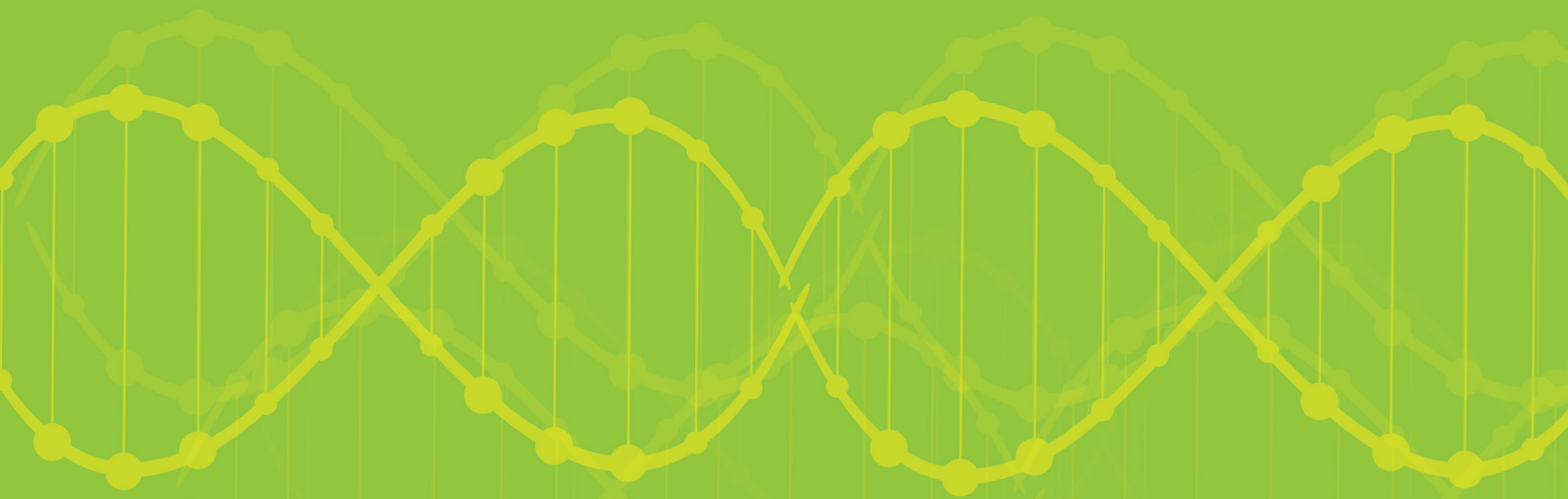

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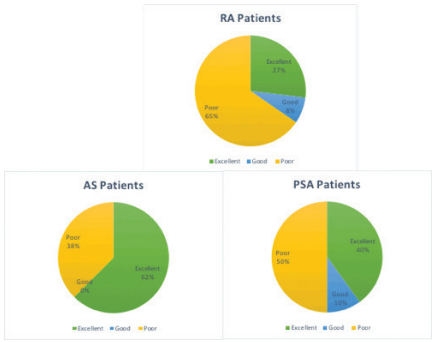
spondylitis, rheumatoid arthritis, psoriatic arthritis or juvenile idiopathic arthritis. 56% were categorised as having poor compliance. Further analysis revealed that 40% were registered as 0% compliant. When contacted these 40% confirmed they were not using the HBRS. Reasons given included: change to treatment, poor understanding of device function and improper use of device. Following exclusion of these patients, 74% of patients had good to excellent compliance (table 1). 2017 analysis of HBRS compliance revealed only 40% as good to excellent, however a detailed review of poorly compliant patients was not performed.

Conclusions

This analysis provides a detailed insight into factors affecting the use of the HBRS and true compliance rates. If the data was interpreted blind, the apparent compliance was poor, but when those not using the device were excluded, the numbers were much improved. We would therefore urge caution in interpretation of HBRS results without further exploration. However the HBRS does have potential to be a useful tool to distinguish between poor compliance and medication failure, once use has been confirmed with the patient. Larger patient numbers and increased experience with HBRS will determine how to fully realise its potential.

Figure

Figure



(18A158) ABSTRACT 52 **POSTER 44**

Smoking Status in patients with Psoriasis and Psoriatic Arthritis: An Irish Perspective

Author(s)

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Department(s)/Institutions

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Introduction

The BIOmarkers of COMorbidities (BIOCOM) in psoriasis study is a longitudinal study which aims to identify clinical, genetic or protein biomarker features associated with the development of co-morbidities, notably cardiovascular disease and psoriatic arthritis (PsA) in patients with psoriasis. Psoriasis usually precedes the development of PsA with an average interval of 10 years. Thus, psoriasis patients are an ideal group in which to study the early events in the evolution to PsA.

Aims/Background

There is a well-established association between smoking and psoriasis, and between smoking and PsA in the general population. Paradoxically however, smoking has been shown to be negatively associated with the development of PsA in patients with established psoriasis. Herein we describe the prevalence of smoking in this BIOCOM cohort.

Method

To date 190 patients with psoriasis have been recruited. Of those, 9 were excluded due to a diagnosis of psoriasis > 10 years previously. One was excluded due to a previous diagnosis of JIA. This left 180 patients with psoriasis who were brought in for an initial assessment. After the initial assessment 7 patients were diagnosed with PsA, meeting CASPAR criteria. This left 173 patients for inclusion in the analysis.

100 patients with established PsA were recruited and were included in the study.

Results

Table 1 describes demographic and clinical characteristics of the study population at baseline assessment.

The proportion of smokers (current and past) was lower in the PsA group compared to the psoriasis group: 52.0 versus 63.6. Table 2 shows smoking characteristics of patients with PsA and psoriasis.

Conclusions

Analysis of patients recruited to date for the BIOCOM-Pso study shows a higher percentage of smokers (current and past) in the psoriasis group compared to the PsA group. The proportion of smokers (current and past) in the PsA group was comparable to the general Irish population.

These findings are consistent with previous studies that showed a negative association between smoking and the development of PsA in patients with psoriasis. However, prospective follow-up of patients with psoriasis, which is ongoing in this BIOCOM cohort, is required to further elucidate the role of smoking in the development of PsA.

Figure

Table 1: Demographic & Clinical Characteristics of the Study Population at Baseline

	Psoriasis	PsA
Age, mean +/- SD years	41.3 +/- 14.9	52.4 +/- 10.5
Male Sex, number (percentage)	105 (60.7)	55 (55.0)
Duration of Psoriasis, mean +/- SD years	6.2 +/- 2.9	26.1 +/- 13.1
Duration of PsA, Mean +/- SD years		17.9 +/- 10.0
PASI score, mean +/- SD	7.31 +/- 3.91	3.56 +/- 3.17
Type 1 Psoriasis, number (percentage)	107 (61.9)	86 (86.0)

Figure

Table 2: Smoking Characteristics of Patients with PsA and Psoriasis

Smoking Status	Psoriasis	PsA	p Value
Never Smoked, number (percentage)	63 (36.4)	48 (48.0)	0.06
Current, number (percentage)	49 (28.3)	10 (10.0)	<0.001
Past, number (percentage)	61 (35.3)	42 (42.0)	0.268

(18A159) ABSTRACT 53 POSTER 45

Development of A Local Needs-Based Gp Curriculum for Shared Care in Rheumatology.

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Introduction
There is a role for shared care between rheumatologist and primary care for Musculoskeletal (MSK) disorders. General practitioners (GPs) are involved in monitoring of clinical status of patients and their management, in addition to psychosocial aspects of chronic pain and disability.

Aims/Background
We aim to: 1) Identify knowledge and skill gaps in primary care related to MSK disorders and to develop a need-based curriculum to address these gaps. 2) Develop an implementation plan to deliver the curriculum components.

Method
There are two rounds of questionnaires to reach a list of important areas to develop the curriculum. Initially we identify the needs and gaps in the current practice using survey in a small group of local GPs. The second round will include large number of GPs. Also, there will be meetings with GPs.

Results
Thirty one out of 36 GPs (86%) returned questionnaires. One GP (3.2%) refer to rheumatology department twice a week, 4 GPs (13%) refer weekly, 23 GPs (74%) refer monthly and three GPs (9.7%) rarely refer to rheumatologist. Reasons for referral were diagnosis and long-term management (21), diagnosis and discharge back to GP (15) and patient's request (4). Thirteen
GPs (42%) have interest in rheumatology conditions management. Long waiting time for rheumatology appointment was the major concern by 71% of GPs. Other issues were delayed clinic letter, need for clear instruction, patients not aware of appointment time, whether there is a fast track clinic. Nineteen GPs (61%) received undergraduate rheumatology training, 16 (52%) during GP training programme and 4 (13%) attended postgraduate courses. Topics of interest by GPs were variable rheumatology conditions in addition to joint injections (3), referral guidance (2) and update on DMARD. Preferred teaching methods to deliver the syllabus were small group tutorials (12), face-to-face lectures (8) and protocols and guidelines (5).

Conclusions
From this initial survey, we could identify that the major concern of local GPs is the long waiting time for rheumatology clinic. Some of GPs (42%) expressed their interest to have further training in rheumatology. When we reach an agreed curriculum with GPs, we aim to deliver the syllabus through preferred methods by GPs.

(18A160) ABSTRACT 54 POSTER 46

Response To Secukinumab (Cosentyx) Among Biologically-Naive And Non Naive Patients In Psoriatic Arthritis.

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Introduction
Secukinumab (Cosentyx) is a recombinant human monoclonal immunoglobulin IgG antibody that selectively targets IL-17A and blocks its interaction with the IL-17 receptor. Inhibition of the downstream effects of this proinflammatory cytokine thereby interferes with key psoriasis disease pathways while promoting normalization of immune function and skin histology.

Aims/Background
The aim of the study was two- fold. Firstly, to compare the response to Secukinumab in psoriatic arthritis (PsA) patients who were biologically naive and non-naïve, and secondly to compare the response between smokers and non-smokers.

Method
In collaboration with the National Psoriatic Arthritis Registry of Ireland, patients who were diagnosed and treated as PsA at University Hospital Kerry between March 2017 and March 2018 were included in this population-based cohort study. Patients demographic, clinical characteristics, treatment strategies (including response rates and adverse effects) were captured at baseline and at follow-up outpatient visits.

Results
A total of 96 patients were identified and included in the study (mean age of 56.6 years; male to female ratio of 1:1, 49 males, 47 females). Of these patients, 13 received Secukinumab (6 biologically-naive patients, 7 patients with previous treatment failure to anti-TNF agents (2 patients received one anti-TNF, 5 received two different anti-TNFs). In the biologically-naive group, 4 patients (66 %) had complete response to Secukinumab, one patient (16.67%) had complete improvement of joint symptoms but remained fatigued (high BRAF score) while 1 patient (16.67%) had no improvement. All 6 of these patients were either smoker or ex-smoker (5 current smokers, one an ex-smoker). In patients who previously failed anti-TNF, five (71.42%) remained symptomatic (tender & swollen joints, PROMs and BRAF score remained high) despite treatment with Secukinumab. Only two patients (28.57%) responded well to treatment. Two of the seven patients never smoked (both did not respond to Secukinumab) while the other 5 patients (2 responded, 3 had no response) were ex-smokers.

Conclusions
In our study, Secukinumab demonstrated better response to the biologically-naive PsA patients, while smoking did not increase the risk of disease activity among PsA patients receiving Secukinumab.

(18A161) ABSTRACT 55 POSTER 47

A rheumatology email service: an audit of its effectiveness as an alternative means of communication with our nursing service.

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Introduction
Our rheumatology email service allows our patients an alternative route of contact with our rheumatology nursing service. The email service has grown significantly in recent months and many of our patients use the service as an alternative point of contact to our telephone helpline. The provision of both our telephone helpline and email service is regarded by most of our patients as a welcome extension of specialist rheumatology outpatient service. The unpredictable nature of chronic diseases often results in a requirement to access our service outside of scheduled outpatient appointments.

Our email service is utilised not only by patients, but their families, GP's, practice and public health nurses and other involved health professionals.

Aims/Background

To audit our rheumatology email service as distinct from our telephone help line. In order to improve our service and care for our patients optimally, audit of this service and identification of areas of greatest need requiring development and enhancement is crucial.

Method

We reviewed our emails over a 6 month time period and divided them into specific categories including, request for repeat prescriptions, flare management, medication side effects and request for earlier/change appointments.

We reviewed the demographics of those patients who used our email service in preference to our phone line and measured our response times.

Results

Our audit confirmed that our younger patient cohort use our email service in preference to our telephone service. The majority of our email queries were related to medication management, however, as with our telephone service, requests for repeat prescriptions continue to be a dominant feature of all contacts to the rheumatology nursing service.

Conclusions

Email is a valuable addition to our nursing service. The service will continue to be audited with the addition of a patient satisfaction survey to be conducted in the next 3 months looking at all current routes of communication with the rheumatology nursing service

(18A163) ABSTRACT 56 **POSTER 48**

No access to DXA? Try the NOGG guidelines.

Author(s)

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Introduction

The NOF (National Osteoporosis Foundation) 2014 guidelines, which are largely used in Ireland, recommended treatment for osteoporosis based on: a diagnosis using BMD, the presence of vertebral or hip fracture, or a diagnosis of osteopenia with a high 10-year fracture risk based on FRAX score (a hip fracture risk ≥3 % or major osteoporosis fracture risk ≥20%).

The NOGG (National Osteoporosis Guideline Group) 2017 guidelines, used in the UK, recommend fracture risk assessment of individuals at risk of osteoporosis before considering a DXA. Based on a FRAX score without BMD, patients are categorised into high, medium, OR low risk (red, yellow, and green). The guidelines recommend treating the high-risk individuals, investigating with a DXA, the intermediate-risk individuals and not treating or investigating the low-risk individuals.

Aims/Background

The aim of our study is to compare the NOF and NOGG guidelines using our patient cohort, and to observe the difference in numbers of patients treated for osteoporosis, and, when using the NOGG guidelines, to note the reduction in number of DXA scans.

Method

Over a 6-month period, in a regional centre, data was collected on all patients who had a DXA scan. We calculated a FRAX score with and without BMD using the UK FRAX website and documented the NOGG recommendation for each individual before and after DXA.

We also noted the patients who would be treated for osteoporosis based on the NOF guidelines – the number of patients and their personal details and compared this to those who would be treated using the NOGG guidelines.

Results

238 patients over the age of 40 had DXA scans performed over a 6-month period. 163 (68%) females and 75 (32%) males. The median age was 67.

Of the 238, 66 (28%) were given Green NOGG recommendations – recommending no treatment or investigation, 66 (28%) were given red recommendations – recommending treatment without a DXA scan and 103 (44%) were given yellow recommendations – recommending a DXA scan. If the NOGG guidelines had been used in our patient cohort, 131 of the DXA scans would not have been performed over the 6-month period which is 55% of the scans.

Nineteen individuals (7%) had a discrepancy in their recommendations (based on NOGG guidelines) before and after DXA scanning.

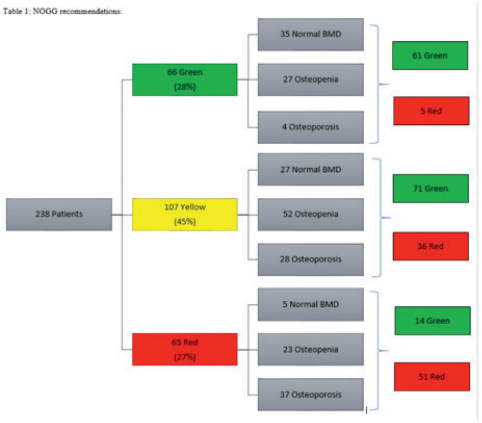
Based on the NOF guidelines, 107 patients would have been treated for osteoporosis and based on the NOGG guidelines post DXA, 92 would have been treated.

Amongst our patient cohort, the NOGG compared to the NOF guidelines recommended treatment for more females aged 50-65 and for less individuals aged above 68. Amongst the female patients aged 50-65, a 10 year hip fracture risk ranging 1-2.8% was recommended treatment by the NOGG.

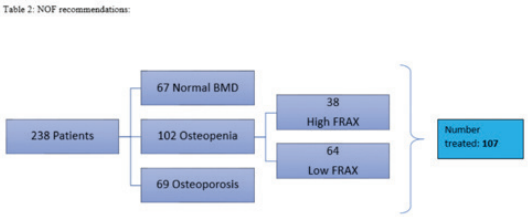
Conclusions

With use of the NOGG guidelines, 55% less DXA scans would have been performed. With little discrepancy (7%) in the NOGG guidelines before and after DXA scan, these guidelines can be used easily in GP surgeries and outpatient departments. In Ireland, the average wait time for a DXA scan, within the public health system, is 20 weeks. The use of the NOGG guidelines would reduce the number of DXA scan requests, reduce the waiting times for those who require the test, and allow earlier treatment for high risk individuals.

Figure



Figure



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Standard dose reductions for any concomitant chemotherapeutic medicinal product should be applied. **Administration:** Give RA, GPA and MPA patients the patient alert card with each infusion. Administer prepared ***Truxima*** as an i.v. infusion, through a dedicated line, with full resuscitation facilities immediately available, under the supervision of an experienced healthcare professional. Do not administer as an i.v. push or bolus. Administer anti-pyretic and an antihistaminic before each infusion. Consider glucocorticoid (GCC) premedication if ***Truxima*** is not given with GCC-containing chemotherapy. Monitor closely for onset or evidence of cytokine release syndrome (CRS). Interrupt infusion immediately if evidence of a severe reaction (e.g. severe dyspnoea, bronchospasm or hypoxia). Evaluate NHL patients for tumour lysis syndrome (TLS). *First infusion:* Recommended initial rate of 50 mg/h for the first 30 minutes, which can then be escalated in increments of 50 mg/h every 30 minutes up to 400 mg/h. *Subsequent infusions:* Recommended initial rate of 100 mg/h and increased by 100 mg/h increments every 30 minutes, up to 400 mg/h. *Alternative faster infusion schedule in RA only (4mg/mL in 250mL infusion volume):* if no serious infusion related reaction (IRR) during first or subsequent infusions at standard rates (above), initiate at 250 mg/h for the first 30 minutes and escalate to 600 mg/h over 90 minutes. Faster infusion not suitable for patients who have clinically significant cardiovascular disease, arrhythmias or previous serious IRR to biologic therapy or rituximab. **Contraindications:** Hypersensitivity to the active substance, murine proteins, or any of the other excipients; active, severe infections; severely immunocompromised patients. Severe heart failure (NYHA class III/IV) or severe, uncontrolled cardiac disease in patients with RA, GPA or MPA. **Precautions and warnings:** To improve the traceability of biological medicinal products, the trade mark and the batch number of the administered product should be recorded in the patient file. *Progressive multifocal leukoencephalopathy (PML):* Very rare cases of fatal PML have been reported. Monitor patients for new or worsening neurological symptoms suggestive of PML and suspend until PML excluded. Permanently discontinue if confirmed. See SPC for further information. *Infusion related reactions (IRRs):* Rituximab is associated with IRRs, including CRS, TLS, anaphylactic and hypersensitivity reactions, including severe reactions with fatal outcome. Severe IRRs are characterised by pulmonary events and may include features of tumour lysis or rapid TLS in addition to reactions such as fever, chills, rigors, hypotension, urticaria and angioedema. Use extreme caution and closely monitor first infusion when treating patients with >25x10⁹/L circulating malignant cells or high tumour burden (higher risk of severe CRS). Consider reduced infusion rate or split dosing where lymphocyte counts >25x10⁹/L. See SPC for further details on severe IRRs. IRRs of all kinds have been observed in 77% of patients treated with rituximab. Common IRRs are generally reversible with a reduction in rate, or interruption, of rituximab infusion and administration of an antipyretic, an antihistaminic and occasionally, oxygen, i.v. saline or bronchodilators. Temporary or permanent discontinuation may be necessary if severe or if the same adverse events recur a second time. In most cases the infusion can be resumed at a 50% reduction in rate when symptoms have completely resolved. Anaphylaxis and other hypersensitivity reactions have been reported following i.v. administration of proteins to patients. IRRs may also be associated with myocardial infarction, atrial fibrillation, pulmonary oedema and acute reversible thrombocytopenia. Consider withholding antihypertensives for 12 hours prior to infusion due to risk of hypotension. Treat with caution and closely monitor patients with a history of pulmonary insufficiency or pulmonary tumour infiltration. *Cardiac disorders:* Closely monitor patients with a history of cardiac disease and/or cardiac chemotherapy. *Infections:* Patients are at an increased risk of developing infections, including serious infections with fatal outcome. Do not administer if active and/or severe infection present or if severely immunocompromised. Caution in patients with a history of, or susceptibility to recurring/chronic infections. Determining immunoglobulin levels in RA, GPA and MPA before treatment is recommended. Hepatitis B (HBV) reactivation has been reported, including cases with a fatal outcome. HBV screening should be performed before initiation of ***Truxima***. Patients with active hepatitis B disease should not be treated. Patients with positive serology for HBV should consult liver specialists and be monitored and managed to prevent reactivation. *Haematological toxicities:* Caution in patients with neutrophil counts <1.5 x 10⁹/L and/or platelet counts <75 x 10⁹/L as clinical experience in this population is limited. Perform regular blood counts during ***Truxima*** therapy in all indications, and prior to each course and regularly up to 6-months after cessation of treatment in RA and GPA/MPA. *Immunisations:* Live viral vaccines are not recommended. Response to non-live vaccinations may be reduced. See SPC for further information. *Skin reactions:* Severe skin reactions such as Toxic Epidermal Necrolysis (TEM) and Stevens-Johnson Syndrome (SJS), including fatal outcomes, have been reported - permanently discontinue treatment. *Malignancy:* The possible risk for the development of solid tumours with the use of immunomodulatory drugs cannot be excluded. *Concomitant/sequential use of other DMARDs in RA:* The concomitant use of ***Truxima*** and anti-rheumatic therapies other than those specified for RA is not recommended. Monitor patents for signs of infection if biologic agents and/or DMARDs are used following ***Truxima*** therapy. **Interactions:** Limited data are available (see SPC). Patients with human anti-mouse antibody or human anti-chimeric antibody titres may have allergic or hypersensitivity reactions when treated with other diagnostic or therapeutic monoclonal antibodies. **Fertility, pregnancy and lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 12 months after ***Truxima*** treatment. ***Truxima*** should not be administered during pregnancy. Do not breast-feed in the 12 months following treatment. **Side effects:** *Very common (≥ 1/ 10) and common (≥ 1/100 to <1/10) side effects:* Viral infection, bacterial infection, bronchitis, acute bronchitis, sepsis, pneumonia, febrile infection, herpes zoster, respiratory tract infections, fungal infection, sinusitis, hepatitis B, infections of unknown aetiology, neutropenia/febrile neutropenia, leucopenia, thrombocytopenia, anaemia, pancytopenia, granulocytopenia, infusion related reaction (hypertension, nausea, rash, pyrexia, pruritus, urticaria, throat infection, hot flush, hypotension, rhinitis, rigors, tachycardia, fatigue, oropharyngeal pain, peripheral oedema, erythema), angioedema, hypersensitivity, hyperglycaemia, weight decrease, face oedema, increased LDH, hypocalcaemia, paraesthesia, hypoaesthesia, insomnia, vasodilatation, dizziness, anxiety, agitation, lacrimation disorder, conjunctivitis, tinnitus, ear pain, myocardial infarction/myocardial arrhythmia, atrial fibrillation, cardiac disorder, orthostatic hypotension, bronchospasm, respiratory disease, chest pain, dyspnoea, cough/increased cough, vomiting, diarrhoea, abdominal pain, dysphagia, stomatitis, constipation, dyspepsia, anorexia, throat irritation, alopecia, sweating/night sweats, skin disorder, hypertonia, myalgia, back pain, neck pain, pain, fever, chills, asthenia, headache, tumour pain, flushing, malaise, cold syndrome, shivering, multi-organ failure, decreased IgG levels, urinary tract infection, gastroenteritis, tinea pedis, hypercholesterolemia, migraine, sciatica, depression, oesophageal reflux, mouth ulceration, arthralgia/musculoskeletal pain, muscle spasms, muscle weakness, osteoarthritis, bursitis, decreased IgM levels. Additional side effects in ≥ 5% GPA/MPA patients in clinical trials: Nasopharyngitis, cytokine release syndrome, hyperkalaemia, tremor, acne, epistaxis, nasal congestion, pain in extremities, decreased haemoglobin. *Uncommon (< 1/100) but potentially serious, including fatal, side-effects:* Serious viral infection, Pneumocystis jirovecii, progressive multifocal leukoencephalopathy, reactivation of hepatitis B, infusion related reactions (generalised oedema, bronchospasm, wheezing, laryngeal oedema, angioneurotic oedema, generalised pruritus, anaphylaxis, anaphylactoid reaction), tumour lysis syndrome, cytokine release syndrome, serum sickness, coagulation disorders, aplastic anaemia, haemolytic anaemia, late neutropenia, depression, peripheral neuropathy, cranial neuropathy, severe vision loss, facial nerve palsy, loss of other senses, left ventricular failure, supra-ventricular tachycardia, ventricular tachycardia, angina/angina pectoris, heart failure, atrial flutter, atrial fibrillation, myocardial ischaemia, bradycardia, severe cardiac disorders, vasculitis, leukocytoclastic vasculitis, asthma, bronchiolitis obliterans, hypoxia, respiratory failure, pulmonary infiltrates, interstitial lung disease, gastrointestinal perforation, Steven's-Johnson syndrome, toxic epidermal necrolysis, renal failure. Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported. Please refer to the SPC for further information and a full list of side effects. **Overdose:** Intravenous doses of up to 5000 mg have been administered in a dose escalation study in CLL patients, which did not identify any safety signals. The infusion should be interrupted immediately and patient monitored closely, if overdose is experienced. **Legal category:** POM. **Presentations:** 100mg (pack of 2 vials) 500mg (1 vial). **Marketing Authorisation numbers:** EU/1/16/1167/001-2.**Marketing Authorisation holder:** Celltrion Healthcare Hungary Kft, 1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410.Hungary. For medical information enquiries, please contact info@mundipharma.ie **PI Code:** UK/TRU-17025(1). **Date of Preparation:** September 2017

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(18A164) ABSTRACT 57 POSTER 49

Facilitating good practice for public and patient involvement (PPI) in translational health research.

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Introduction
Involving patients in research broadens a researcher's field of influence, generating novel ideas, challenges and discussions. Basic, translational and preclinical research (hereto translational) is integral to the progression of innovative healthcare. These are not patient-facing disciplines and implementing meaningful PPI can be a serious challenge in the absence of well-defined support structures.

Aims/Background
PPI is being incorporated as part of standard research practice. As with all new practices in research, there is a need to refine and improve its use. Our aim is to develop standard PPI evaluation tools that can effectively be applied in translational and non-patient-facing research disciplines.

Method
A discussion forum (n=16) and thematic analysis identified key challenge areas of implementing PPI for translational researchers. A literature review was used to define questions for a patient-involvement satisfaction questionnaire. Patient partners (n=12) reviewed, ranked and assessed the questionnaire for language accessibility. Pilot study of the questionnaire (n=60) for face, discriminate and internal validity, with factor analysis to determine substructure. The quantitative analysis informed by the qualitative feedback refined the questionnaire. To adapt the questionnaire to a structure familiar to basic researchers, we developed a flagging system based upon that used in standard quality control assays and a PPI reporting grade based on the risk matrix.

Results
Key challenges implementing PPI: (1) Barriers- institutional challenges (2) Worries- personal challenges (3) Concerns- research challenges. In response a personal "PPI Ready" planning canvas for researchers was developed. For contemporaneous evaluation of PPI, a psychometric questionnaire for patient partner satisfaction and an open source tool for its evaluation was developed. The questionnaire measures information, procedural and quality assessment. Combined with the open source evaluation tool, researchers are notified if PPI is unsatisfactory in any one of these areas. The open source tool is easy to use and adapts a psychometric test into a format familiar to basic scientists. Designed to be used iteratively across a research project, it provides a simple reporting grade to document satisfaction trend over the research lifecycle.

Conclusions
We have developed a tool for translational health researchers to facilitate the implementation and evaluation of PPI during a research project.

(18A169) ABSTRACT 58 POSTER 50

Peri-operative management of rheumatoid arthritis (RA) patients undergoing arthroplasty

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Bone and Joint Unit, Saint Vincent's University Hospital Orthopaedics, Beaumont Hospital

Introduction
Immunosuppression, surgical complexities and atlanto-axial subluxation can complicate arthroplasty in RA. Management guidelines differ significantly.

Aims/Background
To compare peri-operative RA management between rheumatologists and orthopaedists.

Method
An anonymous 24 question survey was distributed at the Irish Society of Rheumatology meeting and the Irish Institute of Trauma and Orthopaedic Surgery Curriculum Day, examining imaging and prescribing in these patients.

Results
33 orthopaedists and 23 rheumatologists responded.

Orthopaedists
22 always perform cervical spine imaging prior to arthroplasty in patients undergoing a general anaesthetic (10 sometimes, 1 not sure). 31 perform X-rays, 1 MRI and 1 CT.
7 never stop steroids pre-operatively (13 sometimes, 6 always, 5 unsure). 9 never increase steroids (13 sometimes, 6 always, 5 not sure). 1 never stops synthetic DMARDs (sDMARDs). 19 never discontinue methotrexate (5 respondents unsure). For other sDMARDs (leflunomide, hydroxychloroquine, azathioprine, sulfasalazine and ciclosporin), a minority (range 3-5 for the different medications) never discontinue. Many (range 11-17) were unsure. 8 stop sDMARDs at 1 week pre-operatively, 13 at 2 weeks, 5 at 4 weeks. 6 were unsure. 19 restart sDMARDs at 2 weeks post-operatively.
2 never stop biologic DMARDs (etanercept, golimumab, adalimumab, infliximab, certolizumab, tocilizumab, rituximab and abaptacept). Depending on the medication, 14-15 stop 8 weeks. 10-12 unsure.

Rheumatologists
11 always perform cervical spine imaging (11 sometimes, 1 never). 22 perform X-rays, 1 MRI. 14 never stop steroids (8 sometimes, 1 not sure). 12 respondents sometimes increase steroid dosing (8 always, 1 never, 1 not sure, 1 no answer).
8 never stop methotrexate/leflunomide. 20 never stop hydroxychloroquine and 14 sulfasalazine. Ciclosporin and azathioprine are never stopped by 5 and 9 respectively. 8 don't stop sDMARDs, 8 stop 2 weeks pre-operatively, 6 at 1 week, 1 no answer. 9 restart sDMARDs at 2 weeks, 5 at 1 week, 1 at 4 weeks.
2-4 never stop bDMARDs pre-operatively. Responses vary medication half-life. For example, 18 hold etanercept for 8 weeks.

Conclusions
There is a high degree of uncertainty and contrasting practices between rheumatologists and orthopaedists. Unified guidelines may facilitate increased agreement.

(18A171) ABSTRACT 59 POSTER 51

Reproductive Health Outcomes In Women with Psoriatic Arthritis In the Biologic Era

Author(s)
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Introduction
Psoriatic arthritis (PsA) requires close management throughout pregnancy. A multidisciplinary (MDT) approach ensures best outcomes for mother and baby. Previous studies of PsA in pregnancy show conflicting results and many predate the use of biologics.
Aims/Background
To prospectively study a series of PsA patients planning pregnancy
Method
Between April 2013 and November 2016, the age, medications, disease control and reproductive health outcomes of PsA patients seen in an MDT rheumatology and reproductive health service (RRHS) were reviewed.
Results
Fifteen women were followed, five of whom later attended with a second pregnancy wish. Median age (range) was 35 (26-42) years.
We recorded 16 pregnancies in 12 women, with 13 live births (one set of twins). 12 births were by spontaneous vaginal delivery and one Caesarean section. There were four miscarriages (2 - 1st trimester, 2 – 2nd trimester). One miscarriage was due to a hyper-coiled umbilical cord, with the other causes unknown. At data collection end point, four women were attempting to conceive. Of these, one is using assistive reproductive therapy and one had previously conceived.
Of the 16 pregnancies, seven were conceived on medications, either a biologic DMARD (bDMARD) (six cases) or oral steroids (one case). No patients were on a synthetic DMARD at conception. In four cases, bDMARDs were discontinued in the 1st trimester. In two cases, they were continued throughout pregnancy (infliximab and certolizumab).
Disease control was adequate prior to pregnancy in 11/16 and remained so in eight cases throughout pregnancy. PsA activity was increased, within 20 weeks of delivery, in 12 cases. In three cases, there was disease remission. One patient was not seen until ten months postpartum. The only postpartum complication was one grade four vaginal tear (on infliximab). At six weeks, six of 13 infants were being breastfed.
Conclusions
These data show high levels of successful pregnancy outcomes in PsA. Six pregnancies were conceived while on a bDMARD. Disease control was adequate in pregnancy, but postpartum flare is common. Miscarriage rates were comparable with the general population (25% versus 20%), but breastfeeding rates were lower (46% versus 55%).

(18A172) ABSTRACT 60 POSTER 52

B cell phenotype and function in the synovium of ACPA+ and ACPA- rheumatoid arthritis patients.

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Introduction
Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease of unknown and complex aetiology with severe detrimental effects for the patient's quality of life. While rheumatoid factors (RF) and anti-citrulinated protein antibodies (ACPA) have been used extensively for the diagnosis of RA, no clear mechanism of action towards disease pathogenesis and progression has been identified. Importantly, both seropositive and seronegative RA patients experience significant improvement in disease severity following B cell depletion. Therefore, we hypothesized that B cells have a central role auto-antibody independent role in ACPA+ and ACPA- RA.
Aims/Background
Phenotypical and functional characterization of B and T cell populations in the peripheral blood and synovium of ACPA+, ACPA- and arthralgia patients.
Method
Flow cytometric analysis of T and B cell populations in the periphery and synovium of ACPA+, ACPA- and arthralgia patients. B cell invasion into the RA synovium as well as activation and function of sorted B cells, cultured and stimulated in vitro under normoxic (21% O2) and hypoxic (1% O2) conditions were examined.
Results
Significant reduction in CD27+ memory and specifically, switched memory B cells, was observed between healthy subjects and APCA+ RA patients. The aforementioned decrease in memory B cells is potentially a result of increased susceptibility to FAS induced apoptosis. B cell invasion of the synovial tissue is strongly mediated by CXCR3. Despite however a marked accumulation of switched and double negative (DN) memory B cells in the synovium, no differences in synovial B cell subpopulation composition between ACPA+ and ACPA- RA patients was observed. Interestingly, sorted B cells from healthy subjects showed increased sensitivity to in vitro stimulation with increased expression of CD80 and CD86 when cultured under hypoxic conditions, while co-culture with RA patient synovial fibroblasts didn't not enhance this effect.
Conclusions
The CXCR3 mediated accumulation of memory B cells in both ACPA+ and ACPA- RA, underlines a common, antibody independent, contribution of B cells in synovial inflammation and an opportunity for therapeutic intervention. While B cell activation under hypoxic conditions and increased CD80/CD86 expression is potentially an important mediator for the emergence of auto-reactive T cells and disease progression in RA.

(18A173) ABSTRACT 61 POSTER 53

Low vitamin D levels in patients with systemic lupus erythematous

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Introduction
Low vitamin D levels have been associated with increased risk flair in patients with systemic lupus erythematous (SLE). Vitamin D deficiency is common in the general Irish population. The Irish Longitudinal Study on Ageing have shown that 13.1% of adults over the aged of 50 are vitamin D deficient in Ireland.

Aims/Background
The aim of this study was to assess the incidence of vitamin D deficiency in a dedicated SLE clinic. We also wished to explore if vitamin D deficiency is more common in patients aged over 50 with SLE than the normal Irish population aged over 50.

Method
Clinical notes and bloods test results were reviewed on patients attending a dedicated SLE clinic at St James's Hospital, Dublin from May 2016 to May 2018. Data collection included sex, age, vitamin D levels, disease stability and whether Vitamin D levels were checked after treatment.

Results
Of the 88 patients, 58 patients had their vitamin D levels checked between May 2016 and May 2018. 8.8% (10) had vitamin D insufficiency (30–50 nmol/l) and 14.77% (13)had deficiency (<30 nmol/l) with 35 patients having normal Vitamin D levels. Table 1 outline their demographics.

Of those with vitamin D deficiency, only one patient had their vitamin levels checked to ensure they had normalised. 15.38% of patients with vitamin D deficiency had active SLE. In comparison 14.28% of patients with normal Vitamin D had active SLE. Only 21.74% of patients with Vitamin D deficiency or insufficiency had their Vitamin D levels rechecked to ensure they had normalised.

In patients aged over 50, 30 patients had vitamin D levels check. 33 % of patients aged over 50 had vitamin D deficiency/insufficiency. with 23.3% having Vitamin D deficiency. In the patients with Vitamin D deficiency,28.5% of patients aged over 50 had active SLE.

Conclusions
Vitamin D deficiency was associated with a slightly higher incidence of active SLE . Vitamin D deficiency was increased in SLE patients aged over 50 compared to Irish older adult population without SLE. Patients with vitamin D deficiency aged over 50 had a higher incidence of active SLE.

Figure

Demographic		Number of patients
Sex	Male	10
	Female	77
Age , years	<30	5
	30-39	12
	40-49	23
	50-59	22
	60-69	18
	70-79	7
	>80	1

Table 1:Patient demographics

(18A174) ABSTRACT 62 POSTER 54

Initial Results of a Rheumatology and Obstetric Service

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Introduction
Rheumatic musculoskeletal disease (RMD) patients when family planning must consider fertility, disease activity and management from pre-conception to lactation. In a 2013 national survey, Irish women with RMD expressed dissatisfaction about the information and care received. To address this, in May 2017, we created the Rheumatology and Obstetric Servie (ROSE) Clinic in the National Maternity Hospital.

Aims/Background
To record data on rheumatic disease patients reproductive health outcomes.

Method
RMD patients with reproductive health needs are treated by a multidisciplinary team (rheumatologists and rheumatology advanced nurse practitioners, obstetricians, midwives, maternal medicine specialists and pharmacists). We identify patients' emotional and healthcare needs, ensure access to expert advice, maintenance of good disease control and positive reproductive outcomes using our evidence based antenatal, pregnancy and postpartum care pathways. Patient outcomes are measured.

Results
42 women with median age (range) of 33 years (27-41) have been cared for by this service.

Patient diagnoses were SLE (n=11), rheumatoid arthritis (9), psoriatic arthritis (6), Sjogren's syndrome (4), antiphospholipid syndrome (2), undifferentiated connective tissue disease (2). There were one case of each of the following conditions: ankylosing spondylitis, reactive arthritis, Behcet's disease, Takayasu's arteritis, mixed connective tissue disease, granulomatosis with polyangitis, scleroderma, spondyloepiphyseal dysplasia congenital, Ehlers Danlos syndrome type 3.

Fifteen patients were on synthetic DMARDs, six on prednisolone, eight on TNF inhibitors, two on non TNF inhibitors, three on aspirin and two on low molecular weight heparin.

There have been 22 successful pregnancies and 23 babies born (one set of twins). There were 7 spontaneous vaginal deliveries, 1 forceps delivery, 4 operative vaginal deliveries and 10 Caesarean sections (2 elective for breech, 6 other elective and 2 emergency). Median (range) birth weight was 3.5kg (1.9-4.4kg). There has been one miscarriage. One patient had post-partum complications (wound infection and mastitis).

Conclusions
These data show 22/23 (96%) successful birth outcomes in women with RMD and a low rate of postpartum complications. 10 patients were on biologic DMARDs.

(18A176) ABSTRACT 63 POSTER 55

Is the incidence of gout similar to other risk factors in patients presenting with stroke or myocardial infarction?

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Introduction
Gout is known risk factor for cardiovascular disease. Studies have suggested that gout is equivalent to diabetes as a risk in patient presenting with stroke.Studies have shown a higher risk of myocardial infarction in patients with gout compared to the general population.

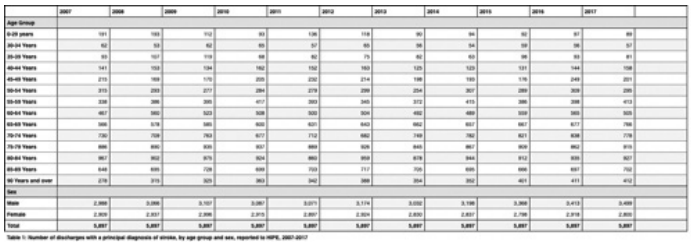
Aims/Background
The aim of this study was to explore wether gout is as strong as a risk factor as diabetes, hypertension, hyperlipidemia or peripheral vascular disease for myocardial infarction or stroke in the Irish populaton.

Method
The Hospital In-Patient Enquiry Scheme (HIPE) was used to identify patients admitted with stroke or myocardial infarction from 62 acute public hospitals in Ireland from 2007 to 2017. Age, gender and number of patients with gout, diabetes, hypertension, peripheral vasclular disease and hyperlipidemia were recorded.

Results
From 2007 until 2017, 64,867 were admitted with a diagnosis of stroke. Patients age and gender of patients admitted with stroke are outlined in Table 1. 70, 628 patients were admitted with myocardial infarction.
In the stroke group patients with diabetes had a significantly higher incidence of stroke compared to those with gout. Incidence of stoke in patients with gout was similar to patient with risks factors of hyperlipidemia or peripheral vascular disease. Chart 1 outline the number of patients with stroke presenting with each risk factor.
The incidence of gout in the myocardial infarction group (0.5%) was lower when compared to the stroke group (0.77%). The presence of diabetes as a risk factor (6.7%)was significantly higher compared to the incidence of gout (0.5%)n patients admitted with myocardial infarction.

Conclusions
Gout is not an equivalent risk factor to diabetes in patients present with myocardial infarction or stroke. The incidence of gout as risk factor is similar to hyperlipidemia in patients presenting with stroke.

Figure



Figure

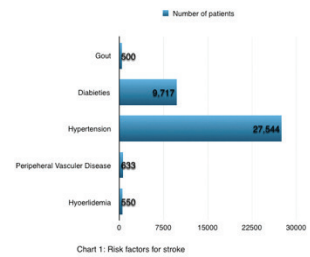


Chart 1: Risk factors for stroke

(18A177) ABSTRACT 64 POSTER 56

Role of Macrophage Migration Inhibitory Factor in Rheumatoid and Psoriatic Arthritis

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Introduction
Macrophage migration inhibitory factor (MIF) is a key regulator of pro-inflammatory cytokines and has been implicated in angiogenesis and pathogenesis of several diseases such as rheumatoid arthritis (RA). Synovial fibroblasts (SF) and macrophages are considered to be key players in the hyperplastic synovial tissue that invades and degrades adjacent cartilage and bone in patients with inflammatory arthritis.

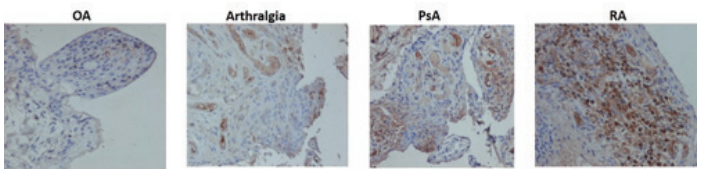
Aims/Background
To perform a comparative analysis of the expression of MIF, its regulation and pathogenic roles in patients with RA, Psoriatic Arthritis (PsA), Osteoarthritis (OA) and in Arthralgia patients (pre-RA) in vitro and ex vivo.

Method
MIF expression was quantified in RA, PsA, OA and arthralgia synovial tissue sections by immunohistology, and real-time PCR. Peripheral blood mononuclear cells (PBMC) were isolated from healthy donors, and patients with OA, RA, PsA and Arthralgia and primary macrophages (Mf) differentiated from isolated CD14+ monocytes and polarised into M1 and M2 phenotypes. Primary synovial fibroblasts (SFC) from OA, RA and PsA patients were cultured with or without TNFa (10ng/mL). PBMC, Mf, SFC and explant mRNA was isolated and MIF gene expression evaluated by RT-PCR. Mf and SFC supernatants were harvested and assayed for soluble MIF by ELISA. Human endothelial (HUVEC) cells and Mf were cultured with recombinant MIF protein pro-inflammatory/ angiogenic markers quantified in supernatants by ELISA and cell lysates by RT-PCR. GraphPad Prism Ver7 was used for statistical analysis.

Results
MIF protein expression was increased in RA and PsA synovial tissue compared to OA and arthralgia. MIF mRNA was higher in RA vs PsA and OA. MIF mRNA expression was increased in Mfs from RA patients in comparison to healthy controls. MIF mRNA expression levels were found to be higher in RA SFC in comparison to PsA SFC patients. Interestingly, treatment with TNF-a resulted in decreased levels of MIF both in RA and PsA SFC. Addition of rhMIF activated pro-inflammatory responses (IL-1b,-IL-6,-IL8,-MCP-1,-GAPDH,-Notch-1 of healthy unpolarised macrophages. However, rhMIF had no effect on the pro-inflammatory and angiogenic markers in HUVEC endothelial cells.

Conclusions
MIF may have a key role in promoting the pathogenesis of RA and has a good potential as a therapeutic target for RA.

Figure



(18A178) POSTER 65 POSTER 57

An Analysis of the Quality and Readability of Online Information For Osteoarthritis with Historical Comparison

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Introduction
Osteoarthritis is the most common cause of disability in people over 65 years old and a major cost to society. Despite increasing availability and usage of online health information, quality and readability is variable.
Aims/Background
This study reviews the quality and readability of online information regarding osteoarthritis and compares this to a 2003 study.
Method
The frequency of four commonly used terms ("osteoarthritis", "osteoarthrosis", "degenerative arthritis", "degenerative joint disease") was reviewed across the three most popular English language search engines. Osteoarthritis was the most frequently used.
The first 25 pages, excluding paid advertisements, from each search engine for "osteoarthritis" were analyzed. Duplicate pages, inaccessible pages (behind a pay wall, not available for geographical reasons) and non-text pages were excluded. Website quality was scored using the validated Journal of the American Medical Association (JAMA) benchmark criteria and DISCERN criteria. Presence or absence of HONcode certification, age of content, content producer and author characteristics were noted. Readability was measured using Flesch Reading Ease Score (FRES), Flesch-Kincaid Grade Level (FKGL) and Gunning-Fog Index (GFI).
Results
Osteoarthritis was the most searched term (33,960,000 results). 37 unique websites were suitable for analysis.
One (2.7%) website met all four JAMA Criteria. Mean DISCERN quality of information for osteoarthritis websites was "fair", comparing with the "poor" grading of a 2003 study. HONCode endorsed websites (43.2%) were of a statistically significantly higher quality, but not readability.
Readability varied by assessment tool from 8th to 12th grade level. This compares with the recommended 7– 8th grade level.
Conclusions
Quality of online health information for osteoarthritis is "fair". 2.7% of websites met JAMA benchmark criteria for quality. HONcode certification was indicative of higher quality. Readability was equal to or more difficult than recommendations.

(18A179) ABSTRACT 66 POSTER 58

An Investigation into C5orf30 and Immune Cell Expression

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Introduction
Rheumatoid arthritis (RA) is a chronic inflammatory condition affecting the joints, resulting in pain, stiffness, mobility restrictions and often systemic effects. It affects around 50,000 people in Ireland. The cause of RA is multifactorial including genetic and environmental components
Aims/Background
We identified a variant in C5orf30 linked with both risk, and severity, of RA. Subsequently we revealed C5orf30 to encode a negative regulator of tissue damage mediated by RA synovial fibroblasts (RASFs) and have recently identified it as a regulator of the resolution of macrophage-mediated inflammation. Neutrophils constitute over 90% of cells found in the synovial fluid of RA patients, however the potential expression and biological roles of C5orf30 have not been determined this cell type. Our aim was to investigate C5orf30 expression in varies immune cells including neutrophils.
Method
Cell populations (neutrophils, monocytes and macrophages) were isolated from healthy volunteer blood donors. Rheumatoid arthritis synovial fibroblasts (RASFs) were derived from patient biopsies. The neutrophil cell line model HL-60 was differentiated to neutrophil phenotype with all-trans retinoic acid (ATRA) or DMSO treatment. Inflammatory stimulations, 20 ng/µl TNF, 100 ng/µl LPS, and 20 ng/µl IL-4, were performed for 4 and 24 h. C5orf30 and variant expression was investigated by QRT-PCR.
Results
C5orf30 was differentially expressed between cell types; RASFs had the highest level of total (all variant) C5orf30 expression, followed by neutrophils, macrophage, PBMCs and monocytes. C5orf30 transcript variants displayed cell-specific expression. Variant-1 expression was greatest in PBMCs, variant-2 in RASFs and neutrophils and variant-3 in PBMCs, macrophage and RASF. Variant 2 was the predominant variant expressed in neutrophils, macrophage and monocytes.
HL-60 cell differentiation resulted in augmented CD11b (neutrophil marker) and attenuated C5orf30 expression. Preliminary data shows C5orf30 expression to be regulated by anti- and pro- inflammatory stimuli TNFα, LPS and IL-4 in differentiated HL-60 cells.
Conclusions
C5orf30 is expressed by immune cells including neutrophils and may play a role in inflammatory responses. Future studies will investigate the requirement of C5orf30 in neutrophil invasion and phagocytosis.

(18A180) ABSTRACT 67 POSTER 59

A Multidisciplinary Care Pathway for a Rheumatology and Reproductive Health Service

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Introduction
A multidisciplinary team (MDT) approach to pregnancy in women with rheumatic and musculoskeletal diseases (RMD) ensures best outcomes for mother and baby. RMD patients have previously expressed dissatisfaction about the information and care received. No standardised or national care pathway has been developed to guide clinicians with respect to RMD in pregnancy in general.

Aims/Background
We developed and report initial results (2013-2016) of standardised reproductive care pathway.
Method
This is a prospective observational study. 98 female RMD patients with reproductive health needs were assessed for age, diagnosis, medications, use of assisted reproductive technology and pregnancy outcomes. Through a literature review and our initial experience, an evidence based reproductive care pathway for women with RMD was established outlining management at each step of the patients' journey from pregnancy planning to breastfeeding.
Results
Ninety-eight patients were seen. Their diagnoses were rheumatoid arthritis (n=41), psoriatic arthritis (16), ankylosing spondylitis (8), SLE (7), JIA (5), fibromyalgia (5), granulomatosis with polyangitis (3), reactive arthritis (2), Behcet's disease (2), Sicca syndrome (2), Takayasu's arteritis (2), sarcoidosis (1), mixed connective tissue disease (1), systemic sclerosis (1).
88 of 98 women decided to have a baby. 76 babies were born to 62 mothers, three of whom used assisted reproductive technology. 49 women had one birth and 27 gave birth twice, including one set of twins. There were 12 miscarriages (11-1st trimester and 1-2nd trimester losses) and one perinatal death due to renal aplasia diagnosed in utero. There was one fourth degree vaginal tear.
24 women were on biologic DMARD therapy at conception. 10 discontinued in the first semester and 5 in the second trimester. 9 continued throughout pregnancy. At six weeks, breastfeeding rates were 28%.
Conclusions
These data show high levels of successful pregnancy outcomes. 70% of women who tried to conceive had a baby. 38% of patients on biologic DMARDS continued throughout pregnancy. There were comparable miscarriage rates with the general population (14% versus 20%) but lower breastfeeding rates (28% versus 55%).

(18A182) ABSTRACT 68 **POSTER 60**

Nature and quality of inpatient rheumatology referrals in a tertiary referral hospital

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Introduction
Consults are an important aspect of the rheumatology service.
Aims/Background
To examine the nature and quality of inpatient rheumatology referrals in a tertiary referral hospital.
Method
All available consults (n=81) were reviewed. Age, gender, urgency and referral source were recorded. The most likely reason for referral was decided by our research fellow. Referral forms were assessed for presence or absence of age/date of birth, gender, location, duration of symptoms, medications, examination findings, reason for consult, urgency and suspected diagnosis. The presence or absence of investigations (any blood result, CRP value and any imaging result) and what referrer details (name, contact details, consultant responsible) were given.
Results
49% of patients were ≥ 70 years old. 68% were female. Referrals were vasculitis (including GCA and PMR) 21%, inflammatory arthritis 20%, crystal arthropathy 19%, connective tissue disease 16%, osteoarthritis 14%, septic arthritis 3%, fibromyalgia 3%, pyrexia of unknown origin 3%, sarcoid 1%, anti-phospholipid syndrome 1% and osteoporosis 1%.
59% of consults came from general medical teams, 14% from acute medicine, 14% from surgery, 3% from psychiatry and 11% from other services.
36% of consults were considered urgent by the referring team (within 24 hours), 64% were routine (within 48 hours).
In 99% of cases, age or date of birth was given. 84 % detailed gender. 78% contained ward. 68% contained bed number. 56% listed urgency.
96% indicated reason for consult. 30% listed duration of symptoms. 21% detailed whether patient known to rheumatology. 57% gave suspected diagnosis. 33% gave medications. 42% detailed any clinical examination findings. 41% reported any blood test. 27% gave a CRP. 44% detailed imaging findings.
49% contained referrer name. 80% had referrer contact details. 70% gave referring consultant.
Conclusions
The majority of consults were elderly, women. There was a wide range of conditions. 3% of referrals were for fibromyalgia, which could perhaps be managed as an outpatient, improving resource utilization. Many referrals lacked important details with less than half including duration of symptoms, medications, examination findings, blood test results or referrer name. An electronic referral system requiring this data is being created.

(18A183) ABSTRACT 69 **POSTER 61**

A comparison of the fibromyalgia (FMS) pathway provided in Tallaght University Hospital (TUH) against recommendations for the non-pharmacological management of fibromyalgia as outlined in the EULAR guidelines 2016.

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Introduction
Management of fibromyalgia should aim at improving health-related quality of life balancing benefit and risk of treatment that often requires a multidisciplinary approach with a combination of non-pharmacological and pharmacological treatment modalities tailored according to pain intensity, function, associated features (such as depression), fatigue, sleep disturbance and patient preferences and comorbidities; by shared decision-making with the patient. Initial management should focus on non-pharmacological therapies (McFarlane GJ et al, 2017).
The FMS pathway in (TUH) provides 4 group based exercise and education sessions for patients referred from Rheumatology and Rheumatology MSK Triage with FMS.
Aims/Background
to audit the FMS pathway in TUH against the revised EULAR guidelines 2016 for the non-pharmacological management of FMS.
Method
The recommendations for the non-pharmacological management of FMS 2016 were used to compare the practise in the FMS pathway. Each chart was reviewed to determine the input from PT and OT and whether each of the guidelines was met, as part of the pathway.
19 patient charts of those who attended the pathway in 2017 were audited. There were recommendations for and against certain

interventions. These were categorised in terms of level of evidence, grade of evidence, strength of recommendation and % agreement among clinical experts.
Data was input to an excel spread sheet and scored for whether or not the recommendation was met for each chart audited.

Results

There was strong evidence for the use of exercise which was provided to 100% of people attending the pathway.
Heated pool therapy with or without exercise is recommended and group based exercise was performed in the aquatic therapy pool in 100% of cases.
Individualised exercise programs were provided in 46.5% of cases either before or after the pathway as 1:1 sessions in PT.
There was weak evidence for acupuncture, CBT (particularly where other interventions have failed), meditative movement, mindfulness and mind body therapy which we do not offer in the pathway.
There was weak evidence for a multi-modal approach to management. The pathway is run by PT and OT providing a partly multi-disciplinary approach.

Conclusions

The FMS pathway in TUH provides a multimodal aquatic exercise and education based format which is supported by the EULAR 2016 guidelines. There are a number of interventions that we do not offer. These include; acupuncture, CBT, meditative movement therapies, mindfulness and mind-body therapy.
There are a number of research questions proposed in the guidelines which when answered may influence practise in the future. These include:

- Which type of exercise is most effective: strength and/or aerobic training?
- Are combined pharmacological and non-pharmacological approaches to management more effective than single-modality management?
- Are there characteristics of patients with fibromyalgia that predict response to specific therapies?
- How should fibromyalgia be managed when it occurs as a comorbidity to inflammatory arthritis?
- What aspects of a healthcare system optimise outcome for patients (who is best for the management of FM patients)?

Reference:

1. EULAR revised recommendations for the management of fibromyalgia. G J Macfarlane, C Kronisch, L E Dean, F Atzeni, W Häuser, E Fluß, E Choy, E Kosek, K Amris, J Branco, F Dincer, P Leino-Arjas, K Longley, G M McCarthy, S Makri, S Perrot, P Sarzi-Puttini, A Taylor, and G T Jones. Ann Rheum Dis 2017;36:318-328

(18A190) ABSTRACT 70 **POSTER 62**

A Survey of Irish Rheumatologists' Practice for Documenting Informed Consent for Corticosteroid Injections

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Introduction

Corticosteroid injection is a common therapeutic intervention for symptomatic joint and soft tissue disorders. Whilst minor local side-effects are possible, serious complications (e.g. septic arthritis) are rare. Nonetheless, recording informed consent for such procedures is a core component of safe practice. A recent audit in our unit indicated a need to improve the documentation of consent. Informal opinion favours verbal consent given the low risk involved; it is unknown to what extent standardised methods are being used nationally.

Aims/Background

Corticosteroid injection is a common therapeutic intervention for symptomatic joint and soft tissue disorders. Whilst minor local side-effects are possible, serious complications (e.g. septic arthritis) are rare. Nonetheless, recording informed consent for such procedures is a core component of safe practice. A recent audit in our unit indicated a need to improve the documentation of consent. Informal opinion favours verbal consent given the low risk involved; it is unknown to what extent standardised methods are being used nationally.

Method

59 registered rheumatologists were surveyed by anonymous postal questionnaire regarding: (i) Number of injections performed over the previous month; (ii) Use of image guidance; (iii) Any procedure-related complaints received over the previous 5 years; (iv) Current process for obtaining consent; (v) Procedural information routinely discussed with patients; (vii) Information documented in the notes

Results

44 surveys were returned (response rate 74.6%).
68% of respondents performed over 10 joint injections in the previous month. 2% used image guidance for all procedures but 52% never used this and 43% only in certain cases.
30% acknowledged a complaint about an injection over the previous five years, most commonly related to post-injection pain flare (77%) and lack of effect (30%).
37% obtained verbal consent and a further 37% obtained written consent, with 20% using a standardised form.
93% advised patients of the indication & anticipated benefits of injection; 86% warned of possible pain and lack of effect; 54% warned of skin changes; 20% advised of facial flushing.
38% documented at least three items in the notes (indication, name of drug and dose); 11% recorded no information and 16% were considering changing their practice in this respect.

Conclusions

Whilst the majority of respondents gave patients verbal information about injection procedures, only 37% obtained written consent and 11% made no written record. This is concerning given that 30% of respondents had received a procedure-related complaint. However 16% were considering changing their practice. In our unit we plan to pilot a standardised consent form to improve documentation of these procedures.

(18A191) ABSTRACT 71 **POSTER 63**

Architectural Distortion of Nailfold Capillaries: Is it a Predictor of Systemic Vascular Damage?

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Introduction

The early detection of microvascular changes in autoimmune connective tissue diseases (CTD) is the main goal of using nailfold capillaroscopy (NFC). This method, when used in conjunction with clinical information and autoantibodies is considered a powerful tool for identifying and differentiating CTDs based on microscopic features. CTDs are multisystemic diseases with a myriad of clinical

complications including digital ulceration (DU) and pulmonary arterial hypertension (PAH).

Aims/Background

To compare the spectrum of NFC findings with autoantibody profile, clinical diagnosis and systemic involvement to identify any association with the degree of NFC findings and the clinical complications of the underlying CTD.

Method

A single center, retrospective, observational study, which evaluated patients who attended NFC clinic between Feb 2017 and July 2018. All patients were evaluated by a rheumatologist prior to attending the clinic and had immunology workup performed. At appointment, patients underwent detailed NFC evaluation through the acquisition of images from eight fingers (excluding thumbs). All the images were performed by a single examiner and images were interpreted by two rheumatologists. A qualitative assessment of video NFC was generated focussing on the presence or absence of avascular areas, haemorrhages, haemosiderin deposition, giant loop capillaries and architectural distortion.

Results

91 patients were investigated with video NFC. Seven of 91 patients had architectural distortion, of whom six had a clinical diagnosis of Systemic Sclerosis (SSc) and one had a clinical diagnosis of undifferentiated CTD. Of the seven patients with complete architectural distortion, four patients had vascular complication; two had PAH and two had DU. PAH and DU was not described in any other patient in this cohort. Of the seven patients with complete architectural distortion, five were anticentromere (ACA) antibody positive.

Conclusions

NFC explores microvascular damage of the nailbeds. Architectural distortion on NFC is seen almost exclusively in SSc and had a strong association with PAH and DU, which are severe systemic manifestations of vascular damage. Further longitudinal studies with a larger sample size are warranted to investigate the assocation between microvascular damage of the nailbeds and systemic vascular damage leading to PAH and DU. Is architectural distortion a harbinger of PAH and DU in CTDs?

(18A192) ABSTRACT 72 **POSTER 64**

To Compare the Clinical and Histological Diagnosis in Patients with Giant Cell Arteritis in a Single Centre

Author(s)

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Department(s)/Institutions

1 Rheumatology Department, University College Hospital Galway (UCHG) 2 Pathology Department, University College Hospital Galway (UCHG)

Introduction

Giant cell arteritis (GCA) is a large vessel vasculitis of unknown aetiology, which, if left untreated could result in permanent blindness. Annual incidence of GCA is 15-35/100,000 per year. The British Society of Rheumatology (BSR) recommends a temporal artery biopsy (TAB) in all suspected cases of GCA. BSR guidelines recommend a minimum TAB length of ≥2.5cm to diagnose GCA .

Aims/Background

To analyse the total number of referrals for GCA requiring a TAB and to compare the clinical diagnosis of GCA to the histological diagnosis at University College Hospital Galway.

Method

We identified all patients who underwent a temporal artery biopsy from the histopathology database between January 2017 and October 2017. We excluded any patient who was not evaluated by the Department of Rheumatology. A retrospective analysis was completed to identify patient characteristics, presentation, histological findings and length of TAB in this cohort.

Results

A total of 12 patients were identified, who had a TAB over a ten month period between January and October 2017. The majority of the cohort was female (67%). 92% of patients were over 60 years old with a mean age of 68 years old. The most common symptoms identified were headache (30%) and visual disturbance (28%). Out of 12 TAB, ten biopsies (84%) were negative. Five (50%) of these patients were treated clinically as GCA. Further analysis of the five negative biopsies revealed that four (80%) were of inadequate length (3mm-12mm, mean 8.8mm). Two TAB (17%) were inconclusive. One of these patients was treated clinically as GCA and the TAB was of an inadequate length (8mm).

Conclusions

GCA is a well described condition. Traditionally, all patients were referred for TAB, for histological confirmation of the diagnosis. This study highlights the challenge of obtaining an adequate TAB length for histopathological analysis. The TABUL study highlighted the utility and superiority of Ultrasound scanning of the temporal artery in GCA which we are exploring further in our Rheumatology department.

(18A193) ABSTRACT 73 **POSTER 65**

Video Nailfold Capillaroscopy: A Single Centre Experience.

Author(s)

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Introduction

Nailfold capillaroscopy (NFC) is a simple, non-invasive, sensitive and low-cost imaging method used to detect early microvascular changes of capillaries in the nailfold area in association with some connective tissue diseases (CTD). When used together, autoantibodies and capillaroscopy findings are generally accepted as a powerful diagnostic tool for detecting emerging CTDs in patients with Raynaud's phenomenon (RP). Nowadays, it is commonly used in the differentiation of primary and secondary RP and in the diagnosis of Systemic Sclerosis (SSc).

Aims/Background

To evaluate the role of NFC in the early diagnosis of CTD.

Method

In this single centre, retrospective, observational cohort study, we evaluated patients who attended NFC clinic between Feb 2017 and July 2018. Patients referred from outside the Rheumatology department of our centre were excluded. All patients were evaluated by a rheumatologist prior to attending the clinic and had immunology workup performed. At appointment, patients underwent detailed video NFC evaluation through the acquisition of images from eight of ten fingers (excluding thumbs). All the images were performed by a single examiner and images were interpreted by two rheumatologists.

Results

77 patients were included in this study, 60 female and 17 male patients. 79% of the studies were reported as abnormal. Almost one-

third of patients were discharged from the service following analysis of video NFC in conjunction with clinical history and examination and results of immunology testing. The commonest diagnosis post Video NFC was Undifferentiated CTD (25% of patients) and SSc (25% of patients).

Conclusions

Video NFC is a valuable tool in supporting early diagnosis of a CTD. It should be included in the work-up algorithm for patients with Raynaud's phenomenon or/and those with features of early CTD. Further studies are required to explore its utility in excluding CTD and facilitating early discharge of patients from Rheumatology clinic.

(18A194) ABSTRACT 74 **POSTER 66**

The Significance of Nailfold Microvascular Changes in Connective Tissue Disease

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Introduction

Microangiopathy is an early sign in numerous autoimmune inflammatory diseases. Nailfold capillaroscopy (NFC) is the standard method for detecting peripheral microvascular abnormalities which has been found to be associated with certain connective tissue diseases (CTD).

Aims/Background

The objective of the study is to prospectively investigate the diagnostic value of NFC in patients with CTD, to assess morphological and structural changes and to recognize useful microvascular features.

Method

A prospective study was carried out in our department between February 2017 and July 2018. A detailed microscopic fingernail examination was performed on all fingers (except thumbs) by the same rheumatologist using video NFC. The images were interpreted by two rheumatologists. Different measurements were detected and analysed as outlined in Table 1. We excluded any patient who was not followed in our unit and/or did not have a diagnosis of a CTD.

Results

44 patients were identified; 16 Undifferentiated CTD, 3 Mixed CTD, 14 Systemic Sclerosis (SSc), 5 Primary Sjogren Syndrome (pSS), 4 SLE, 1 Dermatomyositis and 1 vasculitis. 82% of patients were female. Based on the findings, avascularity was the commonest microvascular abnormality observed (63%) (Table 1). The obtained results were further categorized into normal pattern, nonspecific morphological abnormality (included abnormal morphology, haemosiderin deposition, infrequent dilated loops and avascularity) and SSc pattern (included frequent haemorrhage, giant capillaries, ramification and architectural distortion). 5 patients (11%) were categorised into a normal pattern, 22 patients (50%) were categorised into a nonspecific morphological abnormality and 17 (39%) were categorized into a SSc pattern group.

Conclusions

Among all abnormalities, avascularity is considered a non-specific microvascular change and it is reported in normal populations as well. Knowledge of nailfold changes in CTD is supportive of, but not diagnostic of, a CTD. Certain nailfold changes, particularly giant capillaries, frequent capillary haemorrhages and architectural distortion were significantly more frequent in disease groups. NFC should be employed routinely by all Rheumatologists in the course and follow-up of patients with CTD.

(18A200) ABSTRACT 75 **POSTER 67**

Urate Lowering Therapy (ULT) reduces Plasma Homocysteine Levels: a Potential mechanism for Cardiovascular Risk Disease Modification.

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Introduction

Hyperuricaemia is a risk factor for gout, cardiovascular disease (CVD), Type 2 Diabetes (T2DM) and chronic kidney disease (CKD). Plasma homocysteine levels are elevated in gout and correlate with serum uric acid levels. The associations of elevated plasma homocysteine levels with disease progression in CKD, CVD and T2DM are also well documented, indicating potential overlapping mechanisms of disease involving both monosodium urate (MSU) and homocysteine (1-4).

Aims/Background

This case-control study evaluated the effect of ULT on cardiovascular risk factors in hyperuricaemic individuals.

Method

Hyperuricaemic cases with foot pain +/- ultrasound evidence of early gout (n=16) were compared with asymptomatic hyperuricaemic controls (n=15). Cases were treated with febuxostat 80mg for 3 months. Serum urate, ESR, CRP, fasting homocysteine, glucose, insulin and lipid levels were measured at 0-3 months.

Results

Cases had higher levels of baseline serum urate than asymptomatic controls (449+19 µmol/L vs. 421+7.1 controls; P=0.006), higher levels of homocysteine (23+2.1µmol/L vs. 15+1.6 controls; P=0.002) and lower levels of HDL cholesterol (1.1+0.2 mmol/L vs. 1.5+0.1 controls; P=0.007) (Table 1). ULT reduced serum homocysteine at 1-month (19+1.6 µmol/L; P=0.001) and 3-months (19+1.7 µmol/L; P=0.002). The change in homocysteine at 3-months correlated with the change in serum urate (r=0.394, P=0.05) but not ESR, CRP, lipids or measures of insulin resistance. No significant changes in insulin resistance, ESR, CRP or lipid measurements following ULT were observed.

Conclusions

Elevated levels of plasma homocysteine are reduced following ULT, a novel and previously unpublished finding. Changes in plasma homocysteine correlate with changes in serum urate after ULT. The known cardiovascular benefits of ULT including the amelioration CKD disease progression may be mediated in part through homocysteine effects. A full elucidation of the pathological effects of metabolic intermediates including homocysteine and MSU may lead to the development of future treatment strategies for the systemic complications of inflammatory metabolic diseases

Figure

	Symptomatic Hyperuricaemia CASES (n=16)	Asymptomatic Hyperuricaemia CONTROLS (n=15)	P Value
Age (years)	53±3.7	57±3.5	NS
% Male	36%	50%	NS
Urea (mg/dL)	6±0.4	5.7±0.4	NS
Cr (µmol/L)	89±4.2	89±3.4	NS
eGFR (mL/min/1.73 m2)	71±3.9	65±3.2	NS
Urate (µmol/L)	**449±19**	**421±7.1**	***0.006**
ESR (mm/hr)	17±2.9	16±2.7	NS
CRP (mg/L)	4.3±1.0	3.9±1.1	NS
Homocysteine (µmol/L)	**23±2.1**	**15±1.6**	***0.002**
Insulin (mmol/L)	18.4±3.0	17.8±5.5	NS
Gluc (mmol/L)	5.9±0.2	6.1±0.5	NS
HOMA IR	5.5±1.4	6.3±2.7	NS
Cholesterol (mmol/L)	4.9±0.2	4.8±0.2	NS
HDL (mmol/L)	**1.1±0.2**	**1.5±0.1**	***0.007**
LDL (mmol/L)	2.8±0.2	2.7±0.2	NS
TG (mmol/L)	1.9±0.2	2.0±0.4	NS

Table 1. Baseline Characteristics of the study population. Patients with early Gout (cases) vs. patients with asymptomatic hyperuricaemia. Mean ±S.E. values. *P<0.05, Mann Whitney U.

Figure

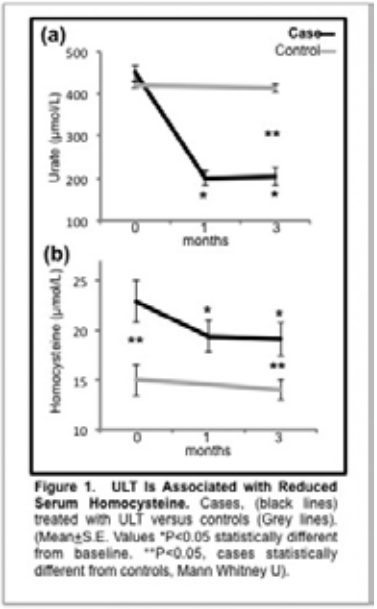

Figure 1. ULT Is Associated with Reduced Serum Homocysteine. Cases, (black lines) treated with ULT versus controls (Grey lines). (Mean±S.E. Values *P<0.05 statistically different from baseline. **P<0.05, cases statistically different from controls, Mann Whitney U).

(18A121) ABSTRACT 76 **CASE POSTER 68**

Necrotising myopathy associated with Anti-HMGCR antibodies

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Introduction
47 year old male, who was admitted to hospital with a two week history of gradual onset proximal muscle weakness. His background was significant for Type II Diabetes Mellitus treated with Metformin and Atorvastatin for> 2 years. Creatinine Kinase (CK) was significantly elevated to a level of 17880 IU/L on admission. Electromyography(EMG) revealed the presence of increased spontaneous activity, increased insertional activity and myotonia, favouring a myopathic process in the proximal upper and lower limbs. Muscle biopsy demonstrated spotty myofibre necrosis with regeneration and an absence of lymphocytic infiltrate.CT thorax, abdomen and pelvis, paraneoplastic and routine myositis antibody panels were non-contributory. Anti HMGCR antibody positive was detected in serum. He was commenced on immunosuppressants (steroids, rituximab) with an associated reduction in CK.

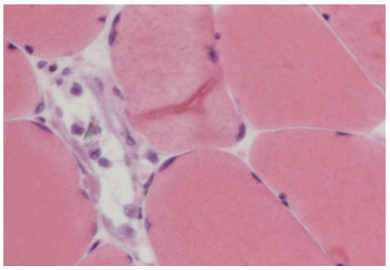
Aims/Background
Autoantibodies against 3-hydroxy-3-methylglutaryl-coenzyme A reductase (anti-HMGCR antibodies) were first identified in 2010 in association with immune mediated necrotizing myopathy. Antibodies have now been described in both statin exposed and statin naive patients and can cause an aggressive and debilitating myopathy. A proportion of patients have an associated malignancy . Response to treatment, despite cessation of statin therapy, can be slow.

Method
EMG, muscle biopsy, serial CK levels, routine bloods, routine autoimmune screen, CT Thorax abdomen pelvis, PET Scan, Anti HMGCR antibody, test to out rule metabolic disease.

Results
Discontinuation of statin and immunosuppression resulted in significant improvement in CK, but despite ongoing treatment CK remained persistently elevated >1000 indication slow response.

Conclusions
Anti-HMGCR antibodies are not routinely tested in a myositis antibody panel but in a research setting have been associated with significant myopathy and increased rates of malignancy. Optimal treatment strategies are yet to be fully elucidated. However, aggressive immunosuppressive treatment and appropriate screening for malignancy is paramount in optimizing the care of these patients.

Figure



(18A136) ABSTRACT 77 **CASE POSTER 69**

Immune mediated necrotizing Myositis due to Malarone (Atovaquone/Proguanil)

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Introduction
Abstract
Immune-mediated necrotizing myopathy (IMNM) is a type of autoimmune myopathy characterized by relatively severe proximal weakness, myofiber necrosis with minimal inflammatory cell infiltrate on muscle biopsy, and infrequent extra-muscular involvement. We describe a case of a 44 old male who was referred to us with a four month history of grade 4/5 weakness of proximal upper and lower limbs. The patient was on anti malarial prophylaxis Malarone (Atovaquone/proguanil combination). Lab investigations revealed raised CK, LDH, Liver transaminases, and Aldolase. He had normal ESR, CRP, urate, renal profile, C3,C4, immunoglobulins and negative ENA, ANA, ANCA, Hepatitis B and C serology, TB Quantiferon, Mysositis specific antibody screen(MI-2,MI02 beta, TIF-1-gamma, MDAS, NXP2, SAE1, KU, PL-SCL 100, PM-SCL 75, JO-1, SRP, PL-7, PL-12, EJ, OJ, RO-52). HMGCOAR auto antibody was positive. CT thorax, abdomen, and pelvis showed mild sigmoid diverticulosis only. Whole body MRI showed no convincing evidence of muscle abnormality (However, patient was on steroids at the time of imaging). EMG findings were consistent with proximal myopathy suggestive of polymyositis.
Muscle biopsy of right thigh showed myopathic features with diagnostic possibilities including drug associated necrotizing myopathy. Ultrasound liver completed for deranged liver function showed possibility of fatty liver. Subsequent liver biopsy was normal. The patient had no cardiopulmonary, gastrointestinal symptoms. There was no history of DVT,PE, parotid swelling, lymphadenopathy, skin lesions, raynauds phenomenon, dysphagia or epilepsy. Chest X-ray, Pulmonary function test, and echocardiogram showed no abnormalities. The patient was treated with prednisolone 60 mg od reducing dose followed by Rituximab infusions 1g IV two weeks apart and also received IVIG (0.4g/kg) monthly and responded very well to treatment with improvement in muscle strength,4+/5

at quadriceps and 5/5 everywhere else. There has been marked improvement seen in his CK, AST,ALT and LDH reduced from peak values. He is currently maintained at 10 mg of prednisolone once daily and will be continuing with monthly IVIG IV infusions with repeat Rituximab infusions every six to nine months. IMNM associated with Malarone has only been reported in the literature once previously. Further details of this rare case will be discussed.

Aims/Background

See Above

Method

As above

Results

NA

Conclusions

NA

(18A146) ABSTRACT 78 **CASE POSTER 70**

A Complex case of Polyostotic Avascular Necrosis

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Introduction

Antiphospholipid syndrome(APLS) is a well-recognized cause of acquired thrombophilia, which can manifest as avascular necrosis(AVN)(1). Diagnosis and management are often challenging in these cases.

Aims/Background

The following case discusses a complex case of a previously well young male who developed significant AVN at multiple sites resulting in numerous surgical repairs. This case aims to provoke discussion on management of APLS.

Method

A 35 year-old male was reviewed in outpatient clinic due to hip pain for 2 years. On examination, range of movement was slightly restricted in both hips but was otherwise normal. XR hips was done, showing nil of note and he was diagnosed as myofascial pain. A full auto-antibody screen at the time was negative. Due to continuing hip pain and worsening mobility over the next 6 years the patient had repeat hip x-rays which showed bilateral collapse of the femoral heads, requiring bilateral total hip replacements. Histology later confirmed avascular necrosis of both femoral heads. Shortly after recovering from these procedures the patient developed shoulder pain, subsequent x-rays of the shoulders showed AVN of both proximal humeri. One year later, the patient developed left ankle pain which was shown to be due to AVN of the left talus. Due to the multiple episodes of AVN the patient was referred to a number of specialist including the National Coagulation Center which sent a lupus anti-coagulant which was found to be positive. All other screens for potential causes of hypercoagability were negative.

Results

The patient was diagnosed as an atypical anti-phospholipid syndrome. The more atypical features of this case are the lack of ischeamia in other organ system, normal baseline bloods and multifocal nature of the disease. This case raises a number of interesting questions. What is the best form of anti-coagulation? Could there be benefit from vasodilators? What is the role for immunomodulation?

Conclusions

The patient has been treated with warfarin and we have contemplated vasodilation and immunomodulation treatments This case raises the awareness of this diagnosis, stresses the need for repeated blood tests in appropriate clinical settings and raises the issue of optimal future management.

(18A151) ABSTRACT 79

CASE POSTER 71

Case report: SLE in Monozygotic twins with same serology and same presentation

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Introduction

Monozygotic (MZ) twins share nearly all of their genetic variants including the same MHC sets, and many similar environments before and after birth. However, they can also show phenotypic discordance for a wide range of traits. Differences at the epigenetic level may account for such discordances in disease course.

Aims/Background

Case report

Method

This is a case report on 38 year old monozygotic female twins whom presented with clinical features of SLE. T.L presented to Rheumatology OPD in 2014 with axillary lymphadenopathy, pancytopenia with marked lymphopenia, fatigue, weight loss, and a history of hair thinning with no rash. Serology was strongly positive for ANA, high DsDNA titres positive anti Ro, and anti LA. She was initially treated with hydroxy-chloroquine (HCQ) 200mg OD to which she was intolerant , she developed alopecia related to severe scalp psoriasis, her skin disease was treated initially with Ustekinamab , then switched to secukinumab and now Guselkumab, with successful hair regrowth.

N.L presented to the emergency department of UHW in 2017 with symptomatic anaemia following referral from dermatology OPD which she is been attending for rash and alopecia, workup show severe megaloblastic anaemia with low folate level, hyperactive bone marrow that represent autoimmune anaemia pattern, Serology was identical to her twin sister except for negative DsDNA .Furthermore , skin biopsy from the scalp and rash on the arm showed acute folliculitis and perivascular inflammatory infiltrate respectively. Following Dermatology MDT meeting she was diagnosed with subacute lupus .She had been treated initially with hydroxy-chloroquine to which she is also developed allergic reaction and stopped .

Results

Both twins presented within 3 years with haematological and systemic features of SLE. Both developed reaction to HCQ . Of interest T.L was been diagnosed with cervical cancer in 2017 for which she underwent hysterectomy , while her identical twin is under investigation for cervical pathology , histology report pending.

Conclusions

The twins presented with similar clinical picture and same serological pattern and had similar reaction to HCQ , they are both experiencing the same genito-urinary symptoms related to cervical pathology . There have been case reports of Lupus and cervical atypia,although none on monozygotic twins !

(18A165) ABSTRACT 80 CASE POSTER 72

ERASMUS syndrome presents with Scleroderma renal crisis and Subarachnoid hemorrhage

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Introduction
Erasmus syndrome is the rare association of Systemic Sclerosis (SSc) with silica exposure, cigarette smoking and Interstitial lung disease resulting in a severe disease phenotype. Scleroderma Renal Crisis (SRC) is a rheumatological emergency and a severe complication of scleroderma which can occur up to 10% of the SSc patients. SRC presents with abrupt onset of moderate to marked hypertension, acute renal failure, thrombocytopenia and hemolytic anemia. Blood pressure control with angiotensin-converting enzyme (ACE) inhibitors is the cornerstone of treatment.

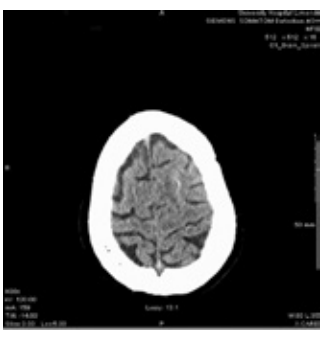
Aims/Background
Case Report

Method
A 50 years old man presented with five days history of severe headache and photophobia. Clinical examination revealed blood pressure of 231/130mmHg and marked neck stiffness. He had a recent diagnose of Erasmus Syndrome and was taking Oral glucocorticoids, Nifedipine and Mycophenolate Mofetil. His serology showed positive ANA (400) and anti Ro antibodies. However, Scl70 and anti-centromere antibodies were negative. His initial presentation also revealed acute kidney injury (AKI), thrombocytopenia, mild anemia and normal CT brain. Later that day he had two episodes of witnessed tonic-clonic seizures for which he required intubation and transfer to Intensive Care Unit (ICU). Urgent repeat CT brain revealed bilateral subarachnoid hemorrhage (Image-1) and the CT cerebral angiogram raised the possibility of middle cerebral artery vasculitis. MRI/MRA brain confirmed he had bilateral subarachnoid hemorrhage. Neurosurgeons advised no surgical intervention required. He was started on IV methylprednisolone and IV broad spectrum antibiotics in the ICU. He was later reviewed by the rheumatologist and promptly diagnosed with SRC and commenced on Ramipril (ACE inhibitor). His IV steroids and antibiotics were discontinued. His blood pressure was controlled with Ramipril and Labetalol while he was under the close surveillance of his renal function (Image-2).

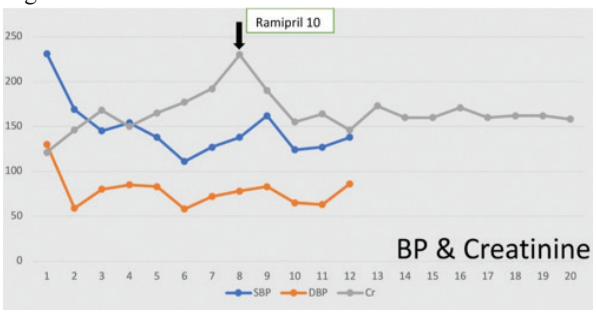
Results
This gentleman recovered from SRC with ACE inhibitor treatment but suffered a chronic kidney injury (Creatinine now averages 150, eGFR 40. In the follow up rheumatology clinic he was commenced on Rituximab (anti CD-20 antibody) as an adjuvant therapy.

Conclusions
Scleroderma renal crisis is a medical emergency and prompt diagnosis and early treatment with ACE inhibitor has a promising outcome.

Figure



Figure



(18A167) ABSTRACT 81 CASE POSTER 73

Basilar invagination. An uncommon complication of long standing Rheumatoid Arthritis

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Introduction
Background
Basilar invagination is defined as an abnormality of the craniovertebral junction in which the odontoid process of the second cervical vertebrae prolapses into the already narrow opening of the foramen magnum. This can result in a plethora of neurological symptoms secondary to compression of the brain stem as it exits the cranium. In recent times it is a rare complication of rheumatoid arthritis due to the introduction of Disease Modifying anti-rheumatoid drugs (DMARDS).

Case
We present the case of a 72 year old lady with a 31 year background of erosive sero-positive ,anti-CCP positive, destructive, deforming rheumatoid arthritis who presented to clinic complaining of new onset bilateral hand numbness from the wrist to the fingertips. Examination proved difficult due to severe deformities, contractures and longstanding peripheral neuropathy. Within these limits, there was reduced power on shoulder abduction bilaterally, altered sensation in hands and feet bilaterally and hyper-reflexia at the supinator and biceps tendon. Hoffmans test was negative. Continence was preserved, and there were no cerebellar signs and cranial nerve examination was entirely intact.
An urgent MRI brain and Cervical-Spine was ordered which demonstrated marked multilevel secondary degenerative changes and ankylosis of the cervical spine. Of particular interest there was evidence of basilar invagination with proximal migration of the odontoid process causing a marked narrowing of the foramen magnum and significant compression of the cervical cord at this level. She await consideration for considered for surgical intervention

Discussion
Rheumatoid arthritis of the C-Spine was first described by Garrod in 1890. Classically it had a variety of pathological manifestations, namely atlantoaxial subluxation, basilar invagination and subaxial subluxation. In recent years however, the advent of synthetic and biologic DMARDs has resulted in a dramatic decrease in the incidence and severity of rheumatic spinal disease, such that the above complications are now rarely encountered in clinical practice. Surgical management of this rare complication in RA is complex given the high likelihood of a comorbid patient, on long-term steroids and immunosuppression –all of which increase the operative risk. It

requires input from all members of the MDT to maximize patient outcome.
Aims/Background
NA
Method
NA
Results
NA
Conclusions
NA

(18A170) ABSTRACT 82 CASE POSTER 74

A complex case of massive ascites, pleural effusions, and pancytopenia, with low complement levels in a patient with bowel malignancy

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Introduction
We present the case of a 78 year old gentleman who presented with a 4 month history of nausea, anorexia, black stools and 10kg weight loss.
Aims/Background
Pre-morbidly this gentleman was fit and active. Over a 4 month period he developed the symptoms above and examination revealed bilateral pitting oedema, tender hepatomegaly and tense ascites. Initial investigations revealed a macrocytic anaemia and thrombocytopenia.
Method
Further investigations were carried out, including paracentesis, OGD, Colonoscopy, CT CAP, and PET. There was large volume ascites and pleural and pericardial effusions present. The ascitic fluid had a high protein level; no malignant cells were detected. There was abnormal uptake in sigmoid colon and rectum on PET scan, but appearances at colonoscopy were non-malignant. Biopsy was not possible as platelets had dropped to <10.
Results
Bone marrow biopsy showed marked fat necrosis with almost complete absence of megakaryocytes. Complement levels were low, and speckled ANA positive (low titre 80). ENA/ Anticardiolipin/ Beta 2 glycoprotein/ Lupus anticoagulant/ IgG4/ CEA/ Viral screen negative.

The patient developed foot drop and nerve conduction studies demonstrated a sensorimotor neuropathy causing left common peroneal nerve palsy.

The patient required nutritional and blood product support, and was treated with corticosteroids, rituximab and intravenous immunoglobulins with little clinical response. Under the care of Haematology he received Eltrombopag with the aim of platelet incrementation to facilitate colonic biopsy. Unfortunately this was not successful and the patient requested withdrawal of active treatment.
Conclusions
Post mortem examination revealed a moderately differentiated adenocarcinoma of the colon and gelatinous transformation of the bone marrow. There was marked serositis present, a very unusual histological finding, with no evidence of IgG4 disease. We are not convinced that the bowel malignancy accounts for all of the clinical features. We speculate that he had co-existing seronegative lupus to account for the pancytopenia, low complement levels, marked serositis and peripheral nephropathy.

(18A175) ABSTRACT 83 CASE POSTER 75

To stop or not to stop- that is the question

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Introduction
Case Report
Aims/Background
Case Report
Method
Case Report
Results
Clinical Case
RB is a 28 year old woman with seropositive rheumatoid arthritis and childhood toxoplasma chorioretinitis. Originally from Brazil, she has worked as a childminder in Ireland for 10 years.
Diagnosed with rheumatoid arthritis (RA) in 2016, she was initially treated with methotrexate, which had limited benefit and caused neutropenia. This was switched to etanercept and remission achieved.
In February 2018, RB informed us that she was pregnant, which had not been planned.
In March, at seven weeks pregnant, she was reviewed in our multidisciplinary Rheumatology and Obstetric SErvice (ROSE) clinic. Her disease was in remission with 0/28 tender and swollen joints, CRP of 2mmol/L. Obstetrics were happy with her progress and advised adding folic acid. Toxoplasma IgG was positive and HIV test was negative. The Infectious Diseases team were happy with her management.
In a further review at 15 weeks pregnant, RB had 0/28 tender and swollen joints, CRP of 3 mmol/L and was keen to stop biologic therapy due to infection and vaccination risks for her baby. Her etanercept was held.
Two weeks later, she had pain and stiffness in her shoulders and the small joints of her hands which responded to restarting her etanercept. At her July review, she remained in remission.
Conclusions
Discussion
Etanercept was chosen as it was felt to be a relatively safe option from an infection perspective in a patient frequently travelling to Latin America. Recent studies have shown certolizumab to have minimal transfer from mother to baby during pregnancy and breastfeeding. This may have been a better option, raising the issue of switching biologic agents in women contemplating pregnancy.
RA remits in almost 50% of pregnancies. However, this patient flared. Factors negatively associated with poor disease control include presence of autoantibodies (Rheumatoid factor, Anti-CCP). Should this woman's flare have been predicted and etanercept continued?
Toxoplasma reactivation and fetal transmission are concerns in patients on anti-TNF therapy. There are published cases of cerebral toxoplasmosis and toxoplasma chorioretinitis on anti-TNF- agents. Congenital toxoplasmosis can cause hydrocephalus, chorioretinitis and hepatosplenomegaly. How should we manage prospective mothers with previous toxoplasma gondii infection who are on biologic therapy?

(18A181) ABSTRACT 84 CASE POSTER 76

Familial Mediterranean fever (FMF), Intestinal Behçet's or Crohn's disease: Does a confirmatory diagnosis matter?

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Introduction
The presentation of Familial Mediterranean Fever (FMF) and Behçet's disease (BD) can be diverse and provide diagnostic challenges.

Aims/Background
Case study

Method
We present an unusual case of a Syrian immigrant in her mid-20s with multiple admissions to our hospital with unexplained high-grade fever with spontaneous resolution within 3-4days,abdominal pain,arthralgia and recurrent oral aphthosis (oral aphthosis since the age of 12).Her past history include a laparotomy with ileocolic resection back in Syria when she developed peritonitis and perforation.
Persistently significant elevation of c-reactive protein in the range of 100-200.Septic screen, autoimmune profile and echocardiogram were unremarkable.Computed tomography (CT) of thorax,abdomen and pelvis (TAP) demonstrated diffuse colonic thickening suggestive of colitis but subsequent colonoscopy and histopathology were unremarkable.CT angiogram not suggestive of vasculitis.

Results
She was discharged on tapering dose of oral prednisolone and colchicine in view of possible periodic fever syndrome or Behçet's disease.Unfortunately she was lost to follow-up and didn't continue with the treatment,then readmitted post C-section when she developed unexplained high-grade pyrexia.CT TAP on this occasion demonstrated localised jejunitis with associated mesenteric lymphadenopathy.We commenced her on intravenous methyl prednisolone with complete resolution of symptoms.In view of recurrence of oral aphthosis and abdominal pain during her outpatient follow-up and consideration that she is currently breast-feeding,she was commenced on an anti-TNF(Certolizumab-pegol) and remained afebrile 2-weeks post treatment;however consideration will be given for IL-1 inhibitors if she gets symptomatic in future

Conclusions
- Ethnic origin should be taken into consideration in the differential diagnosis to ensure that a less common disorder is not overlooked.
- Genetic testing for MEFV mutations can be a vital component in reaching diagnosis.
- Early initiation of treatment in patients with FMF can prevent further complications of secondary amyloidosis.
- The pathophysiology is different between periodic syndromes such as FMF (autoinflammatory disorder; would be sensitive to IL-1 inhibition) and BD (mostly would respond to anti-TNF inhibition) and may require different treatment strategies. Time will tell if our patient would fully respond to the current treatment or would require a different treatment modality in the future.

Figure

Figure

(18A188) ABSTRACT 85 CASE POSTER 77

A case of Rheumatoid Arthritis complicated with side effects of TNF alpha inhibitor

Author(s)
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Department(s)/Institutions
Rheumatology Department, Our Lady's Hospital Manorhamilton, Co.Leitrim

Introduction
We present a case of 58 year old lady who was initially diagnosed with Rheumatoid Arthritis and went on to develop complications of treatment.

Aims/Background
Case Report

Method
A lady, otherwise in good health, diagnosed with RA in 2006 was started on treatment with Methotrexate and was managed for 4 years with unsatisfactory clinical outcome. Then the management was up-scaled by starting adalimumab (TNFa inhibitor). Her primary disease was well under control with this biological therapy.
During the course, she presented with history of cough, shortness of breath ad weight loss. Her radio-logical findings and sputum examination was consistent with active Milliary Tuberculosis. She was treated with anti-tuberculosis therapy for 18 months and her symptoms improved and so her general health.
Few months after finishing her ATT, She felt left sided neck mass with soft consistency. On further investigations it was diagnosed as cold abscess, suspicious for recurrence of tuberculosis. Although aspirate for tuberculosis culture was negative for active tuberculosis. Her follow-up was continued to watch and see after initial drainage.

Results
Later, the neck swelling recurred and was assumed to be Paradoxical Adverse Effect (PAEs) of Biologic therapy on further workup. She was managed well on high dose steroid and is being further followed up in Rheumatology clinic.

Conclusions
This case report is to highlight the occurrence of adverse effects of Biologic therapy for Rheumatological conditions, which poses significant obstacles to diagnose and manage the untoward outcomes. We recommend further clinical input and research to track disease as well as the concomitant therapy's outcome.

(18A196) ABSTRACT 86 CASE POSTER 78

Cryoglobulinaemic Vasculitis: A Rare Manifestation of Long-standing Rheumatoid Arthritis

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Introduction
Several studies have disclosed a relationship between clinical evidence of vasculitis and the presence of cryoglobulinemia in a Rheumatoid Arthritis (RA) cohort. Cryoglobulinemic vasculitis is characterised by the depositions of cryoglobulins in tissues, which precipitate at low temperatures and redissolve with rewarming. This condition is associated with a variety of disorders including malignancy, infection and autoimmune diseases. The spectrum of manifestations ranges from mild to severe disease with skin being commonly affected.

Aims/Background
case report

Method
case report

Results
56-year old Caucasian, male patient, smoker - with a past history of atrial fibrillation and severe erosive seropositive RA presented with a 2-week history of lower limb pain, intermittent numbness, and progressive dusky discolouration of toes associated with pain and numbness. On examination, he was found to have chronic RA changes of the hands and bilateral rheumatoid nodules at the elbows, active synovitis of the small joints of the hands, wrists and ankles and purple discolouration of toes. Peripheral pulses and capillary refill were normal. The remainder of the examination was unremarkable. His workup was negative for any thromboembolic cause, with normal ECHO and CT peripheral angiogram showing three-vessel runoff to the ankles bilaterally and no significant stenosis or dissection. He was found to have raised raised IgA, IgG, IgM and type III cyroglobulinaemia. This clinical picture of chronic seropositive RA with rheumatoid nodules and polyclonal cryoglobulinemia in a smoker led to the diagnosis of cryoglobulinemic vasculitis. Treatment consisted of high dose steroid, DMARD and rituximab. Clinically he made slow recovery but now is improved.

Conclusions
The mean duration between the diagnosis of RA and the onset of vasculitis is 10-14 years. Prevalence is now decreasing with availability of biological therapy. Treatment of Cryoglobulinemic vasculitis is with glucocorticoids and immunosuppressive therapy. Rituximab was reported to be an effective therapy in patients with mixed cryoglobulinemia syndrome not associated with chronic HCV infection. To the best of our knowledge, there are no randomised trials directly comparing rituximab with cyclophosphamide in these patients. Thus, cyclophosphamide should still be considered a therapeutic option in patients with mixed cryoglobulinemia, especially in life-threatening situations.

(18A198) ABSTRACT 87 CASE POSTER 79

Asymptomatic Cardiac Arrhythmia in Systemic Sclerosis

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Introduction
Systemic sclerosis (SSc) is a chronic autoimmune disease characterised by excessive cutaneous and visceral fibrosis. SSc can present with protean manifestations and result in significant organ dysfunction. Cardiac involvement in SSc can virtually affect any structure and when symptomatic, it predicts a poor prognosis.

Results
A 37 year male, smoker, with a background of hypertension presented with generalised arthralgia. Clinical examination was consistent with sclerodactyly, calcinosis and Raynaud's phenomenon. Immunology workup was positive for antinuclear antibodies and anti-SCL70. Over a six month period, he developed diffuse skin thickening with a modified Rodnan skin score of 21/51. He described intermittent dysphagia, dyspnea, worsening of Raynaud's phenomenon and digital ulceration. Pulmonary function test suggested a restrictive pattern with a reduced DLCO 56%. He was admitted for an intravenous prostacyclin to treat active digital ulcers. During routine observation, he was found to have asymptomatic tachycardia. Electrocardiogram showed atrial flutter at a rate of 150 bpm with an elevated troponin T and pro-BNP. Subsequently, he developed supraventricular tachycardia (SVT) at a rate of 200 bpm, he was normotensive and asymptomatic. Patient failed both pharmacological and electrical cardioversion.
Echocardiogram showed extensive wall akinesia and ejection fraction 40%, suggestive of severe cardiomyopathy. Right and left heart catheterisation showed normal coronary structure and no evidence of pulmonary hypertension. Cardiac gadolinium MRI confirmed myocardial fibrosis, significant bi-ventricular impairment, global myocardial oedema, left ventricular ejection fraction (LVEF) 33% and right ventricular EF (RVEF) 24%. This is suggestive of cardiac scleroderma. He was commenced on anti-arrhythmic and life-long anticoagulation. An implantable cardioverter defibrillator was inserted for primary prevention of ventricular arrhythmia and sudden death. He was pulsed with three grammes of intravenous methylprednisolone followed by tapering oral prednisolone and monthly intravenous cyclophosphamide (0.5g/m2).

Conclusions
The majority of patients with cardiac involvement remain subclinical. To successfully manage cardiac scleroderma, it requires a high index of suspicion and a multidisciplinary approach. To the best of our knowledge, no RCTs have compared efficacy of anti-arrhythmic drugs to treat conduction abnormalities in SSc cohort. Thus, medication selection is tailored to the individual patient.

ISR Spring Meeting 2018

Emmet Doyle, BMS, Dr Sinead Harney, Natasha Ellison, BMS;
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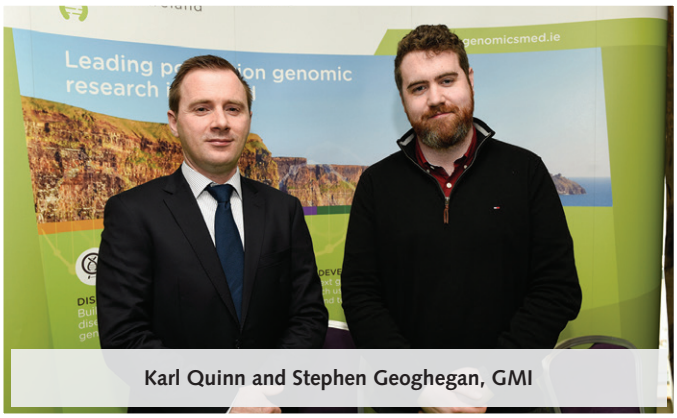

Karl Quinn and Stephen Geoghegan, GMI

Aadil Al Aghfri, SVUH, Ahmed Al Magbail, Manorhamilton, Yousef Alammari, Tallaght

When life is *too busy for RA*

Given a choice, 53% of RA patients would chose a monthly regime[1*]

Simponi 50 mg, 100 mg Solution for Injection in pre-filled pen Simponi 50 mg Solution for Injection in pre-filled syringe (golimumab) **ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active *nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA):* Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSAGE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. *RA*: Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. *PsA:* Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. *AS and nr-Axial SpA*: Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. *UC: Patients weighing < 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. *Patients weighing ≥ 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). *pJIA:* Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). *Missed dose:* If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. *Older patients (≥ 65 years):* no dose adjustment required. *Paediatric patients (<18 years):* For indications other than pJIA, Simponi is not recommended. *Patients with renal and hepatic impairment:* Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. *Hepatitis B (HBV) reactivation:* Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi *Malignancies and lymphoproliferative disorders:* Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6-mercaptopurine (6-MP). The potential risk with the combination of AZA or 6-MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. *Heart Failure:* Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. *Neurological events:* Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. *Surgery:* Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. *Autoimmune processes:* If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. *Haematological reactions:* There

GO further with Simponi

With Simponi, approximately 70% of patients remained on treatment after 5 years.[2] ***Make your 1st choice count.***

have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anaemia, and thrombocytopaenia in patients receiving TNF-blockers. Cytopenias including pancytopaenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. *Vaccinations/therapeutic infectious agents:* It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. *Allergic reactions:* If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. *Special populations: Older patients (≥ 65 years):* Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. *Paediatric patients (<18 years): Vaccinations:* it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. *Excipients:* Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects** *Very Common (≥ 1/10):* upper respiratory tract infection; *Common (≥1/100):* bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma*, leukopenia, thrombocytopaenia, pancytopaenia, aplastic anaemia, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. * Observed with other TNF-blocking agents. *Paediatric population: pJIA:* The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text: February 2017.** *Simponi/PI-IRE/02-17*

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-2998700)

References: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Preference and Adherence, 2014:8; 93-99. **2.** Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. J Rheumatol. 2016;43:298–306.

*Rheumatoid arthritis patients preferring subcutaneous therapies

Date of preparation: May 2017.

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RHEU-1221718-0001

IRHPS Autumn 2018 Update

Welcome to the Annual Scientific Meeting of the Irish Society for Rheumatology and the Irish Rheumatology Health Professional Society.

A very warm welcome to our keynote speakers this year, Dr.Valerie Rogers, Consultant Paediatric Rheumatologist who joins us from the University Hospitals Bristol NHS Foundation Trust and Romayne Orr, Senior Occupational Therapist in the South Eastern Health & Social Care Trust. Romayne is currently leading training in the Bridges approach to practitioners and teams across the UK and will present on using Bridges self-management approach. We also welcome Edel Carberry and Rosalind Peart, Paediatric Rheumatology Physiotherapist and Occupational Therapist from Our Lady's Children's Hospital, Crumlin who will be presenting on an integrated therapy approach to managing chronic pain in paediatric Rheumatology.

Well done to all those who submitted abstracts demonstrating the high quality and varied research that is currently taking place in rheumatology centres and universities throughout Ireland. Please take the opportunity to look at the large number of posters we received this year and remember to vote for the "People's Choice" poster.

I would like to extend my gratitude to the ISR and Michael Dineen. Without their support our annual meeting would not be possible.

Thanks again to the Pharma companies for their continued support, without which valuable educational opportunities would be lost. Full details on this and all our bursaries are available on our website www.irhps.ie.

The IRHPS committee's support and dedication over the past year has been invaluable. My sincere thanks to you all.

Finally, I do hope you enjoy this year's conference and remember this is your society, if you come across a speaker or topic that you would like presented at conference, please let us know on Edofficer@irhps.ie.

Trish Fitzgerald
IRHPS Chair

www.irhps.ie

IRHPS Speakers

Edel Carberry

Edel is a senior paediatric rheumatoloy physiotherapist in OLCHC She works as part of an integrated multi-disciplinary team with children with inflammatory and non-inflammatory rheumatology conditions. She completed her undergraduate physiotherapy training in 2008 at the University of Limerick. In 2013, she achieved an MSc in Advanced physiotherapy in paediatrics at UCL. This year (2018) she completed the Advanced Clinical Practitioner in Arthritis Care (ACPAC) program with the University of Toronto in conjunction with SickKids Hospital. She has worked in both acute adult and paediatric hospital settings and in paediatric primary care. This included University Hospital Limerick, Dublin NW primary care team, Great Ormond Street hospital, London and Al Jalila Children's Hospital, Dubai.

Rosalind Peart

Rosalind is a Senior Occupational Therapist at Our Lady's Children's Hospital, Crumlin. She qualified as an Occupational Therapist in 2006, from Trinity College Dublin and has since then completed a post graduate qualification in Advanced Clinical Practice from the University of Limerick. After working for several years in DATHs hospitals and abroad, she joined the Paediatric Rheumatology team at Our Lady's Children's Hospital, Crumlin in 2011. Rosalind has previously presented at several conferences, such as BSPAR & AOTI, on her clinical work and research. She is a qualified children's yoga teacher, and utilises her expertise in this area to the benefit of her work as a paediatric Occupational Therapist.

Romayne Orr DIP COT

Romayne has worked in Neuro-disability since qualifying as an Occupational Therapist in 1987. She currently works in Brain Injury in the South Eastern Health & Social Care Trust and is the Training and Development Lead for Bridges self-management in Northern Ireland. Bridges self-management works alongside health and social care practitioners supporting them to work in a person centred way – getting to the heart of what matters most to people and helping them to live the best life possible .Bridges is firmly rooted in over 10 years of research and development which has involved listening to people living and caring for those with different conditions and to the health practitioners and teams working with them .Romayne is involved in leading training in the Bridges approach to practitioners and teams across the UK.

Photos from ISR Spring Meeting 2018

Mairead Dockery SVUH and Trish Fitzgerald SVUH

Dr Una Lannin, Dr Rachel Flood and Dr Deniz Demirdal

Professor Georg Schett

ABSTRACT 1

Uptake of influenza vaccination in patients on immunosuppressant agents for rheumatological disease attending nurse-led review appointments.

Author(s):
G Byrne, M Mc Govern, H Reynolds, B McGowan, B Whelan, C Silke, M O'Sullivan.
Department(s)/Institution(s): Northwestern Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim.

Aim/Introduction:
The European League against Rheumatism recommend vaccinations in patients with rheumatic disease during stable disease, ideally prior to initiating disease-modifying anti-rheumatic therapy (DMARDS) (van Assen et al 2011). There is evidence that uptake is sub-optimal (Costello et al 2016).We undertook a study in patients with inflammatory arthritis(IA) attending for nurse-led review to establish (1) vaccination uptake and (2)Sources from where patients had received information regarding vaccination

Method:
Suitable patients were invited to complete a questionnaire enquiring about vaccination status and information sources.

Results:
A total of 118 patients completed the study during November/ December 2017. 67(56%) were female and 48(41%) were > 65 years. 38(37%) were receiving conventional DMARDs and 47(40%) biological DMARDs with 33(28%) on combination therapy. Self-reported uptake of the seasonal influenza vaccine was 49(41.5%). A total of 87 (74%) reported receiving information. The most common source was from primary care teams 56 (64.3%), a further 17(20%) from rheumatology staff with 11(12.6%) from both groups.Of those vaccinated (n49), 47(96%) had received information and 40 (57%) in the non-vaccinated group (n69).Reasons for not being vaccinated included lack of information, fear of adverse effects, perception of good health and contraindications such as current infection or post-operatively.

Conclusion:
Low prevalence of influenza vaccination was observed. More education to highlight the importance of vaccination in patients on DMARD therapy is recommended. We have amended our nursing documentation to include discussion about vaccinations at nursing review appointments. Written information and visual displays will be provided to improve the culture of vaccination practice in the unit.

ABSTRACT 2

"Addressing Employment": A Profile of the Demographics and Work- Related Status of Working-Aged Clients Referred to Rheumatology Occupational Therapy Services in Ireland.

Author(s):
Yvonne Codd1, Melanie Anderson2, Jane Brownlee2, Patricia FitzGerald3, Oriel Glennon4 ,Bindu Irudayaraj4, Lorraine Kernohan5,Sharon McCaffrey6, Aoife McCormack2, Una McKenna5, Brid McOskar7, Helena Magee5, Paula Minchin8, Carol Rafferty8, Lorna Raggett9, Emer Sheridan2, Aoife Synnott2, Nora Verling10.

Department(s)/Institution(s):
Naas General Hospital1, Rheumatic and Musculoskeletal Disease Unit, OLH&CS, Harold's Cross2 St Vincent's University Hospital3, University Hospital Waterford4, Northern Health and Social Care Trusts5,Our Lady's Hospital Manorhamilton6 , Merlin Park University Hospital7, Tallaght University Hospital8, Kilkenny Primary Care9, South Infirmary-Victoria University Hospital10

Aim/Introduction:
Impacts of rheumatic and musculoskeletal diseases (RMDs) on work ability and the role of occupational therapy (OT) to support work retention is recognised. However, variances remain in how rheumatology services address work problems in Ireland. A dearth in OT resources is reported as being central to the problem (Codd et al, 2018). Progressing provision of additional posts is hampered by limited Irish data (Corcoran et al, 2015).

Objectives:
To determine number of working-age clients currently in employment seen in OT; clients' work status and ability; numbers work-disabled due to RMDs, extent of work difficulties; whether work-needs are detected by referrers.

Method:
Rheumatology OTs in Ireland were invited to participate through the AOTI MSD&CP Advisory Group. Retrospective OT chart review of clients referred 1/12/2017-31/5/2018 was completed. Clients aged 18-65, and >65s currently working, were included. Demographics and work data (Global Health Scale, Work Ability Scale, Work Instability Scale, worker role) were recorded on a data collection tool and saved on a spreadsheet unique to each site.

Results:
Ten sites participated and yielded a sample of 531. Age range was 18-65 and >65 (n=9).

Demographics				
Gender	Males (n=136)	Females (n=395)		
Diagnosis	Inflammatory Arthritis (n=268)	Osteoarthritis (n=137)	Regional MSK & FMS (n=121)	Other (n=5)
Length since diagnosis (months)	Range (0-720)	Average 50.33		
Work Status				
Currently Working	Total (n=318)	Full-time (n=202)	Part-time (n=116)	
Currently *not* working but *want to* work	Yes (n=102)			
Number with self-reported work difficulties	Yes (n=350)	(No=181)		
Work Disabled	Yes (n=176)	No (n=326)	Blank (n=29)	
Work Ability				
Work Instability Scores	Range: 0-23	Average 10.64		
	Total (n=318)	Low Risk (score 0-9) (n=143)	Medium Risk (score 10-17) (n=116)	High Risk (score 18-23) (n=59)
Work Ability Scores	Range: 0-10	Average 5.21		
	Total (n=389)			
Global Health Scores	Range: 0-10	Average 5.17		
	Total (n=520)			
Detecting Work Needs				
Number asked about work by referrer	Yes (n=211)			
Work Vulnerable- Number Currently Working:	WIS of 10-23 (n=126)	WAS of 0-5 (n=163)		
	Of which:			
	Full-time (n=81)			
	Part-time (n=45)			

Worker-role data was configured into the International Standard of Occupations Classification (ISCO-08) and analysed to highlight RMDs work instability within the classification and direct potential targeted work interventions.

Conclusion:

Findings recognise discrepancies in numbers of those with self-report work difficulties and those seeking return-to-work, compared with those referred to OT for work-support. Results emphasize work needs of clients attending OT rheumatology services and highlight unmet needs of those without access to OT.

References:

Codd, Y., Stapleton, T., Kane, D., & Mullan, R. (2018) A survey to establish current practice in addressing work participation with inflammatory arthritis in the Irish clinical setting. *Musculoskeletal Care,* 16 158-162. https://doi.org./10.1002./msc.1198.

Corcoran O, Fitzgerald T, Codd Y, Somerville S, Brownlee J, Verling N, McCausland K, Meehan L, Flattery V, Duggan E. *The landscape of rheumatology occupational therapy in vocational rehabilitation in Ireland.* Poster presented at the Irish Society for Rheumatology / Irish Rheumatology Health Professional Society Autumn Conference. 2015, Naas, Ireland.

ABSTRACT 3

Physical activity and aerobic capacity assessment - a survey among rheumatology health professionals in four European countries.

Author(s):

N. Kennedy[1,2], S. G. McKenna[1], A, O'Neill,[3] B. A. Esbensen[4,5], T. Swinnen[6,7], B, Nordgren[8], S. Willemijns[6], N. M. Hammer[4], N. Brodin[8,9]

Department(s)/Institution(s):

1Discipline of Physiotherapy, School of Allied Health, University of Limerick, Limerick, Ireland

2Health Research Institute, University of Limerick, Limerick, Ireland

3 Department of Mathematics and Statistics, University of Limerick, Ireland

4Copenhagen Center for Arthritis Research, Center for Rheumatology and Spine Diseases, Centre of Head and Orthopaedics, Rigshospitalet, Glostrup, Denmark

5Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark

6Skeletal Biology and Engineering Research Center, Department of Development and Regeneration, KU Leuven, Leuven, Belgium

7Division of Rheumatology, UZ Leuven, Leuven, Belgium

8Division of Physiotherapy, Karolinska Institutet, Department of Neurobiology, Care Sciences and Society, Huddinge, Stockholm, Sweden

9Division of Physiotherapy, Orthopaedic clinic, Danderyd University Hospital, Stockholm, Sweden,

Aim/Introduction:

Current practice in the management of patients with inflammatory arthritis (IA) emphasises the importance of health professionals (HP's) in promoting physical activity (PA). The aim of this four country study was to determine PA measurement practices and knowledge gaps among HPs.

Method:

Rheumatology HPs in Denmark, Sweden, Ireland and Belgium participated in an online survey. Descriptive statistics and latent class analysis (LCA) was undertaken (SPSS v21and SASv9.4) to describe data aggregates and range and to identify sub-classes of groups with respect to use of PA measures.

Results:

Three hundred and twenty two (n = 322, 75% female) HPs responded from Denmark (n = 50, 15.5%), Sweden (n = 66, 20.5%), Ireland (n = 28, 8.7%), and Belgium (n = 178, 55.3%) with the majority (n = 286, 92%) reporting it was important to measure PA in people with IA. Moderate levels of confidence were reported for simple body-worn sensors (mean 6.15/10; SD 3.63) and paper questionnaires (6.85/10; SD 3.62), with lower levels of confidence for complex body-worn sensors (3.80/10; SD 3.55) and digital diaries (4.22/10; SD 3.67). LCA generated three classes with different membership for use of measures of PA.

Conclusion:

The majority of respondents reported that they considered measuring PA as important in people with IJDs; however, the majority lacked confidence in how to measure it. There is strong interest in further education around measuring PA. Three distinct respondent classes were identified to inform targeted education on how to measure PA.

ABSTRACT 4

"Smarter Working": Refining a Multisite Interdisciplinary Integrated Care Pathway for Conservative Management of Carpometacarpal Joint Osteoarthritis

Author(s):

Codd Y[1], Gheta D[1,2], Harty O[1], Kane D[1,2], McGrath M[2], Minchin P[1,2], Mullan R[1,2], O'Driscoll S[2], Burke R[1].

Department(s)/Institution(s):

Rheumatology Departments, Naas General Hospital1 and Tallaght Hospital2

Aim:

To develop an integrated care pathway (ICP) for patients with carpometacarpal (CMC) joint OA that delivers inter-disciplinary, evidence-based, person-centred care in an efficient, collaborative way.

Method:

- Following collaborative planning meetings, an OA CMC clinic was established with protected occupational therapy (OT) and physiotherapy time slots.
- Patients referred with multiple musculoskeletal problems were seen separately for their thumb at the OA CMC clinic.
- A common assessment template was employed. A patient information leaflet was developed and this, plus outcome measures, were posted out with the initial appointment letter.
- A data-collection tool was developed and saved on a shared access drive unique to each site.
- Resources including initial assessment form, appointment letter, patient information leaflet, data-collection tool, exercise programme template, and joint protection group format, were shared across sites.
- A pathway feature was a joint protection group co-facilitated by OTs.
- This initiative was exempt from ethics according to organizational research ethics committee policy.

Results:

- A cross-site review of the ICP was completed at quarterly intervals for one year.
- Establishment of designated clinic slots had a positive impact on waiting times for this cohort.
- The average overall improvement in function was statistically significant1.
- Communication channels were improved between disciplines across the two sites with streamlined administrative and clinical practices, facilitating a smooth flow of referral management

within the service, with clear expectations and roles for all team members.
- Anecdotal evidence suggested patient satisfaction with the ICP.

Conclusion:
This ICP facilitates efficient, quality interdisciplinary, conservative management of CMC joint OA.

References:
1. O'Driscoll S, Minchin P, McGrath M, Burke R, Codd Y, Harty O, Kane D, Mullan R, Gheta D. "Smarter Working": Patient outcomes from a Multisite Integrated Care Pathway for Conservative Management of Carpometacarpal Joint Osteoarthritis". Abstract submitted to ISCP and IRHPS conferences 2018: awaiting acceptance.

Acknowledgement:
Eimear Flood, Occupational Therapist, Naas General Hospital

ABSTRACT 5

A Profile of the Impact of Arthritis on Sexual Activity and Relationships in Service Users Attending a Rheumatology Service

Author(s):
Yvonne Codd, David Kane, Ronan Mullan, Stephanie Naramore
Department(s)/Institution(s):
Rheumatology Department, Naas General Hospital

Aim/Introduction:
Arthritis is recognised as having potential to disrupt participation and engagement. Limited research on impacts of arthritis on sexual activity and relationships exists, and no Irish research was identified. This scoping study aimed to explore patients' perceptions of effects of arthritis on their sexual relationship and sexual activity; to establish causes of any difficulties; to identify perceived persons of support with these difficulties.

Method:
A self-report questionnaire was distributed to a random sample comprising return patients attending a rheumatology clinic over a consecutive four-week period (May-June 2018). Eighty patients received an invitation to participate, self-report questionnaire and stamped-addressed envelope.

Results:
Fourteen questionnaires were returned (response rate 17.5%). Four males and ten females with an age range 34-80 years. Conditions included inflammatory arthritis (n=10), musculoskeletal conditions (n=4).

28.5% (n=4) perceived that arthritis put a strain on their relationship. 50% (n=7) reported arthritis altered their sexual relationship with qualitative data highlighting fatigue and reduced libido as contributing factors. 50% (n=7) reported arthritis limited sexual intercourse due to mobility, pain and disinterest.

78.5% (n-11) rated their sexual ability as important or very important. Many respondents did not discuss impacts of arthritis on sexual relationships with their partner and perceived lack of partner's understanding was reported.

Respondents were not asked about impacts of arthritis on sexual relationships by health professionals although 78.5% (n=11) would consider talking to someone about problems. Information leaflets (50%) and one-to-one appointments (57%) were identified as helpful supports.

Conclusion:
Findings highlight this is a significant sensitive issue currently not addressed by rheumatology services.

ABSTRACT 6

Advancing nurse education in chronic rheumatic diseases (RMD): Connolly Hospital and the Irish Rheumatology Nurses Forum (IRNF) introductory and advanced education programme.

Author(s):
Madeline O'Neilla, , Clara Bannona,b,1, Trevor Duffy b,
Department(s)/Institution(s): Irish Rheumatology Nurses Foruma, and Connolly Hospital, Blanchardstown, Dublinb.

Aim:
1) To address the educational needs of nurses in the provision of healthcare to patients with chronic rheumatic diseases,
2) To enhance the rheumatology nursing career pathway in Ireland.

Method:
Educational and financial support was sought from rheumatology medical and nursing specialists, physiotherapists, occupational therapists and the pharmaceutical industry, respectively. The programme is promoted through the IRNF, Irish Practice Nurses Association and coordinators for 5 homecare teams nationally. The governance team coordinates the structure, content and delivery of the programme. Programme content includes the pathophysiology of rheumatic disease and skills for clinical practice to improve the care delivered to patients

Results:
- Since 2012 weekend study days have been undertaken by 367 participants, representing 230 individual nurses.
- The total number of rheumatology nurse participants = 181, representing 76 individual nurses.
- Since 2015 the number of practice nurse participants = 74, representing 63 individual nurses and the number of homecare team nurse participants = 112, representing 76 individual nurses.
- Nine (9) nurses progressed to undertake post-graduate nursing studies (diploma n = 8; MSc = 1) related to rheumatology practice at University College Dublin.
- Outputs related to participant numbers and anecdotal evidence of interest in a clinical career pathway supported projections of potential manpower capacity for the IRNF business case endorsed by the national clinical programme for rheumatology in 2014.

Conclusion:
The programme was designed for registered nurses to raise awareness of the needs of patients with chronic rheumatic diseases and serve as a stepping stone to higher post-graduate education.

ABSTRACT 7

"Smarter Working": Patient Outcomes from a Multisite Integrated Care Pathway for Conservative Management of Carpometacarpal Joint Osteoarthritis

Author(s):
O'Driscoll S1 McGrath M1, Minchin P1, C. Rafferty1, Mullan R1,2, Burke R2 Codd Y2, Gheta D1,2, Harty O2 Kane D1,2.
Department(s)/Institution(s):
Rheumatology Departments, Tallaght University Hospital1 and Naas General Hospital2

Aim:
- To evaluate patient outcomes on an Integrated Care Pathway (ICP) for Carpometacarpal (CMC) joint Osteoarthritis (OA).
- To determine if waiting times impacted on outcomes.

Method:
- Patients treated on the ICP for CMC joint OA within a 12 month

period (1st April 2017 to 31st March 2018) were included
- The Disability of Arm, Shoulder & Hand (DASH) self-report questionnaire was employed as an outcome measure
- A feature of the pathway was attendance at a two hour Hand OA/joint protection group

Results:
Sixty-three patients were eligible for the pathway and 25 patients completed it. Of the 25 patients who completed the pathway n=23 (92%) were female and n=2 (8%) were male. Average age was 61.72 (range 32-79). Fifteen (60%) waited < 3 months for initial appointment, and n= 10 (40%) waited > 3 months.
DASH scores improved for 72% of patients (n=18), with 10 (56%) of those achieving a minimal clinically important difference (MCID-10.83 points). Of those who waited >3 months, 73% (n=11) had improved, with 55% (n=6) displaying an MCID. Of those who had waited < 3 months, 70% (n=7) had improved, with 57% (n=4) achieving an MCID.
Twenty-three (92%) patients were discharged, while n=2 (8%) were referred for CMC joint injection.

Conclusion:
This ICP provided an efficient template for the management of CMC OA with favorable outcomes in line with MCID. The pathway results were comparable between those groups seen within and outside of the three month target.

References:
The DASH, disability of the arm shoulder hand Outcome Measure website. http://dash.iwh.on.ca/faq (retrieved on 24th April 2018)
Minchin P, Rafferty C, O'Driscoll S, McGrath M. (2017) Revision of an Occupational Therapy and Physiotherapy combined care pathway for the conservative management of OA of the first CMC joint; a quality improvement project. Poster presented at: Irish Society for Rheumatology & IRHPS Autumn Meeting; Sept 21-22; Galway
O'Driscoll S, Sommerville S, Kane D, Mullan R. (2016) An Evaluation of a New Management Pathway for Carpometacarpal Osteoarthritis (CMC OA) in Tallaght Hospital – A Pilot Study. Poster presented at IRHPS conference; Sept 15-16; Naas, and ISCP conference; Oct 14, 15; Wexford.

ABSTRACT 8

Early Inflammatory Arthritis Clinic – The Role and frequency of Physiotherapy Intervention.

Author(s):
Nicole O' Keeffe, Catherine Cullinane
Department(s)/Institution(s): Physiotherapy Department, University Hospital Waterford.

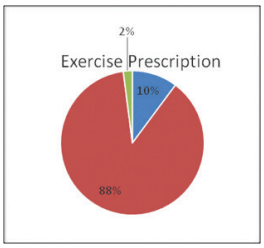
Aim/Introduction:
Early Inflammatory Arthritis Clinics (EIAC) facilitate meeting the NICE guidelines on the care of adults with Rheumatoid Arthritis (RA) through a 'one-stop-shop' approach. Such a pathway was set up in University Hospital Waterford in 2011. Most articles looking at EIAC report results of pharmacological interventions, with multidisciplinary interventions being underrepresented. This audit was undertaken to ascertain the components of Physiotherapy management within such a clinic and the number of treatments each patient received during the first-year post diagnosis.

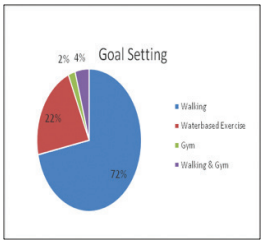
Method:
A retrospective chart audit was undertaken from December 2016-May 2017 yielding 56 charts. Male (N=12); Female (N=44) Diagnosis RA=35; IA=9; PsA=12.

Results:
Patients received on average 3 sessions of Physiotherapy, ranging from 1 to 12. Physical disability (MD HAQ and AIMS-2) measured at initial contact shows a trend that patients with moderate physical impairment required above average treatments, (Table 1).The frequency was determined by joint goal setting with each individual patient, depending on their individual needs (NICE 2009).The range of Physiotherapy Interventions included education, exercise prescription, biomechanical assessment, health promotion advice and goal setting around physical activity.

Table 1

Number of Rxs	MDHAQ Physical Function	AIMS-2 Physical
Average 3 >	1.24	3.75
Average 0-2	0.75	2.68





Conclusion:
Physical disability scores may help in predicting the intensity of physiotherapy follow up. Future areas of interest are to look at psychological scores at entry to the pathway. Investigating if higher anxiety, depression and catastrophising are predictors to a less favourable outcome. EIAC pathway could be streamlined by distinguishing between those patients who could be supported to self-manage and those who need more physiotherapy treatment. This will ensure in getting more intensive treatments to the right patients earlier in their pathway and improving 12-month patient outcomes.

References:
Diane Home and Maggie Carr *'Rheumatoid Arthritis : the role of early intervention and self-management.'* British Journal of Community Nursing, October 2009
SL Hider, AJ Silman, W Thomson, M Lunt, DPM Symmons *'Can clinical factors at presentation be used to predict outcome of treatment with methotrexate in patients with early inflammatory polyarthritis?'* Ann Rheum Dis, February 2008
McKenna S, Kelly G, Kennedy N *'A Survey of physiotherapists' current management and the promotion of physical activity, in people with Rheumatoid Arthritis.'* Disabil Rehabil, 2018.

ABSTRACT 9

Aligning our service to best practice: Analysis of Occupational Therapy interventions in an Inflammatory Arthritis Clinic

Author(s):
Glennon O[1], Irudayaraj B[1]
Department(s)/Institution(s):
Rheumatology Department, University Hospital Waterford1

Background/Introduction:
There is a strong evidence base acknowledging that a patient centred approach in the management of Inflammatory Arthritis (IA) is the gold standard of care. The Inflammatory Arthritis Clinic (IAC) model promotes a patient centred care pathway through integrated multidisciplinary teamwork. This pathway of care includes both pharmacological and non pharmacological therapies. There are

currently 4 sites in Ireland that utilise the IAC model. The IAC model was developed in University Hospital Waterford (UHW) in 2012 and provides multidisciplinary support to patients in the first year of their diagnosis. The service offers access to the rheumatology team including nursing, Occupational Therapy (OT), physiotherapy and psychotherapy.

The aim of this audit is to analyse OT interventions provided for patients newly diagnosed with IA.

Method:

A retrospective chart audit of patients attending the IAC clinic over a 6 month period was carried out in May 2017.

Results:

56 charts were included in the audit. Patients received an average of 4.27 sessions of OT (Table 1).

Table 1

Demographics	N= 56	
Gender	Males (N=12) females (N = 44)	
Diagnosis	Ra: 35, IA: 9, PsA: 12	
Relationship status	Married: 35, Single: 10, Widowed: 2,	
Age range	51 range (21 – 83)	
Employment status:	Employed: 19, Selfemployed: 1, U/E: 6, housewife: 15, education/training: 4, retired: 5, redundancy: 1, benefit: 5	
Details in table 1 below		
No of OT interventions	Average 4.27sessions (range 1 – 13)	
Types of OT interventions	**Yes %**	**No%**
Vocational Rehabilitation (VR)	62%	38%
JP Individual	82%	18%
Activity management/pacing	89%	11%
COT referral	2%	98%
Fatigue management	71%	29%
Hand exercises	80%	20%
Gloves	70%	30%
Oedema Management	77%	23%
Sleep hygiene	75%	25%
posture	20%	80%
Aids & adaptations	75%	25%
Relaxation techniques	16%	84%
Splinting prefabricated	37.50%	62.50%
Splinting fabricated	33.90%	66.10%

Conclusion:

Interventions focusing on education and self management of IA by the patient improve adherence and effectiveness of early treatment. These results support the importance and need for IAC pts to have access to OT from early diagnosis. IAC patients receive a comprehensive package of OT on this pathway.

Self management/health promotion strategies are increasingly provided with gloves, while splinting, provision of aids and devices, as well as COT referrals are needed less. This study identified the need to return to providing JP and working with arthritis groups on a more regular basis as no groups were run during that period due to waiting list demand.

References:

Codd Y, Burke R, Naramore S, Kane D, Mullan R. Review of a new service: *A profile of service users attending an allied health professional clinic on an inflammatory pathway.* Poster presented at the Irish Society for Rheumatology / Irish Rheumatology Health Professional Society Autumn Conference. 2015, Naas, Ireland.

Corcoran O, Fitzgerald T, Codd Y, Somerville S, Brownlee J, Verling N, McCausland K, Meehan L, Flattery V, Duggan E. *The landscape of rheumatology occupational therapy in vocational rehabilitation in Ireland.* Poster presented at the Irish Society for Rheumatology / Irish Rheumatology Health Professional Society Autumn Conference. 2015, Naas, Ireland

ABSTRACT 10

Plantar Fasciitis treated with loading, advice and radial extracorporeal shockwave therapy

Author(s):

Paul Kirwan[1,2], Trevor Duffy[3], Helen French[2], David Green[1]

Department(s)/Institution(s):

1. Physiotherapy Department, Connolly Hospital, Dublin 15
2. School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin 2
3. Rheumatology Department, Connolly Hospital, Dublin 15

Aim/Introduction:

Plantar fasciitis (PF) is the most commonly reported cause of plantar heel pain. It is characterized by pain of the calcaneal origin of the plantar fascia and altered function. Results from a recent randomised controlled trial demonstrated favourable outcomes from a loading program in the treatment of this condition. Extracorporeal Shockwave Therapy (ESWT) has been shown to benefit those who suffer from PF. The purpose of this study was to review the outcomes of patients with PF to a standardised treatment program of advice, loading exercises and ESWT.

Method:

Plantar fasciitis (PF) is the most commonly reported cause of plantar heel pain. It is characterized by pain of the calcaneal origin of the plantar fascia and altered function. Results from a recent randomised controlled trial demonstrated favourable outcomes from a loading program in the treatment of this condition. Extracorporeal Shockwave Therapy (ESWT) has been shown to benefit those who suffer from PF. The purpose of this study was to review the outcomes of patients with PF to a standardised treatment program of advice, loading exercises and ESWT.

Results:

The treatment program was completed by 20 patients. All patients received ESWT and completed the exercise program. The mean FFI score at baseline was 57%. The mean FFI score was 37% at 4 weeks, 30% at 8 weeks and 20% at 12 weeks.

Conclusion:

The aforementioned program of exercise, advice and ESWT has been shown to bring about improvements in the management of PF. The results suggest a structured program of exercise and advice, alongside ESWT is an appropriate treatment option for those suffering from PF.

ABSTRACT 11

Title of paper: An Irish study exploring the optimal nursing and midwifery healthcare requirements of women with a rheumatic disease during the post-partum period

Author(s):

Louise Moore[1], Caroline Brophy[2], Celine O'Brien[2], Madeline O'Neill[1], Grainne O'Leary[3], Kieran Murray[4], Fionnuala McAuliffe[2], Douglas Veale[1,4] and Patricia Minnock[1]

Department(s)/Institution(s):

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2 UCD Perinatal Research Centre, Obstetrics and Gynaecology, School of Medicine, University College Dublin, National Maternity Hospital, Dublin, Ireland
3Arthritis Ireland, 1 Clanwilliam Square, Grand Canal Quay, Dublin, Ireland
4 Rheumatology Department, University College Dublin and St. Vincent's University Hospital, Dublin, Ireland

Introduction: Evidence based multidisciplinary and interdisciplinary approach to care for women with rheumatic disease during each phase of reproduction has been established within a national academic centre in Ireland. During this critical period, care is provided in a more ad hoc manner to the detriment of the systematic approach to care enjoyed by women ante-natally and during pregnancy. Local study has identified that only 28% of mothers with rheumatic disease attempt breastfeeding which is far lower than the already poor figure of 55% of the general Irish population. Moreover, other aspects of care need to be considered including post-partum flare management, maintenance of good physical health, supporting good mental health, as well as care of the new born. Rheumatology and public health nurses and midwives wish to explore how best to provide collaborative healthcare in order to improve support and wellbeing of women during this key health care period.

Method:

Focus group interviews are planned with key stakeholders simultaneously whose attitudes and understanding will be sought. Stakeholders include i) patients who have experienced current rheumatology post-partum care, ii) advanced nurse practitioners (rheumatology), iii) advanced midwife practitioners/experienced midwives, iv) public health nurses, v) patient organisation (Arthritis Ireland). Key topics to be explored include: -

- Perspectives of mothers caring for a new born while living with a rheumatic disease
- Supports required to promote breastfeeding among this population group
- Avoidance and or management of post-partum flare
- Preferred access mode to clinical staff i.e. actual; face to face; telehealth access
- Environment preference e.g. acute hospital setting (rheumatology or obstetric services), community setting, primary care setting
- Supports required from rheumatology patient organisation

Results:

Preliminary discussions have begun with key stakeholders and keen interest has been expressed in working collaboratively on this important life phase for women with rheumatic disease. A focus group is planned for autumn 2018.

Conclusion:

Findings will form the basis for the development of a collaborative nurse and midwife post-partum service to enhance care, and support women with rheumatic disease in the post-partum period. Results will be disseminated among rheumatology, obstetric and primary care clinicians in order to enhance healthcare provision to mothers living with a rheumatic disease.

ABSTRACT 12

An Audit of Physical Activity Guideline Compliance amongst People with a New Diagnosis of Inflammatory Arthritis

Author(s):
Burke R.[1,2], Murray R[1], Kane D.[2], Mullan R.[2]
Department(s)/Institution(s):
Physiotherapy Department, Naas General Hospital, Rheumatology Department, Naas General Hospital

Aim:

To establish compliance of WHO Physical Activity (PA) Guidelines amongst people with a new diagnosis of Inflammatory Arthritis (IA) who are referred to Physiotherapy.

Introduction:

- The WHO guidelines currently state that all people between the ages of 18-64 should achieve 150 minutes of aerobic exercise and 2 days of resistance training weekly. Patients aged over 65 years are recommended to exercise to this level once they are physically able to manage[1].
- There is strong evidence supporting the benefits of PA on improvements on disease course in IA2, as well as activity limitations and participation. Promoting PA consistent with general PA recommendations should be an integral part of standard care throughout the course of disease in people with Rheumatoid Arthritis (RA) and Spondyloarthritis (SpA) 3.

Methods:

- A retrospective electronic chart audit was carried out on all patients with a new diagnosis of IA referred to physiotherapy from January to June 2018. An excel spreadsheet was used to audit compliance with the guidelines for aerobic exercise, resistance exercise and combined aerobic & resistance exercise.

Results:

- Twenty two patients (17 female, 5 male), with a mean age of 49 (range: 22-75) years were audited.
- Diagnoses comprised RA (n=11, 50%), SpA (n=8, 36%) and IA (n=3, 14%).
- See Table 1 for results.

Conclusion:

Patients with a new diagnosis of IA are mostly non-compliant with WHO PA guidelines at initial physiotherapy assessment. A re-audit of this patient cohort will be undertaken to assess changes in compliance following a course of MDT input.

References:

1. WHO. 2010. Global recommendations on physical activity for health. World Health Organization. Geneva, Switzerland.
2. Sveaas, S., Smedslund, G., Hagen, K. and Dagfinrud, H. (2017). Effect of cardiorespiratory and strength exercises on disease activity in patients with inflammatory rheumatic diseases: a systematic review and meta-analysis. British Journal of Sports Medicine, 51 (14), pp. 1065-1072.
3. Rausch Osthoff, A-K., Niedermann, K., Braun, J., Adams, J. (2018). 2018 EULAR recommendations for physical activity in people with inflammatory arthritis and osteoarthritis, Ann Rheum Dis, Epub ahead of print: viewed 23 July 2018. doi:10.1136/ annrheumdis-2018-213585

Table 1

	Aerobic Exercise	Resistance Exercise	Combined Aerobic and Resistance Exercise
Compliant with Guidelines	23% (n=5)	14% (n=3)	5% (n=1)
Non-compliant with Guidelines	77% (n=17)	86% (n=19)	95% (n= 21)

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SAIE.SARI.18.07.0204 Date of preparation: August 2018

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Empowering Life

ABSTRACT 13

Social Work in Rheumatology: What are the referrals telling us?

Author(s):
Gillian Casey
Department(s)/Institution(s):
Social Work Department, Our Lady's Hospice & Care Services

Aim/Introduction:
The Medical Social Worker (MSW) in Rheumatic & Musculoskeletal Disease Unit (RMDU) noticed an increasing number of referrals from MDT members where mental health issues were identified. The aim of this study was to explore if this impression was in fact true. If so, how this information could be used to influence future practice in the area of Social Work in Rheumatology.

Method:
With a focus on quantitative data collection and analysis, the pre-existing Social Work Referral Form was used to gather referral information over a 6 month period in 2016. This information was then reviewed to establish overall numbers of patients referred & patterns and trends in the nature of the issues identified as requiring social work input. As well as mental health issues identified on referral, those which emerged during the MSW psychosocial assessment were included in the results.

Results:
The results show that a significant proportion of the referrals to the MSW in the RMDU relate to mental health issues (usually referred to by the MDT as stress, low mood and anxiety), identifying the impact of living with chronic illness on mental health. It was also noted that a percentage of the people who these referrals related to reported having experienced abuse in the past.

Conclusion:
The findings suggest that further exploration examining the psychosocial needs of this client group and the links between trauma and rheumatological conditions would be beneficial.

ABSTRACT 14

Correlates of Sleep in Adults with Rheumatoid Arthritis: A Systematic Review

Author(s):
Dr. Norelee Kennedy, Sinead Gaffney , Sean Hanley
Department(s)/Institution(s): Allied School of Health, University of Limerick

Aim/Introduction:
Over 50% of those with a diagnosis of Rheumatoid Arthritis (RA) experience poor sleep quality. This may result in altered health-related quality of life, in addition to decreased daytime function. The aim of this systematic review is to identify and compile an account of the correlates of poor sleep in those with RA

Method:
Two reviewers carried out literature searches of nine electronic databases. Literature was chosen based on the application of eligibility criteria and quality assessment in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The correlating factors were extracted and categorised thereafter.

Results:
Fifteen studies were included in the review – fourteen of cross-sectional design, and one randomised controlled trial (RCT). This included 3,283 participants with a diagnosis of RA in accordance with the American College of Rheumatology criteria. The outcome measures included in the literature were largely heterogeneous in nature and therefore a meta-analysis was deemed to be unsuitable.

Conclusion:
There was evidence within the literature to suggest interactions between pain, fatigue, depression and functional ability contribute to sleep quality in those with RA. Interventions to target these may result in improvements in sleep as well as other RA-related symptoms. Longitudinal data is required in order to determine the directionality of these relationships. There was conflicting evidence with regard to the association between sleep quality and medications and patient demographics.

ABSTRACT 15

Screening for osteoporosis and risk factors in Inflammatory Arthritis.

Author(s):
Noreen Harrington, Bernie McGowan, Carmel Silke, Bryan Whelan
Department(s)/Institution(s): Northwestern Rheumatology Unit (NWRU), Our Lady's Hospital, Manorhamilton, Co Leitrim.

Introduction:
Nurses have a key role in the screening and detection of co morbidities and osteoporosis is one of six co morbidities to be targeted under a EULAR initiative in 2016 which aimed to improve a) reporting of co-morbidities, b) Screening for the disease (to include smoking, BMI , bone mineral density) and c) prevention . (1)

Aim
1. To evaluate the prevalence of osteoporosis among patients with early inflammatory arthritis.
2. Identify prevalence of risk factors for osteoporosis
3. Identify benefit of routine screening for osteoporosis as a preventative strategy.

Method:
All data pertaining to patients with Early Inflammatory Arthritis (EIA) delegated to advanced nurse practitioner care at the NWRU between September 2014-July2018 are routinely recorded on an SPSS database and updated during each clinic visit (N=275). Demographics collected include: age, gender, body mass index (BMI) and smoking status. All patients have a DEXA scan and are screened for vitamin D deficiency. Statistical analyses was performed using (SPSS), version 24.0

Results:
Data on 275 patients (60% female) were analysed, Mean age was 54 (sd15). 144 (53%) patients were Sero positive RA, 65(23%) were Sero- negative RA and 66(24%) had undifferentiated or psoriatic arthritis. In total 250 patients had a DEXA scan, 138 (55%) had normal BMD, 79(32%) were osteopenic and 33 (13%) were osteoporotic. Over 60% were deficient in vitamin D.
Of the 252 pt who had a BMI calculated , 2(1%) were underweight, 95(38%) were overweight and 73(29%) were obese. At baseline assessment 57% of patient were not exercising and 27% of patients were current smokers

Conclusion:
There is a high prevalence of osteoporosis, suboptimal bone density and risk factors for osteoporosis detected in this cohort of early inflammatory arthritis patients. Advanced nurse practitioners can play a key role in screening and prevention of osteoporosis with the advanced scope of their role.

References
1) https://www.researchgate.net/publication/298726646 Points_to_consider_for_reporting_screening_for_and_preventing_selected_comorbidities_in_chronic_inflammatory_rheumatic_diseases_in_daily_practice_A_EULAR_initiative [accessed Jul 27 2018].

ABSTRACT 16

'Occupational stress and its impact on nurses' ability to care for patients with chronic illness: a review of the literature'

Authors
Alexia Kelly, Nimmi Abraham. Bini Jolly John, Norma Ferris
Institution
Department of Rheumatology, St. Vincent's University Hospital

Introduction
Our ability to provide optimal care for our patients may be impacted by our stress levels.(1) It is important that where it exists, we can recognise, acknowledge and address this impact. Addressing the impact of occupational stress on nursing care may improve not only patient outcome, but also, job satisfaction for nurses.

Aim
To examine the impact that occupational stress may have on our ability to care for patients with a chronic illness. By reviewing and reflecting on the literature and identifying occupational stress as a factor in sub-optimal nursing care, the author hopes to highlight the need for acknowledgment of the impact of occupational stress, thereby encouraging discussion on management and coping strategies and ultimately improving patient outcome and job satisfaction.

Method
A literature review was conducted to explore the thesis that occupational stress may impact negatively on nursing care in chronic illness.

Results
The review identified occupational stress as a negative influence on nurse's ability to care for patients with chronic illness. (1, 2)

Conclusions
The recognition of occupational stress is crucial in promoting job satisfaction, avoiding burnout and ensuring positive impactful nursing care for patients with chronic illness. Support structures for nurses suffering occupational stress should be identified and where none exist in the workplace, efforts should be made to establish such support.

References
Sarafis, P; Rousaki, E; Tsounis, A; Malliarou, M; Lahana, L; Bamidis, P; Niakas, D and Papastavrou, E (2016). The impact of occupational stress on nurses'caring behaviors and their health related quality of life. BMC nursing. 15 (56)
Geuens, N; Braspenning, M; Van Bogaert, P and Franck E (2015). Individual vulnerability to burnout in nurses: The role of Type D personality within different nursing specialty areas. Science direct 2(2) pg: 80 - 86

ABSTRACT 17

A rheumatology email service: an audit of its effectiveness as an alternative means of communication with our nursing service.

Authors
Norma Ferris, Nimmi Abraham, Bini Jolly John, Alexia Kelly
Institution
Department of Rheumatology, St. Vincent's University Hospital

Introduction
Our rheumatology email service allows our patients an alternative route of contact with our rheumatology nursing service. The email service has grown significantly in recent months and many of our patients use the service as an alternative point of contact to our telephone helpline. The provision of both our telephone helpline and email service is regarded by most of our patients as a welcome extension of specialist rheumatology outpatient service. The unpredictable nature of chronic diseases often results in a requirement to access our service outside of scheduled outpatient appointments. Our email service is utilised not only by patients, but their families, GP's, practice and public health nurses and other involved health professionals.

Aim
To audit our rheumatology email service as distinct from our telephone help line. In order to improve our service and care for our patients optimally, audit of this service and identification of areas of greatest need requiring development and enhancement is crucial.

Method
We reviewed our emails over a 6 month time period and divided them into specific categories including, request for repeat prescriptions, flare management, medication side effects and request for earlier/ change appointments.
We reviewed the demographics of those patients who used our email service in preference to our phone line and measured our response times.

Results
Our audit confirmed that our younger patient cohort use our email service in preference to our telephone service. The majority of our email queries were related to medication management, however, as with our telephone service, requests for repeat prescriptions continue to be a dominant feature of all contacts to the rheumatology nursing service.

Conclusions
Email is a valuable addition to our nursing service. The service will continue to be audited with the addition of a patient satisfaction survey to be conducted in the next 3 months looking at all current routes of communication with the rheumatology nursing service.

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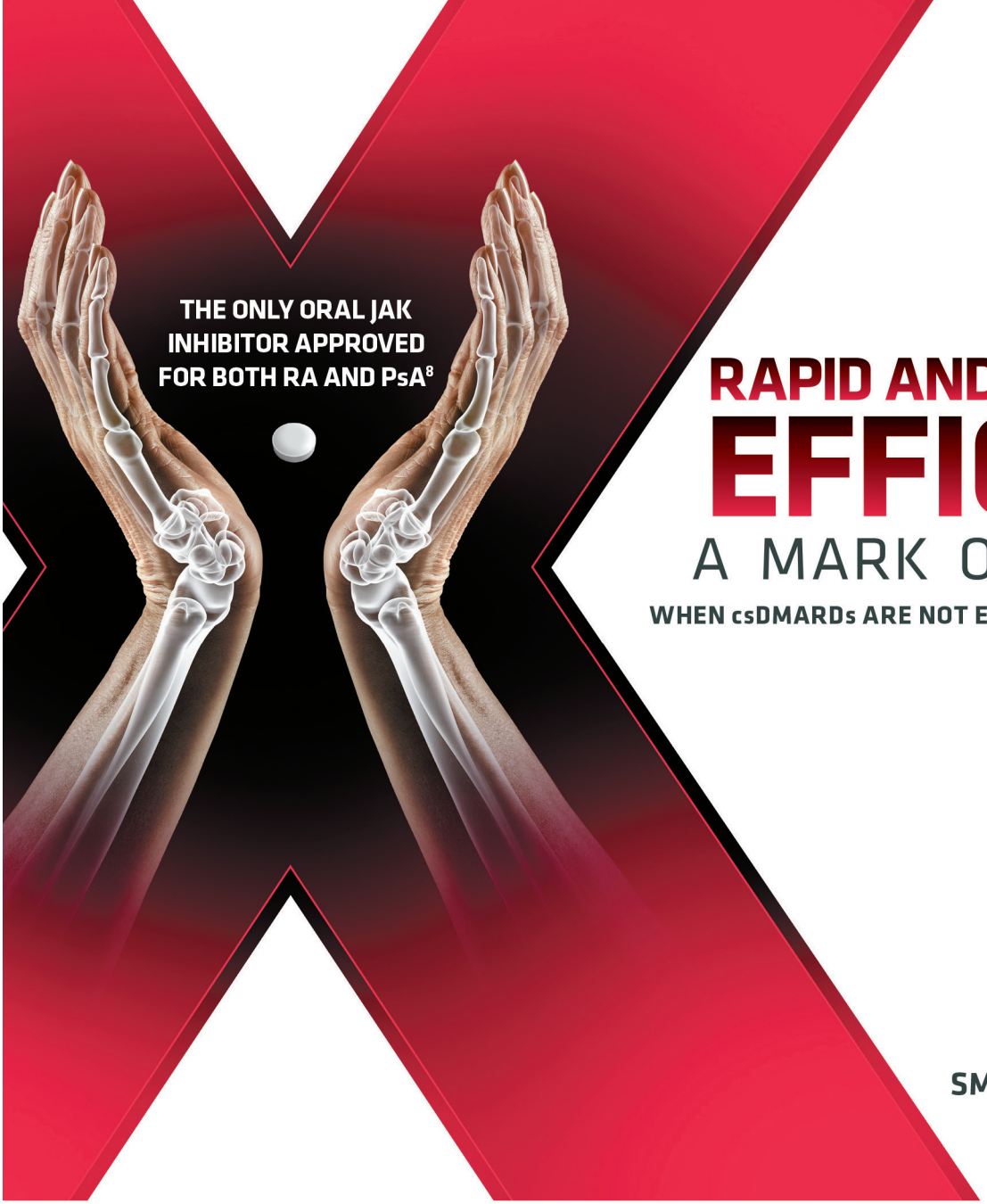

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WHEN csDMARDs ARE NOT ENOUGH: PRESCRIBE XELJANZ [8-10]

XELJANZ® ▼
(tofacitinib citrate)
5 mg tablets

SMALL PILL. BIG IMPACT.[1-3, 11]

XELJANZ® ▼(tofacitinib) Prescribing Information:

Please refer to the Summary of Product Characteristics (SmPC) before prescribing XELJANZ 5 mg film-coated tablets. **Presentation:** Film-coated tablet containing tofacitinib citrate, equivalent to 5 mg tofacitinib. **Indications:** In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In combination with MTX for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease modifying antirheumatic drug (DMARD) therapy. **Dosage:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. The recommended dose is 5 mg administered orally twice daily, taken with or without food. It is recommended not to initiate dosing in patients with an absolute lymphocyte count (ALC) less than 0.75x109/l, an absolute neutrophil count (ANC) less than 1x109 /l or in patients with haemoglobin less than 9 g/dL. ***Renal impairment:*** No dose adjustment is required in patients with mild or moderate renal impairment. XELJANZ dose should be reduced to 5 mg once daily in patients with severe renal impairment. Patients with severe renal impairment should remain on a reduced dose of 5 mg once daily even after haemodialysis. ***Hepatic impairment:*** No dose adjustment is required in patients with mild hepatic impairment. The dose should be reduced to 5 mg once daily in patients with moderate hepatic impairment. XELJANZ is contraindicated in patients with severe hepatic impairment. ***Elderly:*** No dose adjustment is required in patients aged 65 years and older. Use with caution as increase risk and severity of adverse events. ***Drug-drug Interactions:*** XELJANZ dose should be reduced to 5 mg once daily in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole). XELJANZ dosage should be reduced to 5 mg once daily in patients receiving one or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole) Coadministration of XELJANZ with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with XELJANZ is not recommended. **Contraindications:** Hypersensitivity to any of the ingredients, active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections, severe hepatic impairment, pregnancy and lactation. **Warnings and Precautions:** XELJANZ should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. Patients treated with XELJANZ should be given a patient alert card. There was a higher incidence of adverse events for the combination of XELJANZ with MTX versus XELJANZ as monotherapy in RA clinical studies. XELJANZ should be avoided in combination with biological disease modifying antirheumatic drugs (bDMARDs) and potent immunosuppressants such as azathioprine, ciclosporin and tacrolimus. ***Infections:*** Serious and sometimes fatal infections have been reported in patients administered XELJANZ. Patients should be closely monitored for infections, with prompt diagnosis and treatment. Treatment should be interrupted if a serious infection develops. Use carefully in elderly or patients predisposed to, or with a history of infection (e.g. diabetes). ***Tuberculosis:*** Patients should be evaluated for both active and latent TB prior to being treated with XELJANZ, patients who test positive for latent TB should be treated with standard antimycobacterial therapy before administering XELJANZ. ***Viral Reactivation:*** In clinical studies viral reactivation and cases of herpes zoster have been observed. Screening for viral hepatitis should be performed in accordance with clinical guidelines prior to starting therapy with XELJANZ. The impact on chronic viral hepatitis is not known. ***Vaccinations:*** Prior to initiating XELJANZ, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Live vaccines should not be given concurrently with XELJANZ. ***Malignancy:*** Lymphomas and other malignancies have been observed in patients treated with XELJANZ. Patients with highly active disease may be at higher risk than the general population. The effect of XELJANZ on the development and course of malignancies is not known. NMSCs have been reported, periodic skin examination is recommended in patients at increased risk. ***Interstitial lung disease:*** Caution is recommended in patients with a history of chronic lung disease as they may be more prone to infection. Asian patients are known to be at higher risk of ILD caution should be exercised with these patients. ***Gastrointestinal perforations:*** XELJANZ should be used with caution in patients who may be at increased risk e.g. diverticulitis or concomitant use of corticosteroids or NSAIDs. ***Cardiovascular risk:*** Risk factors should be managed as part of usual standard of care. ***Hypersensitivity:*** Cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately. ***Laboratory Parameters:*** Increased incidence of lymphopenia and neutropenia have been reported and decreases in haemoglobin and should be monitored in accordance with the SmPC. Monitor ANC and haemoglobin at baseline, 4-8 weeks and 3 monthly, ALC at baseline and 3 monthly. XELJANZ has been associated with increases in lipid parameters maximal effects are observed at 6 weeks. Monitoring should be performed 8 weeks after initiation and managed according to hyperlipidemia guidelines. Increases in liver enzymes greater than 3x ULN were uncommonly reported, use caution when initiating with potential hepatotoxic medicinal products. **Pregnancy & Lactation**: Use of XELJANZ during pregnancy and breast-feeding is contraindicated. **Side Effects:** The most common serious adverse reactions were serious infections; pneumonia, cellulitis, herpes zoster, UTIs, diverticulitis, appendicitis and opportunistic infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension. Commonly reported adverse reactions (≥1/100 to <1/10), were pneumonia, influenza, herpes zoster, urinary tract infection, sinusitis, bronchitis, nasopharyngitis, pharyngitis, anaemia, headache, hypertension, cough, abdominal pain, vomiting, diarrhoea, nausea, gastritis, dyspepsia, rash, arthralgia, oedema peripheral, blood creatine phosphokinase increased. Refer to section 4.8 of the SmPC for further information on side effects, including description of selected adverse reactions. **Legal Category:** S1B. **Marketing Authorisation Number**: EU/1/16/1178/003 – 5 mg (56 film-coated tablets). **Marketing Authorisation Holder:** Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. 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.

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

Last revised: 06/2018

Ref: XJ 3_0

References:
1. van Vollenhoven RF *et al. N Engl J Med* 2012; 367: 508–519. **2.** van der Heijde D *et al. Arthritis Rheum* 2013; 65: 559–570. **3.** Fleischmann R *et al. N Engl J Med* 2012; 367: 495–507. **4.** Strand V *et al. Ann Rheum Dis* 2017; 76: 1335. **5.** Wollenhaupt J *et al.* Poster presented at: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; November 3–8, 2017; San Diego, CA, USA. **6.** Mease P, et al. N Engl J Med 2017; 377: 1537–1550. **7.** Gladman D, et al. N Engl J Med 2017; 377: 1525–1536 **8.** XELJANZ Summary of Product Characteristics. **9.** Smolen JS *et al. Ann Rheum Dis* 2017 Mar 6. [Epub ahead of print]. **10**. Singh JA *et al. Arthritis Rheumatol* 2016; 68: 1–26. **11.** Burmester GR *et al. Lancet* 2013; 381(9865): 451–460.

PP-XEL-IRL-0269 | Date of preparation: July 2018

For DMARD-IR patients who need to add a biologic to control their RA symptoms, but can't/won't continue with methotrexate (MTX)[1]

NOW IS THE TIME TO START RoACTEMRA

Over 8 years of proven efficacy in rheumatoid arthritis, with or without methotrexate (MTX)[2-4]

RoACTEMRA®
tocilizumab

ABRIDGED PRESCRIBING INFORMATION (API). For full prescribing information, refer to the Summary of Product Characteristics [SmPC]. RoActemra® (tocilizumab) 162mg solution for injection in pre-filled syringe (RoActemra SC PFS). RoActemra® (tocilizumab) 162mg solution for injection in pre-filled pen (RoActemra SC PFP). RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV). Indications: RoActemra SC PFS & PFP: In combination with methotrexate (MTX) for (i) the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX (ii) the treatment of moderate to severe active 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. RoActemra SC is also indicated for the treatment of Giant Cell Arteritis (GCA) in adults. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients ≥ 2 years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients ≥ 2 years of age, who responded inadequately to previous therapy with MTX. RoActemra IV and RoActemra SC (in RA) can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC 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 MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, GCA, sJIA or pJIA and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP before administering the next dose if they experience symptoms of an allergic reaction. Patients should be instructed to seek immediate medical attention if they develop symptoms of serious allergic reactions. The first injection should be performed under the supervision of a qualified health care professional. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. Patients switching from RoActemra IV to RoActemra SC should administer their first subcutaneous dose at the time of the next scheduled IV dose under the supervision of a qualified HCP. The first injection should be performed under the supervision of a qualified health care professional. A patient can self-inject RoActemra only if the physician determines that it is appropriate and the patient agrees to medical follow-up as necessary and has been trained in proper injection technique. **RA:** *RoActemra IV:* 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100kg, doses >800mg per infusion are not recommended. No data on doses above 1.2g. *RoActemra SC PFS & PFP:* Not intended for IV administration. RoActemra SC PFS is administered with a single-use PFS+NSD. RA - 162mg subcutaneous once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently (see SmPC for further details). Do not shake the syringe or pen. **GCA (RoActemra SC PFS & PFP only):** 162mg subcutaneous once every week in combination with a tapering course of glucocorticoids. RoActemra can be used alone following discontinuation of glucocorticoids. RoActemra monotherapy should not be used for the treatment of acute relapses as efficacy is not established in this setting. Based upon the chronic nature of GCA, treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice. Glucocorticoids should be given according to medical judgement and practice guidelines. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30kg or 12mg/kg diluted to final volume of 50ml for patients < 30kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients <2 years of age - no data. Patients ≥2 years of age, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 10 mg/kg diluted to final volume of 50ml for patients <30kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. A change in dose for sJIA/pJIA patients should only be based on a consistent change in the patient's body weight over time. *Dose adjustments:* For raised liver enzymes, modify concomitant DMARDs (RA) or immunomodulatory agents (GCA) if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). In patients not previously treated with RoActemra, initiation is not recommended in patients with an absolute neutrophil count (ANC) below 2 x 10^9/L. Refer to SmPC for information regarding missed subcutaneous doses. *Special Populations:* No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients >65 years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Special Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Do not initiate treatment in patients with active infections. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Vigilance for the timely detection of serious infection is recommended - signs and symptoms of acute inflammation may be lessened, due to suppression of the acute phase reaction. Consider effects of RoActemra on C-reactive protein (CRP), neutrophils and signs and symptoms of infection when evaluating a patient for a potential infection. Instruct patients and parents/guardians of sJIA and pJIA patients to contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Advise patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Promptly evaluate patients presenting with symptoms potentially indicative of complicated diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment 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 during treatment with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, immediately stop administration and permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. In clinical trials, transient or intermittent mild-moderate elevations of hepatic transaminases reported commonly with RoActemra treatment, without progression to hepatic injury. An increased frequency of these elevations was observed when potentially hepatotoxic drugs (e.g. MTX) were used in combination with RoActemra. When clinically indicated, consider other liver function tests including bilirubin. Not recommended in patients with baseline ALT or AST > 5 x ULN; caution in patients with ALT or AST > 1.5 x ULN (see SmPC for frequency of monitoring and dose modifications/interruptions). Decreases in neutrophil and platelet counts have occurred following treatment with RoActemra 8 mg/kg in combination with MTX. Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC < 0.5 x 10^9/L or platelet count < 50 x 10^3/µL. Do not initiate RoActemra treatment where ANC is below 2 x 10^9/L. Caution in patients with low platelet count; monitor neutrophils and platelets in RA,GCA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; assess every 4 to 8 weeks; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). RA patients have an increased risk for cardiovascular disorders - manage risk factors (e.g. hypertension, hyperlipidaemia) as part of usual standard of care. Not recommended for use with other biological agents. RoActemra (for IV use) contains 1.17 mmol (or 26.55 mg) sodium per maximum dose of 1200 mg – to be considered by patients on a controlled sodium diet. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name and batch number should be clearly recorded in patient file to improve traceability of biological medicines. **Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-foetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. 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. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** *RA:* The most commonly reported ADRs (occurring in > 5% of patients treated with tocilizumab monotherapy or in combination with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALT. The most serious ADRs were serious infections, complications of diverticulitis, and hypersensitivity reactions. ADRs occurring in RoActemra trials: *Very Common (≥ 1/10):* upper respiratory tract infections, hypercholesterolaemia. *Common (≥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. *Uncommon (≥1/1000 - <1/100):* diverticulitis, stomatitis, gastric ulcer, hypertriglyceridaemia, nephrolithiasis, hypothyroidism. *sJIA:* ADRs were similar to those seen in RA patients. sJIA patients experienced a higher frequency of nasopharyngitis, decrease in neutrophil counts, hepatic transaminases increased, and diarrhoea. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. *Common (≥1/100 - <1/10):* diarrhoea, infusion related reactions, headache, platelet count decreased, cholesterol increased. *pJIA:* ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, headache. *Common (≥1/100 - <1/10):* nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. *Uncommon (≥1/1000 - <1/100):* platelet count decreased, cholesterol increased. **RoActemra SC PFS & PFP:** *RA -* The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. *GCA -* The safety of subcutaneous RoActemra has been studied in one Phase III study (WA28119) with 251 GCA patients. The overall safety profile observed in the RoActemra treatment groups was consistent with the known safety profile of RoActemra. 6% of patients reported an ADR occurring at the site of a subcutaneous injection. Injection site reactions are reported as very common (≥ 1/10) with the use of the PFS and common (≥1/100 - <1/10) with the use of the PFP. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of suspected adverse reactions. **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & 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); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled pen (EU/1/08/492/009). **Marketing Authorisation Holder:** Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. 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) 4690700. Fax: (01) 4690791. **Date of API Preparation:** April 2018. API (IE/RACTE/0816/0019(3)) based on the RoActemra 162 mg solution for injection in PFS and PFP SmPCs dated 12th Apr 2018 and RoActemra 20 mg/ml concentrate for solution for infusion SmPC dated 12th Apr 2018.

References: 1. RoACTEMRA Summary of Product Characteristics 12 April 2018. Available at www.medicines.ie. **2.** EMA. Doc Ref EMEA/CHMP/580914/2008. 2008. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/000955/WC500059466.pdf Last accessed October 2017. **3.** Jones G, et al. Five-year efficacy and safety of tocilizumab monotherapy in patients with rheumatoid arthritis who were methotrexate- and biologic-naïve or free of methotrexate for 6 months: the AMBITION study. J Rheumatol 2017; 44(2):142-146. **4.** Dougados M, et al. Adding tocilizumab or switching to tocilizumab monotherapy in methotrexate inadequate responders: 24-week symptomatic and structural results of a 2-year randomised controlled strategy trial in rheumatoid arthritis (ACT-RAY). Ann Rheum Dis 2013; 72(1):43-50.

Date of item: July 2018. IE/RACTE/0218/0003(1)

Roche