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NOVARTIS
PHARMACEUTICALS



Irish Society
for Rheumatology

Autumn Meeting 2016



15 - 16 September 2016
Killashee Hotel





Transforming lives¹

15 years of clinical trials and real world experience¹

1st EMA-approved anti-TNF in RA¹⁷

More than 350 trials¹⁸

4 Over million patient-years of collective clinical experience¹¹

More than 5700 publications¹⁹

1 Over million patients treated¹⁰

of partnership and experience
15 years



ABBREVIATED PRESCRIBING INFORMATION

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 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. 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:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients 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 life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. 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 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/199/126/013 Enbrel Pre-filled Syringe 50 mg: EU/199/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/199/126/020 Enbrel Powder 25 mg: EU/199/126/003 Enbrel Paediatric 10 mg: EU/199/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NU, UK. For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 8_0_P fleet number: 2013-0003980. **Date of Prescribing Information:** July 2014.

[†] Across all indications.

References: 1. Scott LJ. Drugs 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. November 2015. 3. Humira Summary of Product Characteristics. November 2015. 4. Remicade Summary of Product Characteristics. September 2015. 5. Cimzia Summary of Product Characteristics. December 2015. 6. Simponi Summary of Product Characteristics. November 2015. 7. Remicade EMA report 8. <http://clinicaltrials.gov>. Accessed 12 Nov 2014. 9. www.pubmed.org. Accessed 12 Nov 2014. 10. Data on File. January 2015. 11. Data on File. March 2014.



Welcome Message from the ISR President Dr Sandy Fraser



Dear Colleagues and Friends

I have great pleasure in welcoming you all to The Killashee Hotel Naas for this year's ISR Autumn Meeting. The programme for this year's autumn meeting has been put together by our colleagues in Beaumont hospital, Dr Donough Howard, Dr Grainne Kearns and Dr Paul O'Connell and I think you will agree that it is a fascinating agenda addressing topics which are of interest to all of us. I look forward with great interest to hear the thoughts of Professor Dennis McGonagle, Professor of Investigative Rheumatology, Leeds Institute of Rheumatic and Musculoskeletal Medicine and indeed Dr Bruce Kirkham, consultant Rheumatologist at Guys and St. Thomas' NHS Foundation Trust. Professor Sean Gaine from The Mater Misericordiae Hospital Dublin will present on the current management of pulmonary hypertension and Dr. Patrick Kiely from St Georges Hospital London will help us to pick the right biologic for our patients. Finally Professor Donal O'Shea from St. Vincents Hospital Dublin will address the issue of obesity and its relationship to inflammation.

During the year the work of the ISR has continued unabated and Professor David Kane, as National Programme Director, has continued to develop the National Rheumatology Programme with consensus and inclusivity core to the process. The steering group (CAG – Clinical Advisory Group) for the programme is open to all members of the ISR and the last meeting at the spring meeting in Cork was very well attended and very productive and there was a great deal of agreement regarding the direction the programme should lead. In particular there was acknowledgement that there be sufficient resources in place to support the delivery of Rheumatological care nationally before there can be an expectation that targets be impacted upon. I would encourage all members interested to attend the CAG meeting on Thursday morning before the official opening of the meeting. The 10 year plan for rheumatology has also been submitted to the oireachtas 10 year strategy committee.

We continue to work closely with our colleagues in Arthritis Ireland who so ably represent the people of Ireland with arthritis and their friends and relatives. Professor Gerry Wilson Arthritis Ireland/UCD professor of Rheumatology, Professor Ursula Fearon Arthritis Ireland/TCD professor of Molecular Rheumatology and colleagues continue to promote the development of research into Rheumatic Disease in Ireland on a national basis and we wish them continued success in the coming year.

The ISR website is now up and running and I think you will agree that it has been a great success with further developments to come. The abstract submissions this autumn are of extremely high quality and I would urge you all to take the time during the poster viewing sessions and indeed whenever you get a chance, to view the posters and talk to the presenters who have put so much work into their submissions.

I would like to thank our colleagues in the pharmaceutical industry for their continued support and again please take the time to visit their stands and talk to their representatives.

I would also like to express the appreciation of the ISR Board to the society administration and particularly Michael Dineen for his continued service.

I sincerely hope you all enjoy the meeting.

Yours sincerely

Dr Sandy Fraser,
ISR President

Proud of our Heritage...



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INFLIXIMAB



...Committed to our future

Remicade® 100mg Powder for Concentrate for Solution for Infusion (infliximab) Prescribing Information [Refer to full SPC text before prescribing Remicade (infliximab)] 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 therapy (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 immunosuppressant 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 5-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. **Psoarthritis (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. **Psoarthritis (PSD)** Remicade is indicated for the treatment of moderate to severe plaque PsD 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 PsD. Remicade should be administered intravenously over a 2 hour period. All patients administered Remicade should be observed for at least 1 to 2 hours post infusion for acute infusion-related reactions by appropriately trained healthcare professionals. **Shortened infusions across adult indications:** In carefully selected adult patients who have tolerated at least 3 initial 2-hour infusions of Remicade (induction phase) and are receiving maintenance therapy, consideration may be given to administering subsequent infusions over a period of not less than 1 hour. If an infusion reaction occurs in association with a shortened infusion, a slower infusion rate may be considered for future infusions if treatment is to be continued. Shortened infusions at doses >6 mg/kg have not been studied. RA: 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Adult moderately to severely active CD: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment should be given. Adult, fistulising, active CD: 5 mg/kg intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after the first infusion. If a patient does not respond after 3 doses, no additional treatment should be given. UC: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. Clinical response is usually achieved within 14 weeks of treatment (3 doses). AS: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 to 10 weeks. If a patient does not respond after 2 doses, no additional treatment should be given. PSA: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. PsD: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. If a patient shows no response after 4 doses, no additional treatment should be given. **Readministration:** Remicade can be readministered within 16 weeks following the last infusion. The safety and efficacy of readministration after a Remicade-free interval of more than 16 weeks has not been established in either CD or RA. The safety and efficacy of readministration in AS, after two every 8 to 8 weeks and in PSA and UC, after two every 8 weeks, has not been established. Readministration with one single Remicade dose in PsD after an interval of 20 weeks suggests reduced efficacy and a higher incidence of mild to moderate infusion reactions when compared to the initial induction regimen. Limited experience from retreatment, using a readministration regimen suggests a higher incidence of infusion reactions, some serious, when compared to 8 weekly maintenance treatment. In case maintenance therapy is interrupted in any indication, and there is a need to restart treatment, Remicade should be reinitiated as a single dose followed by the maintenance dose recommendations. **Paediatric population: CD (6 to 17 years):** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond by 18 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 treatment in paediatric patients not responding within the first 8 weeks of treatment. **Contraindications:** Tuberculosis or other serious 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 TNFs may mask symptoms of infection such as fever. Tuberculosis, bacterial infections including sepsis and pneumonia, invasive fungal, viral and other opportunistic infections, have been observed, some of which have been fatal. Infections were reported more

frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving Remicade. Patients should be evaluated for active or latent tuberculosis before Remicade treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active tuberculosis is diagnosed, Remicade therapy must not be initiated. If latent tuberculosis is diagnosed, treatment with anti-tuberculosis therapy must be initiated before initiation of Remicade. Patients on Remicade treatment should be advised to seek medical advice if symptoms of tuberculosis appear. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected in patients if a serious systemic illness is developed, a physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD and acute suppurative fistulas must not initiate Remicade therapy until possible source of infection is excluded. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Remicade who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Remicade. **Hepatobiliary events:** Very rare cases of jaundice and non-infectious hepatitis, some with features of autoimmune hepatitis have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. **Vaccinations:** It is recommended that live vaccines not be given concurrently. Prior to initiating Remicade therapy it is recommended that paediatric patients be brought up to date with all vaccinations. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Remicade and is positive for antibodies against double-stranded DNA, treatment must be discontinued. **Neurological events:** Anti-TNF α agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of Remicade therapy. Discontinuation of Remicade should be considered if these disorders develop. **Malignancies and lymphoproliferative disorders:** A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution is advised in patients with history of malignancy and in patients with increased risk for malignancy due to heavy smoking. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. 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 PsD 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. **Heart failure:** Remicade should be used with caution in patients with mild heart failure (NYHA class VII) and discontinued in case of new or worsening symptoms of heart failure. **Others:** Patients requiring surgery whilst on Remicade therapy should be closely monitored for infections. **Haematologic reactions:** Discontinuation of Remicade therapy should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leucopenia, neutropenia and thrombocytopenia. **Special populations:** Particular attention should be paid when treating the elderly (65 years) due to a greater incidence of serious infections seen in Remicade treated patients. Some of these had a fatal outcome. **Interactions:** No interaction studies have been performed. Combination of Remicade with other biological therapeutics used to treat the same conditions as Remicade, including anekina and abatacept is not recommended. It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently with Remicade. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Remicade treatment. Administration of Remicade is not recommended during pregnancy or breastfeeding. Administration of live vaccines to infants exposed to infliximab in utero is not recommended for 6 months following the mother's last infliximab infusion during pregnancy. Effects of infliximab on fertility and general reproductive function are unknown. **Side effects:** Very Common (>1/10): Viral infection, headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, infusion related reaction, pain. Common (1/10 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 flash, flushing, liver 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 & sole), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, aczema, alopecia, arthralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills and oedema. In phase 3 clinical studies, 18% of infliximab-treated patients compared with 5% of placebo-treated patients experienced an infusion related reaction. In post-marketing spontaneous reporting, infections are the most common serious adverse event. The most frequently reported opportunistic infections with a mortality rate of >5% include pneumocystosis, candidiasis, listeriosis and aspergillosis. Other less common and rarely reported side effects are listed in the SPC. **Overdose:** No case of overdose has been reported. Single doses up to 20 mg/kg have been administered without toxic effects. **Package Quantities:** Type I vials, with rubber stoppers and aluminium crimps protected by plastic caps, containing a lyophilised powder (infliximab) 100mg. **Legal Category:** POM. **Marketing Authorisation Number:** EU/1/99/116/001. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinvogel 101, 2333 CD Leiden, The Netherlands. **Adverse events should be reported to MSD (Tel: 01-299 8700). Date of Revision:** June 2014. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. © Merck Sharp & Dohme Ireland (Human Health) Limited, 2014. All rights reserved. Date of preparation: March 2015.

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 18, Ireland



PROGRAMME ISR Autumn Meeting

Killashee Hotel, Thursday & Friday 15th & 16th September 2016

Wednesday 14th September 2016

MSD Satellite meeting
IRNF - Nurses Meeting

Thursday 15th September 2016

- 8.45 CAG Meeting – Chair Prof David Kane
9.00 **Registration & Visit the Industry**
- 10.00 **Official Opening**
by Dr. Sandy Fraser, President ISR
- 10.10 **ORAL Free Scientific Papers 1 – 4**
- 11.00 **Coffee, Poster Viewing & Visit the Industry**
- 11.30 **Plenary Session 1 – Pulmonary Hypertension**

Prof. Sean Gaine, Consultant Physician,
Prof of Respiratory Medicine.
Mater Misericordiae University Hospital. Dublin
**“Current Management of Pulmonary Hypertension
& New Developments”**
- 12.15 **Oral Free – Clinical Papers (5 – 8)**
- 13.05 **Lunch, Poster Viewing and Visit the Industry**
- 14.20 **Plenary Session 2.**
Sponsored by Novartis Ltd
Prof. Dennis McGonagle
Professor of Investigative Rheumatology,
Leeds, UK
“Enthesitis & Dactylitis”
- 15.10 **Coffee Break, Posters Viewing & Visit the Industry**
- 15.40 **Plenary Session 3.**
Sponsored by Novartis Ltd
Dr Bruce Kirkham, Consultant Rheumatologist,
Guy’s & St Thomas NHS Foundation Trust. UK
“MOA Developments & Potential Targets for IL 17”

- 16.30 **Young Investigator Award – Joint Award winners.**
- 17.10 **Close of Meeting**
- 17.15 **ISR AGM**
- 18.15 **Private Practice Meeting**
- 19.30 **Drinks Reception**
- 20.00 **Conference Dinner**

Friday 16th September 2016

- 8.00 **AbbVie Satellite meeting**
Prof Trevor Duffy, Connolly Hospital, Dublin
“Improving hospital unit efficiencies”
- 9.00 **Registration & Visit the Industry**
- 9.30 **Oral Cases (9 – 12) with audience participation**
- 10.30 **Bernard Connor Medal Award**
- 10.45 **Coffee Break, Posters Viewing & Visit the Industry**
- 11.15 **Plenary Session 4 – Biologics**
Sponsored by BMS Ltd.
Dr Patrick Kiely, St Georges’ Hospital, London
**“Getting it right first time- predictive factors for
initiating biologic therapy”**
- 12.15 **Plenary Session 5 - Obesity**
Prof Donal O’Shea
Consultant Endocrinologist & Physician
St Vincents’ University Hospital. Dublin
“The vicious cycle of Obesity and inflammation”
- 13.15 **Prize Giving & Close of Meeting**

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- Over 16,000 patient-years experience in clinical trials³
- Clinical efficacy demonstrated over 2 years^{4,5}
- Favourable safety profile³



ORENCIA® (abatacept)
ClickJect®
PRE-FILLED PEN

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ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.
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 pre-filled pen, ClickJect for SC injection. Each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.

INDICATION: Rheumatoid arthritis (IV infusion and SC pre-filled syringe and pen): Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF)-alpha inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC.
Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only): Orenzia 250 mg powder for concentrate for solution for infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

DOSAGE and ADMINISTRATION: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. **Orenzia 250 mg powder for concentrate for solution for IV infusion Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg to ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 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, Orenzia should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended.

Orenzia 125 mg solution for injection (SC pre-filled syringe and pen) Adults and elderly: Orenzia SC may be initiated with or without an intravenous (IV) loading dose. Orenzia 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 Orenzia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** Administration in children below 18 years of age is not recommended.

CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections.

WARNINGS AND PRECAUTIONS: Allergic Reactions:

Cautions in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orenzia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactoid 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 Orenzia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orenzia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orenzia. Co-administration of Orenzia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orenzia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of Orenzia in the development of malignancies is unknown, see SmPC. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orenzia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orenzia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orenzia in combination with sulfasalazine, hydroxychloroquin or leflunomide. **PREGNANCY AND LACTATION:** Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In adult placebo-controlled trials the following adverse drug reactions were reported. **Very Common (≥ 1/10):** upper respiratory tract infection including tracheitis, nasopharyngitis. **Common (≥ 1/100 to < 1/10):** Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthenia, local injection site reactions*, systemic injection reactions* (e.g. pruritus, throat tightness, dyspnea) (*Orenzia SC) **Uncommon (≥ 1/1,000 to < 1/100):** Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell and squamous cell carcinoma, skin

papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhoea, menorrhagia, influenza like illness, weight increased. **Rare (≥ 1/10,000 to < 1/1,000):** Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm malignant, throat tightness. See SmPC for further details.

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER: Orenzia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack; Orenzia 125 mg solution for injection- EU/1/07/389/008, 4 pre-filled syringes with needle guard and EU/1/07/389/11, ClickJect12 pre-filled pens.

MARKETING AUTHORISATION HOLDER:

Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.
FURTHER INFORMATION FROM: Bristol-Myers Squibb Pharmaceuticals, Watery Lane, Swords, Co. Dublin, Tel: 1-800-749-749 or medical.information@bms.com.
DATE OF PREPARATION: April 2015
Job No: 427IE15PR03297-01

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Freepost, HPR Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

REFERENCES: 1. ORENZIA® Summary of product characteristics; 2. Choy EH. *Clin Exp Rheumatol* 2009;27:510-18; 3. Genovese MD, et al. Presented at ACR/ARHP 2012; Poster 1691; 4. Schiff M, et al. *Ann Rheum Dis* 2014;73:86-94; 5. Weinblatt ME, et al. *Arthritis Rheum* 2013;65:28-38.
ABBREVIATIONS: DMARD, disease modifying anti-rheumatic drug; RA, rheumatoid arthritis.
DATE OF APPROVAL: April 2016
427IE1600040-02



Programme for IRHPS Meeting and AGM

September 15th & 16th 2016,
Killashee Hotel, Naas, Co. Kildare

Thursday 15th September 2016

- 10.00 **Registration / coffee / poster viewing / Meet the industry**
- 10.30 **IRHPS Programme**
Chairs: Rhona Galway & Eileen Shinnors.
- 10.30 **Welcome by IRHPS Chairperson; Derek Deely**
- 10.35 **Oral Presentation 1:**
'Implementation of a Registered Advanced Nurse Practitioner (RANP) led Treat to Target (T2T) in early Rheumatoid Arthritis (RA) patient.'
Noreen Harrington, RANP, Our Lady's Hospital, Manorhamilton, Co. Leitrim.
- 11.00 **Oral Presentation 2:**
'The development and evaluation of a Multi-disciplinary team (MDT) Programme for the management of Osteoarthritis (OA) of the Thumb.'
Patricia Fitzgerald, Clinical Specialist Occupational Therapist, Rheumatology Services, St. Vincent's University Hospital, Dublin
- 11.30 **ISR Programme**
- 12.30 **Lunch / Poster viewing / Meet the industry**
- 13.30 **Keynote Speakers:**
- IRHPS Programme**
Chairs: Una Martin, Catherine Cullinane
- 'Managing pregnancy in Rheumatic disease'**
Dr Anita Banerjee, Consultant Obstetric physician, Guys & St. Thomas Hospital, NHS foundation Trust.
- 'The challenges of parenting/grand parenting in Rheumatic disease'**
Dr Helene Mitchell, Clinical Psychologist, De Montfort University Leicester.
- 'Exercise for Bone Health'**
Dr Caitriona Cunningham, School of Public Health, Physiotherapy and Sports Science TCD.
- 15.15 **ISR Programme**
- 17.00 **IRHPS AGM**
- 19.30 **Drinks Reception**
- 20.00 **Conference Dinner**

A man and a woman are seen from behind, standing on a rocky outcrop overlooking a vast, hazy mountain landscape at sunset. The man is standing, wearing a white t-shirt, dark shorts, and a large black backpack with a rolled-up mat. The woman is sitting on the rock, wearing a patterned tank top, dark shorts, and a large black backpack. The sky is filled with soft, golden light from the setting sun, with scattered clouds. The overall mood is peaceful and contemplative.

abbvie

THEN, NOW,
— AND IN THE —
FUTURE

CARE AND SUPPORT FOR PATIENTS
THROUGHOUT THEIR JOURNEY



Speakers

Prof. Sean Gaine

Consultant Physician,
Prof of Respiratory Medicine.
Mater Misericordiae University Hospital. Dublin



Prof Sean Gaine is Consultant Respiratory Physician at Mater Misericordiae University Hospital in Dublin and director of the National Pulmonary Hypertension Unit. Prof Gaine completed his medical education at Trinity College Dublin and his medical residency and fellowship training at the Johns Hopkins Hospital, Baltimore. During his Pulmonary and Critical Care fellowship Prof Gaine obtained his PhD for work exploring the control of pulmonary vasculature function. He subsequently held faculty positions at the Johns Hopkins Hospital and at the University Of Maryland School Of Medicine. He established the Pulmonary Hypertension Center at the Johns Hopkins Hospital in 1999 and subsequently the National Pulmonary Hypertension Unit upon his return to Dublin. His research interests include novel biomarkers and new therapeutic agents in pulmonary vascular diseases. Prof Gaine has been a working member of the European Society of Cardiology and European Respiratory Society guidelines committee on Pulmonary Hypertension in the past and a task force member of the WHO World PH symposiums since 2003. Professor Gaine is a member of numerous international associations, and is a Fellow of the College of Chest Physicians, the Royal College of Physicians in Ireland and the Faculty of Sports and Exercise Medicine. He is Chief Medical Officer of the Olympic Council of Ireland and led the medical team at the Olympic Games in Athens, Beijing and London.

Prof. Dennis McGonagle

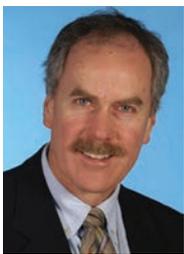
Professor of Investigative Rheumatology,
Leeds, UK



Professor McGonagle is internationally recognised for his work in microanatomy and imaging to elucidate the pathogenesis of inflammatory diseases and for his work in the biology of Mesenchymal stem cells in arthritis and their role in pathogenesis/repair in rheumatic diseases and has published over 240 articles on these topics. He is Professor of Investigate Rheumatology, the Clinical Lead in the WelmeC-EPSC Centre for Medical Engineering, and Section Head of Experimental Musculoskeletal Medicine. He has lead in the establishment of a new academic Dermato-Rheumatology group between the Universities of Leeds and Bradford termed (Dr Miriam Wittmann). He has served on the Editorial Board of Arthritis & Rheumatism and is currently a member of the Scientific Committee of EULAR.

Dr Bruce Kirkham

Consultant Rheumatologist,
Guy's & St Thomas NHS Foundation Trust. UK



Dr Kirkham qualified as a doctor in New Zealand before travelling to the United Kingdom to complete his postgraduate rheumatology training, during which he studied monoclonal antibody therapy in rheumatoid arthritis. Throughout his career Dr Kirkham has continued his work in clinical trials of new treatments and investigation of immune mechanisms, particularly IL-17 pathways, in inflammatory arthritis. In 2004, he developed the RA Centre service to optimise the treatment of inflammatory arthritis, using treat-to-target strategies in routine care. In 2001 he was co-CI of the first study of infliximab in psoriatic arthritis. This special interest continues with a close working relationship with the St John's Institute of Dermatology, the largest centre for psoriasis in southern England. His translational research interests are synovial correlates of disease with a focus on IL-17 immunology and cardiovascular complications of inflammatory arthritis.

Dr Patrick Kiely,

St Georges' Hospital, London



Clinical interests

Dr Kiely specialises in all aspects of adult rheumatology. He holds specialist clinics in rheumatoid arthritis, inflammatory muscle disease (myositis), primary systemic vasculitis and interstitial lung disease associated with connective tissue diseases.

Professional profile

Dr Kiely qualified from the University of London in 1988, and has been a consultant at St George's University Hospitals NHS Foundation Trust since 1999.

His research has resulted in papers published on subjects such as rheumatoid arthritis, vasculitis, vitamin D deficiency and myositis.

- Member: British Society of Rheumatology
- Member: American College of Rheumatology
- Council and external affairs committee member, British Society of Rheumatology
- Chairman: South West Thames Regional Rheumatology Group
- Medical Advisor: National Rheumatoid Arthritis Society
- Executive member: Early Rheumatoid Arthritis Network

Prof Donal O'Shea,

Consultant Endocrinologist & Physician
St Vincents' University Hospital. Dublin



Prof Donal O'Shea qualified in Medicine from UCD in 1989. He moved to Hammersmith Hospital in London in 1992 and completed his MD on how the brain controls appetite and hunger - funded by the Wellcome Trust Training Fellowship. In 1996 Donal was appointed a Senior Lecturer in Diabetes and Endocrinology at Hammersmith Hospitals Trust. In 1999 he moved to his current position and set up the first hospital based multidisciplinary treatment unit for obesity in Ireland. Prof O'Shea was a member of the Department of Health National Obesity Taskforce, chairing the detection and treatment subgroup. He is currently Chairman of the Nutrition Council of the Irish Heart Foundation and has a research programme looking at the overlap between fat cell function and the metabolic/immune systems focussing on the patients having surgery for their obesity. Donal is on the executive of the UK and Ireland Neuroendocrine Tumour Society and has published on diabetes, gut endocrine obesity, steroid metabolism, gender identity disorder and thyroid disorders. Donal is a Consultant Endocrinologist at St Columcilles and St Vincents University Hospitals and Associate Professor of Medicine at University College Dublin.

Dr Helene Mitchell,

Clinical Psychologist, De Montfort University,
Leicester.



Following a degree in psychology Helene started working in Rheumatology nearly twenty years ago, as a research assistant at King's College Hospital, London. She then went on to work with Professor Mike Hurley on the ESCAPE-Knee Pain trial, whilst undertaking her PhD on expectations of exercise behaviour in osteoarthritis.

In 2005 Helene took up a lecturing post at De Montfort University in Leicester, where she teaches on the undergraduate and postgraduate programmes, with a particular focus on long-term conditions. In recent years her research interests have expanded to include women's health and the impact of chronic illness on couples and the family.

Introducing Cosentyx®

- Discover a new way to treat psoriatic arthritis and ankylosing spondylitis with the first and only fully human IL-17A inhibitor approved in Ireland¹
 - Rapid and sustained relief from signs and symptoms of SpA²⁻⁷
- 80% of biologic-naïve SpA patients achieve clinical outcomes at one year²⁻⁷



WATCH ME

SHOW MY FAMILY THAT I CAN STILL BE MYSELF.

 **Cosentyx**®
secukinumab

LIFE IN MOTION

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 and 3, followed by monthly maintenance dosing starting at Week 4. *Ankylosing Spondylitis:* The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. 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 discontinuation of 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. No interaction studies have been performed in humans. A clinically relevant effect on CYP450 substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin) cannot be excluded. Therapeutic monitoring should be considered on initiation in patients treated with these types of medicinal products. 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, Frimley Business Park, Camberley, GU167SR, United Kingdom. **Marketing Authorisation Numbers:** EU/1/14/090/004-005. **Date of Revision of Abbreviated Prescribing Information:** November 2015. 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 (ACR), April 2016. 2. Novartis Data on File 2015. MEASURE 2 Clinical Study Report. 3. Beelen D, et al. Arthritis Rheum 2015; 67 (S10): 3482. Poster 2890 at the American College of Rheumatology (ACR), 10 November 2015, San Francisco, USA. 4. McInnes IB et al. Lancet 2015; 386: 1137-46. 5. Kavanaugh A, et al. Ann Rheum Dis 2015; 74 (S2): 345-6. Poster THJ0411 at European League Against Rheumatology (EULAR), 10 June 2015, Rome, Italy. 6. Kavanaugh A, et al. Arthritis Rheum 2015; 67 (S10): 2573. Abstract 2146 at the American College of Rheumatology (ACR), 9 November 2015, San Francisco, USA. 7. Novartis Data on File 2015. FUTURE 2 Clinical Study Report. **Date of Preparation:** August 2016. IE2/COS16-CNF010b

 **NOVARTIS**
PHARMACEUTICALS



Dr Anita Banerjee,

Consultant Obstetric physician, Guys & St. Thomas Hospital, NHS foundation Trust.

Dr Banarjee is an obstetric physician working in Guys and St Thomas's, London. Her role involves managing pregnant patients with complications sometimes due to chronic diseases in dermatology, rheumatology, endocrinology (eg. Metabolic syndrome) through their pregnancy. She also has a specialist interest in medical emergencies during pregnancy.

Dr Caitriona Cunningham,

School of Public Health, Physiotherapy and Sports Science TCD.



Caitriona Cunningham is a Lecturer at University College Dublin (UCD) School of Public Health, Physiotherapy and Sports Science. As a graduate of UCD's B.Physio programme, she gained extensive clinical physiotherapy experience in Ireland the UK and USA. Specialising in musculoskeletal physiotherapy, she completed her MSc (Neuromusculoskeletal Physiotherapy) at University College London in 1997, also completing the Musculoskeletal Association of Chartered Physiotherapists (UK) exams at that time. She completed her PhD at University College Dublin in 2007 and continues to conduct research in relation to occupational musculoskeletal disorders. Her research findings have been published widely in international, refereed journals and at national and international research meetings. She and her colleagues launched UCD's Better Bones programme in 2013, in collaboration with St Vincent's University Hospital. Caitriona continues to teach across both undergraduate and graduate Physiotherapy programmes with a focus on musculoskeletal disorders, exercise and promotion of physical activity and she is committed to the translation of evidence into clinical and professional practice. Current research: occupational MSK disorders, bone health and fracture prevention, exercise for MSK health, evaluation MSK Physiotherapy services

ISR Board members

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.



Professor David Kane

Prof David Kane attended medical school at Trinity College, Dublin, Ireland and was conferred MB BCH BAO BA in 1991, PhD in 2002 and FRCPI in 2006. He has trained in rheumatology with Prof. Barry Bresnihan and Prof. Oliver FitzGerald at St. Vincent's University Hospital, Dublin, Ireland and with Prof Roger Sturrock, Prof Iain McInnes and Dr Peter Balint at Glasgow Royal Infirmary, Glasgow, United Kingdom. He was appointed as Senior Lecturer in Rheumatology at the University of Newcastle (2003-2005) and is currently working as Consultant Rheumatologist at the Adelaide and Meath Hospital and Clinical Professor in Rheumatology at Trinity College Dublin. His special interests are musculoskeletal ultrasound, spondyloarthritis and synovial inflammation. He is a member of the European Working Party on Musculoskeletal Ultrasound and the OMERACT special interest group on musculoskeletal ultrasound, previous organiser of the BSR Musculoskeletal Ultrasound course and is Faculty member of the EULAR Musculoskeletal ultrasound course. He has served as a Board member of the Irish Osteoporosis Society, as President and Treasurer of the Irish Society for Rheumatology and is currently a Board member of Arthritis Ireland.



Dr Frances Stafford

Frances is a graduate of UCD, spent almost a decade in North America, training in Rheumatology first at University of Toronto, followed by a fellowship at Massachusetts General Hospital & Harvard Medical School. She was awarded a 4 year Arthritis Foundation Postdoctoral Fellowship, which I completed at the NIH, and then went on staff at the NIH. Frances is American Board Certified in Internal Medicine and in Rheumatology. She has been Consultant at Blackrock Clinic since 1995.



Dr Sinéad Harney

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 Suzanne Donnelly

Dr Suzanne Donnelly graduated from Trinity College Dublin, trained in Ireland and England and was appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. She returned to Ireland in 2005 to work part time as Consultant Rheumatologist in the Mater Misericordiae University Hospital. Her clinical and educational research interests include systemic autoimmune disease, Systemic Lupus Erythematosus and Care in Medicine. Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London, and joined UCD as Director of Clinical Education in 2008, to lead the development of early clinical education. She was responsible for a series of innovative educational strategies across all disciplines including the development of a patient educator programme in association with Arthritis Ireland. She led the first national undergraduate curriculum project in Ireland, published as the ISR Undergraduate Curriculum in Rheumatology in 2009, and is a contributing author to the textbooks Medicine at a Glance & 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 is a medical patron of Lupus Group Ireland.



BERNARD CONNOR MEDAL AWARD 2016

Anca Smyth

Queen's University Belfast



Medical Student Observations in Rheumatology

When it comes to our health most of us are guilty of thinking that we are invincible. Imagine waking up one morning with excruciating pain, having stiff, swollen joints and weakness which markedly interfere with your ability to carry out the normal activities of daily living. To a rheumatoid arthritis (RA) sufferer such debilitating symptoms may constitute 'a significant disease flare', an episodic exacerbation of this chronic, symmetrical, small joint inflammatory condition. Or does it?

Unlike the ACR/EULAR classification criteria for RA [1] which is based on objective measurements of serological parameters, acute phase reactants, numbers and sites of swollen or tender joints and symptom duration, there has been no standard definition of what constitutes a RA flare or how it can be objectively assessed and classified according to severity. Apart from measuring the efficacy and safety of novel pharmacological agents used in the treatment of RA by means of randomised controlled clinical trials, a valid definition and classification of a flare would prove to be an invaluable tool in guiding clinical care and monitoring disease outcome.

When a patient is experiencing a flare, a significant increase in the disease activity so that it requires a change of treatment [2], there is often discrepancy in the interpretation of the severity of signs and symptoms between the doctor and the patient [3]. This may lead to inappropriate treatment, patient dissatisfaction and non-adherence to therapeutic interventions [4, 5]. Such discordance is due to the heterogeneous nature of the patient experience during this acute episode, which not only affects objectively measured clinical parameters but also generates self-reported symptoms such as pain, weakness, sleeplessness or fatigue [6, 7]. From the patient's perspective the experience of a flare is also about functional impairment, disability and social participation [8, 9] which interfere with the patient's quality of life and psychological well-being.

There is also variation between RA sufferers regarding what constitutes a significant disease flare. Reasons for this include the fact that patients report the severity of a flare according to their baseline disease activity and previous experiences with the disease [10], thus what seems a severe flare to an early RA patient may be classified as a normal fluctuation of disease activity by someone who has been living with this disease for an extended period of time. Additional factors in defining a significant flare include the level of a patient's tolerance to worsening of signs and symptoms, health beliefs and coping skills [11, 12].

Current methods of assessing RA patients include measuring the disease activity in 28 joints using the DAS28 score and evaluating physical disability by means of a Health Assessment Questionnaire (HAQ28) and patient's global health status by employing a 10cm Visual Analogue Scale (VAS). However, none of these approaches are without flaws. Two of the main determinants of the patient's global health are pain and fatigue [13], subjective symptoms which cannot be measured accurately and which are influenced by many factors including mental health status and co-morbidities [14]. Considering the ACR/EULAR disease remission criteria of a score of 1 or less on the patient's global assessment scale of 0-10 such targets may be difficult to achieve accounting for the fact that many RA patients suffer from depression [15] or chronic pain syndrome [16].

The HAQ tool, limited by its 'ceiling effect' due to lack of adequate sensitivity in detecting a worsening of disability towards its upper limits or assessing lower limb function [17] does not accurately evaluate the severity of a RA flare. The DAS 28 score, a weighted composite of the number of swollen joints, level of the inflammatory marker ESR (erythrocyte sedimentation rate) and patient global assessment score is currently employed in clinical practice to classify disease activity, guide therapeutic treatment and function as an outcome measure in the treat-to-target approach [18]. Limitations of this approach include a misleadingly low DAS28 score if the flare predominantly affects the patient's feet, which are not included in the DAS28 joint count, or if it is concentrated on a single joint, causing debilitating pain and rendering the patient unable to work. Conversely, a high DAS28 score based on a large number of swollen joints in the absence of pain or elevated ESR may initiate an unnecessary escalation in therapeutic treatment [19]. Some studies have used the inverse of the improvement criteria based on the DAS28 score to assess the severity of a flare but such a correlation seems inappropriate [20].

Given the complexity of patient experiences and heterogeneity of assessment tools that affect the interpretation of a significant disease flare, there is no 'one size fits all' approach to monitoring a flare. In an era of demedicalisation, there is an emphasis on treating the individual in the community, with medical care providers offering evidence based patient education and counselling regarding management of flares or side-effects of medication in the form of leaflets, telephone consultation with various members of the multi-disciplinary team or telecare services for people to report and be advised on their flares [21]. Such a model of care not only promotes self-efficacy and helps achieve an internal locus of control but it also increases accessibility and reduces travelling time for patients in the rural communities.

Since RA is a chronic condition, the patient may be the expert in monitoring their condition and self-management of a flare by means of non-pharmacological (such as exercise, bed rests, applying ice or heat packs or via complementary and alternative therapies) or pharmacological interventions (by increasing the dose of glucocorticoids, analgesics or non steroidal anti-inflammatory medication alongside a fixed-dose of disease modifying anti-rheumatic drugs) seems to be the approach employed by most RA sufferers [22]. There are times, however, when self-management of a flare is ineffective and the patient decides to seek medical help. Although the threshold at which such a decision is made is unknown, the doctor must adopt a holistic approach in assessing the patient and based on shared-decision making determine an appropriate change in treatment.

In conclusion, the concept of a significant disease flare in RA is complex, non-standardised and its interpretation depends on interplay between a patient's physical and psychological parameters, previous disease experience and health beliefs. Monitoring of this acute episode should occur in the community, with health professionals providing ongoing patient education and counselling



Dr Adrian Pendleton

Consultant Rheumatologist
Muskgrave 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 (BASME). 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 John Stack (SPR Rep)

John Stack is this years SpR representative on the ISR committee. He is a 4th year rheumatology SpR currently based at Connolly Hospital Blanchardstown and has previously worked at St James Hospital, Midlands Regional Hospital Mullingar and Cork University Hospital. He is a graduate of University College Cork.



Dr Clare Matthews

Consultant Rheumatologist
Ulster Hospital, Belfast



Dr Donough Howard

Donough Howard is a Consultant Rheumatologist at St James's Hospital and Hermitage Medical Clinic. Dr Howard is the national specialty director for rheumatology. He graduated from RCSI and completed postgraduate training both in Ireland and the US. He previously worked in Lahey Clinic Medical Centre, with academic appointments to both Harvard and Tufts Medical Schools. Dr Howard has published in the fields of vasculitis and also has subspecialty interests in the fields of scleroderma.



Young Investigator Award 2016

Mary Canavan

Mary received her Ph.D in 2012 in the field of Immunology in Dublin City University. She then began her first postdoctoral research position in the Translational Rheumatology Research Lab in UCD and has since moved to the Molecular Rheumatology Research lab in Trinity College Dublin. Her research includes the characterisation and functional analysis of immune infiltrates in the inflamed synovium in both Rheumatoid Arthritis and Psoriatic Arthritis. She is currently an Editorial Member of Annals of the Rheumatic Diseases where she holds the position of Social Media Editor. Finally in addition to this she is on the working group committee for EMEUNET- a young rheumatology network for young clinicians and scientists where her role is to provide educational materials to all members.



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 (NCP), 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.



Amanda Eakin

Amanda was awarded a 1st class BSc Hons in Chemistry with Forensic Analysis from Queen's University of Belfast in 2013. She was then appointed as a research scientist at Randox Laboratories Ltd, developing novel immunoassays for the detection of cardiovascular disease biomarkers. In January 2015, Amanda was awarded a Department of Education and Learning (NI) funded Ph.D. fellowship in stratified (precision) medicine at Ulster University, under the supervision of Dr David Gibson and Professor Tony Bjorsson. Her project is focussed on investigating cellular and protein biomarkers which could be used to manage treatments in early stage rheumatoid arthritis.



Dr Eamonn Molloy

Eamonn Molloy graduated from University College Dublin (1997) and completed rheumatology and internal medicine training in Ireland. He obtained an MD at RCSI (2006), which focused on calcium crystal induced inflammation. From 2005, he underwent subspecialty fellowship training in vasculitis at the Cleveland Clinic, completed a MS (Clinical Research) at Case Western Reserve University and then joined the staff at the Vasculitis Center and RJ Fasenmeyer Center for Clinical Immunology at the Cleveland Clinic. In 2010, he was appointed as a consultant rheumatologist at St Vincent's University Hospital and is a UCD Senior Clinical Lecturer. He is the author of approximately 50 publications largely pertaining to vasculitis, complications of biologic therapy and crystal induced arthritis. Currently, his primary research focus is giant cell arteritis.



Bernard Connor Medal Award 2016

Anca Smyth

Queen's University Belfast

I'm a fourth year medical student at Queen's University Belfast. I have developed an interest in Rheumatology during my third year MSK attachment at Altnagelvin and subsequently undertook a Student Selected Component module in Rheumatology.

Previously I graduated from University of Ulster with a first class honours degree in Biomedical Sciences in 1998 and was awarded a PhD in Biomedical Sciences in 2002. I worked for 10 years as a post doctoral researcher within the Cancer and Ageing Research Group at the University of Ulster.



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Hannah - Early RA

"I want to be able to plan for the future and commit to my career path"

- Hannah, 25 years old, Policewoman*



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Kate - RA

"I want reassurance that things are going to get better"

- Kate, 51 years old, Nurse*



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Lucy - PsA

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Matt - AxSpA

"I need rapid relief from back pain so I can get back to work"

- Matt, 35 years old, PE Teacher*



*Patient profiles and quotes are for illustration purposes only.



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1. CIMZIA® Summary of Product Characteristics. 2. Mease PJ, Fleischmann R, Deodhar AA, Wollenhaupt J, Khraishi M, Kielar D, et al. Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a Phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). *Ann Rheum Dis*. 2014;73(1):48-55. 3. Landewe R, Braun J, Deodhar A, Dougados M, Maksymowych WP, Mease PJ, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis*. 2014;73(1):39-47. 4. Keystone E, Heijde D, Mason D, Jr., Landewe R, Vollenhoven RV, Combe B, et al. Certolizumab pegol plus methotrexate is significantly more effective than placebo plus methotrexate in active rheumatoid arthritis: findings of a fifty-two-week, phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. *Arthritis Rheum*. 2008;58(11):3319-29.

Further information is available in the Cimzia SmPC.



YOUNG INVESTIGATOR JOINT AWARD WINNERS - 2016

Young Investigator Award 2016

DR MARY CANAVAN (16A150)

CD141+ DC are enriched in the inflamed synovium of Rheumatoid Arthritis patients and induce both CD4+ and CD8+ T cell responses

Author(s) Mary Canavan¹, Barry Moran², Carl Orr³, Ronan Mullen³, Jean Fletcher², Douglas Veale³ and Ursula Fearon¹

Department(s)/Institutions 1Department of Molecular Rheumatology, Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland. 2School of Biochemistry & Immunology, Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland. 3Translational Rheumatology Research Group, Dublin Academic Medical Centre, St. Vincent's University Hospital, Dublin, Ireland. 4Department of Rheumatology, Adelaide and Meath Hospital, Dublin, Ireland.

Introduction Dendritic cells (DC) are a heterogeneous group of antigen presenting cells. Currently their classification within blood & skin has been well characterised however their identification within other tissues, in particular in the context of autoimmunity is limited. CD141 DC in particular have yet to be identified in RA and it is unknown what role they may play in the pathogenesis of the disease.

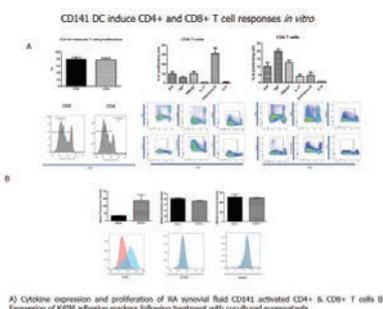
Aims/Background The aim of this work was to identify DC within the inflamed synovium and determine if these DC are phenotypically and functionally distinct from their blood counterparts.

Method Synovial tissue was digested to yield a single cell suspension which was subsequently stained with a panel of antibodies & analysed by multicolour flow cytometry. PBMC/SFMC were isolated from blood or fluid using a density-gradient separation & stained with DC specific markers for flow cytometry analysis. DC were sorted from SFMC & cocultured with T cells. T cells were intracellularly stained with antibodies specific for T cell related cytokines. Finally, supernatants from DC-T cell cocultures were used to treat a normal synovioocyte cell line & the expression of adhesion molecules was measured.

Results mDC are significantly decreased in RA blood compared to HC ($p < 0.05$), suggesting DC are recruited to the site of inflammation. There is a significant increase in the frequency of DC within the synovial tissue of RA patients compared to matched blood ($p < 0.05$). These DC have a more activated phenotype with a significant increase in CD80 ($p < 0.001$) & CD40 ($p < 0.05$) expression compared to blood DC. DC can be subdivided into different subsets, one of which, the CD141 DC has never been described in RA. CD141 DC were discovered in 2010 & little is known about their function in health & indeed disease. We can report that CD141 DC are significantly enriched in RA synovial fluid (SF) compared CD141 DC found in blood ($p < 0.001$). SF CD141 DC express higher levels of CD80, CD86 and CD40 compared to blood DC. CD141 DC induce both CD4 and CD8 proliferation. In addition to this, SF CD141 DC induce a strong CD8 response - as seen by the production of Granzyme B. SF CD141 DC also induce TNF α , IFN γ and GM-CSF from CD4 T cells. Finally, synovial fibroblasts play a key role in mediating damage in the RA joint; therefore we examined the effect of this CD141-T cell interaction on fibroblast activation. Supernatants from CD141 activated T cells were cultured with fibroblasts & induced expression of the adhesion molecule ICAM-1

Conclusions The novel DC population, CD141 DC are significantly enriched in the RA joint & display heightened expression of activation markers compared to their blood counterparts. These cells are capable of inducing both CD4 & CD8 T cell responses and can subsequently activate synovial fibroblasts. This data suggests that CD141 DC may orchestrate a number of inflammatory processes that can occur in the inflamed joint.

Image 1



Young Investigator Award 2016

DR AMANDA EAKIN (16A173)

Association of CD169 Positive Monocytes with Disease Activity in Rheumatoid Arthritis

Author(s) Eakin AJ¹, McGeough CM¹, Ahmed T¹, Alexander HD¹, Wright GD², Small D³, Gardiner PV³, Bjourson AJ¹, Gibson DS¹

Department(s)/Institutions 1. Ulster University, Northern Ireland Centre for Stratified Medicine, Altnagelvin Hospital, Londonderry, BT47 6SB, United Kingdom. 2. Department of Rheumatology, Musgrave Park Hospital, Belfast, United Kingdom. 3. Department of Rheumatology, Altnagelvin Hospital, Londonderry, United Kingdom.

Introduction CD169 (Siglec-1) is expressed by monocytes and has been shown to correlate with disease activity in RA patients [1]. This cell-surface protein drives pro-inflammatory processes including the suppression of Tregs through its cognate ligand (CD169-L). The suppression of Tregs leads to loss of control in the immune response as it prevents damage-causing effector T cells from being reduced.

Aims/Background

Treatment of RA includes small molecule DMARDs, which have immunosuppressive and anti-inflammatory mechanisms. 30% of patients have no response to traditional DMARDs for unknown reasons [2]. Additionally, patients starting on DMARD therapy undergo a three month treatment regimen before response is determined. This pilot study investigates the relationship between CD169 and CD169-L density on peripheral cells and disease activity.

Method Peripheral blood mononuclear cells (PBMCs) were isolated from RA patients (ACR diagnosis criteria fulfilled) who have failed DMARD treatment (n=9) and healthy controls (n=9) using Ficoll density gradient separation. FACS was used to both immunophenotype and isolate CD169 positive (+ve) monocytes and CD169-L +ve Tregs using five and eight colour antibody panels, respectively. Isolated CD169 and CD169-L +ve cells were stored for downstream qPCR and analysis of proteins including FoxP3 and TNF- α .

Results RA patients have monocytes with significantly higher median fluorescence intensity (MFI) of CD169 compared to healthy controls (1441.6 ± 1201.1 vs 198.0 ± 87.3 , (mean \pm SD), $p < 0.01$). Also, the MFI of CD169-L +ve Tregs is significantly decreased in RA patients relative to healthy controls (1395.3 ± 345.6 vs 3797.6 ± 863.6 , $p < 0.01$). FACS data indicates FoxP3, an intracellular transcription factor of Tregs, is expressed at lower levels in RA patients compared with healthy controls. A positive association was observed between increased CD169 MFI and DAS28-ESR, whereas the opposite was true for CD169-L MFI and DAS28-ESR.

Conclusions CD169 plays a significant role in autoimmune disease [3] and here we show its elevation in patients with high disease activity. The CD169 counter receptor, CD169-L is significantly reduced in RA compared to health. Low levels of FoxP3 in RA patients indicates reduced Treg activation, which may subsequently lead to increased disease activity. We postulate that this balance of cells is key in the immune response and could be a surrogate measure of disease activity.

References 1. Xiong YS, Cheng Y, Lin QS, Wu AL, Yu J, Li C, Sun Y, Zhong RQ, Wu LJ: Increased expression of Siglec-1 on peripheral blood monocytes and its role in mononuclear cell reactivity to autoantigen in rheumatoid arthritis. *Rheumatology (Oxford)* 2014, 53(2):250-259. 2. Lopez-Olivo MA, Siddhanamatha HR, Shea B, Tugwell P, Wells GA, Suarez-Almazor ME: Methotrexate for treating rheumatoid arthritis. *Cochrane Database Syst Rev* 2014, 6:CD000957. 3. Eakin AJ, Bustard MJ, McGeough CM, Ahmed T, Bjourson AJ, Gibson DS: Siglec-1 and -2 as potential biomarkers in autoimmune disease. *Proteomics Clin Appl* 2016, 10(6):635-644.



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Abstract No	Author(s)	Abstract Title	Time
Oral Presentations - Basic Science			
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(16A147) Abstract 1 Oral Presentation 1 (Basic Science)

High prevalence of seropositivity for anti-MCV antibodies in a population of adult Irish Early RA patients: An association between anti-CCP and/or anti-MCV status and clinical decision making

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Department(s)/Institutions: 1. Mater Misericordiae Hospital, Dublin 7. 2. South Infirmery Victoria University Hospital, Cork. 3. Cork University Hospital, Cork. 4. St. Vincent's Hospital, Dublin 4. 5. AbbVie Ireland Ltd.

Introduction: In RA patients, early intervention with disease modifying anti-rheumatic drugs (DMARD) reduces disease progression and is associated with clinical remission. Antibodies to cyclic citrullinated peptide (anti-CCP) and, to a lesser extent, mutated citrullinated vimentin (anti-MCV) in patients with undifferentiated inflammatory arthritis are predictive of disease progression. The proven efficacy of available treatment strategies has led to an emphasis on early diagnosis of rheumatoid arthritis (RA).

The presence of rheumatoid factor (RF), anti-CCP and anti-MCV are considered important diagnostic criteria in early RA. A better understanding of their prognostic significance is needed to better identify patients with early RA at risk of developing an aggressive disease. The prevalence of anti-MCV in an Irish RA population is unknown.

Aims/Background:

- Describe the prevalence of anti-MCV in an Irish RA population
- Assess the association of anti-MCV with RF and anti-CCP in this population.
- Assess the impact of known anti-CCP and anti-MCV status on management of patients.

Method: Multi-centre, observational study of patients diagnosed with RA (within the year prior to the baseline visit) in an Irish rheumatology setting. 35 patients were enrolled. Patients had a baseline, 6 month and 12 month visit, and were included in the study if they were 18 years or older and had a clinical diagnosis of RA with evidence of disease activity within the past year. Patient's also needed to have a known anti-CCP status to be included.

Results: This study demonstrated a high prevalence of 74.2% (95% CI 55.4%, 88.1%) for anti-MCV (n=31, positive result n=23, negative result n= 8) and 91.4% (95% CI % (76.9%, 98.2%) for anti-CCP antibodies (n=35, positive result n=32, negative result n = 3) in adult Irish RA patients. The association between anti-CCP and anti-MCV status was statistically significant and suggests a moderate agreement.

A statistically significant association between the anti-CCP or anti-MCV results and clinical decision making was observed. Physicians ranked the importance of the anti-CCP result on their decision on how to manage these patients as significant, and anti-MCV as moderate or significant.

A higher ranking of the importance of the anti-MCV result on clinical decision making at baseline was associated with a lower number of swollen joint counts in anti-MCV positive patients compared to anti-MCV negative patients.

Conclusions: This study confirmed a high prevalence for anti-MCV & anti-CCP antibodies in adult Irish RA patients

A statistically significant association between the anti-CCP or anti-MCV results and clinical decision making was observed.

A higher ranking of the importance of the anti-MCV result on clinical decision making was associated with a lower number of swollen joint counts in anti-MCV positive patients compared to anti-MCV negative patients. Confirmation of whether the ranking of anti-MCV importance affects this variable and the mechanism for that interaction would require further study but suggests that awareness of the significance of anti-MCV positive status may be important for clinical decision making in RA patients.

(16A158) Abstract 2 Oral Presentation 2 (Basic Science)

The Ratio of Serum soluble CD23:BAFF is Associated With Relapse After Rituximab in ANCA Associated Vasculitis

Author(s): Len Harty¹, Rona Smith¹, Seerapani Gopaluni¹, Maria Leandro², Geraldine Cambridge², David Jayne¹

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Introduction: B cell depletion with rituximab (RTX) induces remission in 95% ANCA associated vasculitis (AAV) patients (pts). However it is costly and there is the risk of developing hypogammaglobulinaemia. Myeloperoxidase (MPO) & proteinase 3 (PR3) AAV have overlapping genetic associations, clinical presentations and prognoses but PR3-AAV patients relapse more frequently than MPO-AAV, particularly with return of anti-PR3 but this is inconsistent for relapse prediction. CD23 is an IgE receptor and is shed as soluble CD23 (sCD23) from B cells upon maturation to memory status. Serum B-cell activating factor (BAFF) levels depend on relative binding to it's receptors and is thus related to B cell numbers. In humans, BAFF primarily functions as a survival factor for naïve B cells.

Aims/Background: To determine whether serum sCD23 and BAFF are differentially expressed in MPO and PR3-AAV pts before and after induction of remission with RTX and if there is an association with relapse.

Method: 138 serum samples (36 samples from 11 AAV pts who relapsed and 90 samples from 24 remaining in remission) were available at multiple time points pre- and post RTX with longitudinal clinical follow up. Serum CD23 and BAFF were measured by ELISA with post RTX assays performed at median 56 weeks (24-76). Results were analysed using non-parametric statistical methods and confidence intervals calculated for any associations (CI's).

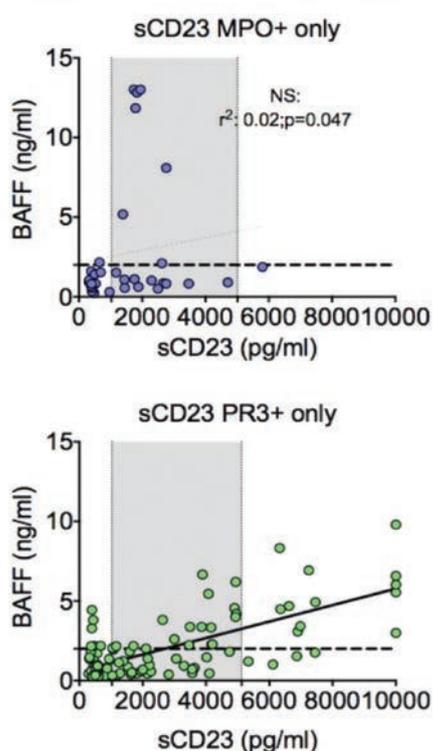
Results: 39 pts (59% male), median age 63 yrs (53-65) with active AAV (72% PR3, 23% MPO, 5% ANCA negative) were included. Both pre RTX baseline sCD23 (2155 pg/ml (1284-3637) v 1084 pg/ml (529-1441)) and BAFF (1.2 ng/ml (0.5-2.3) v 0.6 ng/ml (0.3-1.1)) were higher in PR3 than MPO-AAV pts respectively with active disease. PR3-AAV pts who relapsed had higher post RTX serum sCD23 (2891 pg/ml (578-4904) v (1813 pg/ml (1046-3496)) but lower BAFF levels (1 ng/ml (0.7-3) v 1.8 ng/ml (1.3-2.2)) than those remaining in remission. Conversely MPO pts who relapsed had lower sCD23 levels (563 pg/ml (328-1880) v 2561 (1759-3470)) and higher BAFF levels (1.4 ng/ml (0.9-5.2) v 1 (0.8-1.5)) than those remaining in remission. sCD23 increased with time from RTX and was strongly associated with total B-cell numbers (r=0.7, p<0.01) in PR3 pts who relapsed only. sCD23 correlated positively with BAFF post RTX (r=0.6,



$p < 0.01$) in PR3- but not MPO-AAV pts (Fig 1).

Conclusions: Pts with active PR3-AAV have higher serum sCD23 and BAFF levels than active MPO AAV at baseline. High serum sCD23 with low BAFF in PR3 pts and low sCD23 with high BAFF in MPO pts within 1 yr after RTX was associated with relapse. sCD23 increased with B cell repopulation in PR3-AAV pts who relapsed. BAFF and sCD23 were positively correlated in PR3 pts after RTX yet BAFF but not in MPO patients. Contrasting expression of these soluble markers may reflect differential pathogenic pathways of B cell biology in MPO and PR3-AAV pts and may prove useful in stratifying therapeutic regime design.

Image 1 Figure 1. Serum CD23 associates with BAFF after RTX in PR3 but not MPO AAV



(16A105) Abstract 3 Oral Presentation 3 (Basic Science)

Changing Trends In The Incidence Of Hip And Other Osteoporotic Type Fractures In Ireland

Author(s): M.S. Kelly¹, B. McGowan¹, M. McKenna², K. Bennett³, B. Whelan^{1,4}, C. Silke¹.

Department(s)/Institutions: 1. The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim, Ireland, 2. St. Vincent's University Hospital, Dublin, Ireland, 3. Dept of Population Health, The Royal College of Surgeons, Dublin 1. 4. The Department of Medicine, NUIG

Introduction: Recent studies have indicated a possible reversal of the secular trend of fractures in many countries across Europe and the USA. Previously, we reported a continuous increase in the incidence of all osteoporotic type fractures in Ireland between 2000 and 2009 with a decrease in the age standardised rates with the exception of the 55-59 year age group[1].

Aims/Background: The aims of the study were to continue the trend analyses from 2009 onwards of all hospitalisations for osteoporotic-type fractures in males and females aged 50 years

and over in Ireland between 2010 and 2014. A second objective was to project the number of hip fractures in the Republic of Ireland expected by 2046 based on the 2014 incidence data

Method: Age- and gender-specific trends in the absolute numbers and direct age-standardised rates of hospitalisations for all osteoporotic-type fractures in men and women ≥ 50 years were analysed along with the associated length of stay using the Hospital In-Patient Enquiry system database. Future projections of absolute numbers of hip fractures in years 2021, 2031, 2041 and 2046 were computed based on the 2014 incidence rates applied to the projected populations.

Results: Between 2010 and 2014, the absolute numbers of all osteoporotic-type fractures decreased by 0.4% in females and by 3.9 % in males while the absolute numbers of hip fractures increased by 0.2% in women but decreased by 12.8% in males. The age-standardised rates for hip fractures decreased in all age groups in both females and males with the exception of males 85 years and older who showed a 1.8% increase. Assuming stable age-standardised incidence rates from 2014 over the next 30 years, the number of hospitalisations for hip fractures is projected to increase 3 fold from 4,301 in 2014 to 12,708 in 2046. 50% of these hip fracture patients in 2046 will be in the 85 or older age group, increasing from 36% in 2014.

Conclusions: In contrast to the results of previously published studies on trends in fracture incidence in Ireland [1] the present study identified a stabilising of the trends in the number of hospitalisations for osteoporotic-type fractures in Ireland since 2010. The incidence of hospitalisation for hip fractures decreased by 12.8% in males. The age standardised rates in both women and men also fell with the exception of men aged 85 years. The declining trends may be partly explained by the specific measures taken in recent years in falls prevention in at risk groups and the heightened awareness of osteoporosis in general in Ireland.

1. McGowan B , Casey MC, Silke C, Whelan B, Bennet K. Hospitalisations for fracture and associated costs between 2000 and 2009 in Ireland: a trend analysis Osteoporosis International March 2013, Volume 24, Issue 3, pp 849-857

(16A151) Abstract 4 Oral Presentation 4 (Basic Science)

Decreased Expression of miR-125 in PsA Synovium Drives Joint Angiogenesis.

Author(s): Sarah Wade, Nils Ohnesorge, Monika Biniecka, Trudy McGarry, Carl Orr, Breandán Kennedy, Douglas Veale, Ursula Fearon

Department(s)/Institutions: Centre for Arthritis and Rheumatic Diseases, St. Vincent's University Hospital, Dublin, Ireland. University College Dublin Trinity College Dublin

Introduction: Psoriatic Arthritis (PsA) is a chronic immune-mediated inflammatory disease, characterised by proliferation of synovial tissue and destruction of articular cartilage/bone with associated psoriasis. Dysregulated angiogenesis is a key early pathogenic event in PsA which potentiates disease processes. These processes may be governed by microRNA (miRNA), a class of evolutionary conserved short non-coding RNAs, which function as post-transcriptional repressors of gene expression. On such miRNA is miR-125, which has been previously associated with altered angiogenic, invasive and migratory processes. To date microRNA have been poorly investigated in PsA.



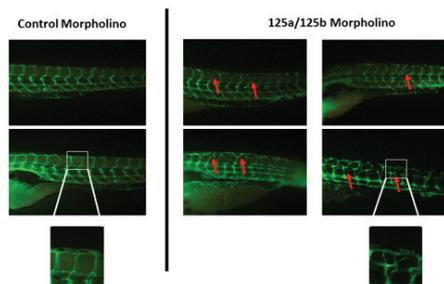
Aims/Background: To examine the expression and angiogenic associations of miR-125 in PsA.

Method: Synovial tissue biopsies, fibroblasts like synoviocytes (FLS), synovial fluid and PBMC were obtained from patients with PsA. MiR-125 levels were analysed by real-time PCR. Endothelial cells (HMVEC) were cultured in the presence of microRNA treated FLS supernatant to elucidate how microRNA regulates FLS angiogenic processes. Matrigel tube formation assays were performed to elucidate angiogenic functions. Synovial vasculature, determined by immunohistochemistry and RT-PCR, was compared microRNA expression. Clinical markers, including synovitis, vascularity, ESR, CRP, DAS28, ascertained at the time of arthroscopy, were correlated with synovial miRNA expression. The angiogenic function of miR-125 was confirmed *In vivo* using GFP tagged zebrafish.

Results: Expression of miR-125 was significantly decreased in PsA synovial biopsies compared to OA. MiR-125 levels were lower in SF mononuclear cells compared to peripheral blood, further supporting a decreased expression of miR-125 at the site of inflammation. Decreased expression of miR-125a in HMVEC displayed increased tube formations. Similarly, decreased expression of miR-125a in PsA FLS increased the ability of HMVEC to form tube networks. Synovial expression of miR-125 distinguished patients according to joint vascularity. Zebrafish treated with a morpholino designed to inhibit miR-125 displayed increased vascular sprouting just 5 days following treatment.

Conclusions: Our data demonstrates decreased expression of miR-125a in the joint of PsA patients and was strongly associated with joint vascularity and angiogenic mechanisms. This highlights the potential role of miR-125 in mediating key pro-angiogenic and thereby pro-inflammatory mechanisms in the synovium. Correcting these microRNA deficiencies, either by conventional pharmacological agents or as novel drug targets, or monitoring their expression may provide a therapeutic benefit especially in early disease stages.

Image 1



(16A164) Abstract 5 Oral Presentation 5 (Clinical Science)

Behçet's disease in Ireland: Prevalence, Clinical Manifestations, and Management.

Author(s)

Fahd Adeeb^{1,2}, Austin Stack^{2,3}, Alexander Fraser^{1,2}

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Introduction: Behçet's disease (BD) was originally seen along the Silk Route and first described by a Turkish Professor, Hulusi Behçet in 1937. While having its highest prevalence in the

Mediterranean (highest reported 370:100 000 population in Turkey) and Far East, BD is not commonly seen in Northern Europe population (varies between 0.64 to 4.9/100 000 population). Ireland is the twentieth largest island in the world and lies on the European continental shelf in the periphery of the Northwest of Europe. Being an island nation, Ireland remained a genetically pure population with a high degree of ethnic homogeneity for many years.

Aims/Background: The aim of this review is to look at the prevalence, clinical characteristics and previous & current management of BD in the catchment area of Limerick, North Tipperary and Clare in the Midwest Region of Ireland (population 390 000).

Method: Patients meeting the ISGBD and ICBBD criteria for BD were identified from our institutional database. A retrospective analysis was performed and a proforma was completed based on patients' demographic data, clinical characteristics, type and frequency of clinics attended, and patients' current and previous treatments.

Results: 22 patients (16 female, 6 male) of Irish descent were identified satisfying the diagnosis for BD. The point prevalence of BD on 1st of August 2016 was 5.64:100 000 population. The commonest clinical manifestation of BD patients in our cohort that occurred at any point during the course of the disease is oral ulcers (100%); followed by genital ulcers (90.9%) and skin lesions (90.9%), arthralgia/arthritis (45.5%), ocular manifestations (31.8%), vascular thrombosis (13.6%) and pathergy phenomenon (9.1%). 18 patients (81.9%) were on anti-TNF biologics, 11 (50%) maintained on long-term low oral steroid doses, and one remained on conventional immunosuppressant as a combination therapy in the form of methotrexate 15mg weekly. Previous unsuccessful immunosuppressant therapies among our patients include methotrexate in 3 patients, azathioprine in 7 patients, cyclosporine in 2 patients, and thalidomide and mycophenolate mofetil in 1 patient each (a patient may have been on more than one conventional immunosuppressant at different times). The time a patient was on conventional immunosuppression before a different immunosuppressant was used or an anti-TNF was added was 1 to 2 years. A long-term multidisciplinary approach involving rheumatologist, dermatologist, otolaryngologist, specialist nurses and general practitioners were seen in majority of patients.

Conclusions: The prevalence of BD in Ireland is higher than previously reported in the region, consistent with current literature that the prevalence is gradually increasing globally. Its management requires long-term multidisciplinary involvement. No patients on conventional DMARDs alone achieved full remission. The percentage of our BD patients treated with anti-TNF is higher compared to other countries and we acknowledge that it is an important alternative option in patients with resistant, severe, or life-threatening manifestations.

(16A175) Abstract 6 Oral Presentation 6 (Clinical Science)

Glycoprotein VI: A Potential Target for Antibody-Mediated Platelet Activation in Rheumatoid Arthritis?

Author(s): J Stack¹, A Madigan¹, L Helbert¹, N Redmond¹, E Dunne², D Kenny², GM McCarthy¹

Department(s)/Institutions: 1. Mater Misericordiae University Hospital 2. Royal College of Surgeons of Ireland



Introduction: The importance of platelet activation in rheumatoid arthritis (RA) pathogenesis is increasingly recognised. A number of auto-antibodies including anti-citrullinated protein antibodies (ACPA) have been shown to cause platelet activation in vitro, through the low-affinity immunoglobulin G (IgG) receptor (FcγRIIa) on platelets. Platelet activation via engagement of FcγRIIa results in proteolytic cleavage and shedding of platelet specific glycoprotein VI (GPVI) which can be detected in the plasma as soluble GPVI (sGPVI).

Aims/Background: We hypothesized that plasma levels of sGPVI would be increased among patients with seropositive RA as a consequence of antibody-induced platelet activation and GPVI shedding.

Method: Samples from 84 patients with RA (65 seropositive and 19 seronegative) and 67 healthy controls were collected prospectively and analysed for sGPVI using a standardised ELISA. Characteristics of seropositive vs seronegative RA are presented in Table 1. Mann-Whitney U test and Kruskal-Wallis test was used to compare groups. Spearman's Rank Correlation Coefficient was used to assess for associations between sGPVI levels and demographic and clinical markers.

Results: Patients with seropositive RA had significantly higher levels of sGPVI compared to seronegative RA and controls. Median (IQR) sGPVI levels were 4.2 ng/ml (3.2, 8.0) in seropositive RA, 2.2 ng/ml (1.5, 3.5) in seronegative RA and 2.2 ng/ml (1.6, 3.4) in controls ($p < 0.0001$) (See Fig 1). sGPVI levels correlated with ACPA titres ($r = 0.32$, $p = 0.0026$) and with RF titres ($r = 0.48$, $p < 0.0001$).

Conclusions: Plasma sGPVI, a specific marker of platelet activation is increased among patients with seropositive RA, providing further in vivo evidence that the GPVI pathway is involved in antibody-mediated platelet activation in humans.

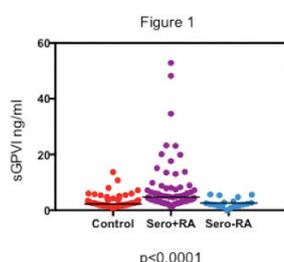
Image 1

Table 1 Characteristics of Patients with Seropositive RA vs Seronegative RA

	Sero + RA	Sero - RA	P value
Total Number	65	19	
Female, n (%)	51 (78)	16 (84)	ns
Male, n (%)	14 (21)	3 (15)	ns
Age, yr (median [IQR])	62 [54-71]	48[38-64]	0.01
CRP, mg/l (median [IQR])	8 [4-15]	6 [2-21]	ns
ESR, mm/hr (median [IQR])	21 [11-32]	13 [7-38]	ns
Fibrinogen g/l (mean +/- SEM)	3.33 +/- 1.12	4.06 +/- 1.92	ns
Platelet Count x 10 ⁹ (mean +/- SEM)	281 +/- 98	285 +/- 81	ns
DAS28-CRP (Mean +/- SEM)	3.83 +/- 1.49	4.37 +/- 2.2	ns
RF titre	81 [20-271]	2.3 [1.5-4.7]	<0.0001
CCP titre	212 [100-340]	2.1 [1.1-3.6]	<0.0001

RA rheumatoid arthritis, CRP c-reactive protein, ESR erythrocyte sedimentation rate, DAS28 Disease Activity Score in 28 joints, RF rheumatoid factor, CCP citrullinated c-protein, IQR interquartile range, SEM standard error of the mean, ns not significant.

Image 2



(16A124) Abstract 7 Oral Presentation 7 (Clinical Science)

Exercise significantly improves cardiorespiratory fitness and reduces disease-related fatigue without any adverse effects on disease activity in systemic lupus erythematosus: A systematic review with meta-analysis.

Author(s): Tom O'Dwyer¹, Laura Durcan², Fiona Wilson¹

Department(s)/Institutions: 1 Discipline of Physiotherapy, Trinity College, Dublin. 2 Division of Rheumatology, University of Washington, Seattle.

Introduction: Systemic lupus erythematosus (SLE) associates with accelerated mortality, frequently attributable to cardiovascular (CV) causes, which is not fully explained by traditional CV risk factors. Individuals with SLE are commonly sedentary with many perceived barriers to exercise. Physical inactivity likely contributes to the burden of CV risk and may also be a significant factor in co-morbid chronic fatigue, poor sleep and fibromyalgia.

Aims/Background: This meta-analysis evaluates whether exercise has a deleterious effect on disease activity in SLE, and assesses the impact of exercise on cardiorespiratory fitness and fatigue.

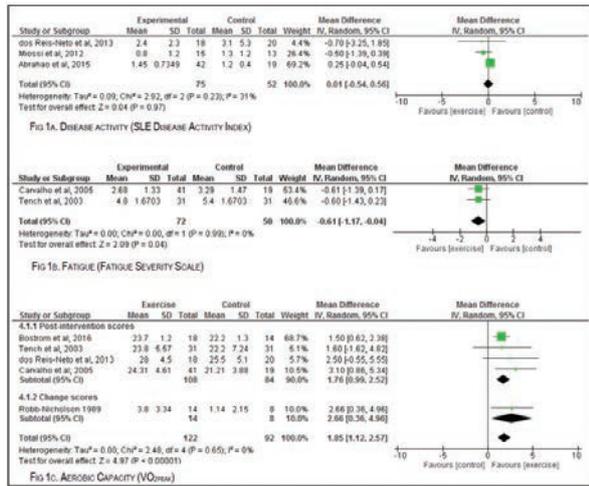
Method: A systematic review and meta-analysis was conducted, including quasi-randomised and randomised controlled trials in SLE comparing at least one exercise group to controls. Studies were retrieved by searching MEDLINE/PubMed, EMBASE, PEDro, AMED, CINAHL and The Cochrane Central Register of Controlled Trials for keywords and medical subject headings relating SLE and exercise. Relevant conference abstracts and reference lists of included studies were manually searched. Two reviewers independently determined study eligibility and assessed risk of bias (Cochrane Risk of Bias tool). Data were extracted using a standardised template. Random-effects meta-analyses were used to pool extracted data as mean differences (MD). Heterogeneity was evaluated with Chi² test and I², with p -values < .05 considered significant.

Results: The search strategy produced 2980 records. Titles and abstracts screening identified 30 full-texts for eligibility appraisal. Of these, seven were suitable for inclusion in the meta-analyses. Studies included 178 participants and 125 controls; mean age ranged from 31.2 to 52.9 years, and disease duration from 2.5 to 17.9 years. Median (IQR) duration of the interventions was 12 (0) weeks. All interventions included aerobic components, and three also included strength training. There was a high risk of bias relating to blinding of participants and personnel; remaining domains were largely under-reported, with the overall risk of bias unclear. Fig. 1 summarises meta-analyses results. Disease activity was not significantly changed following exercise interventions (MD 0.01; 95% CI, -0.54 to 0.56). Fatigue (MD 0.61; 95% CI, 0.04 to 1.17) and aerobic capacity (MD 1.85 ml/kg/min; 95% CI, 1.12 to 2.57) were significantly improved.

Conclusions: This meta-analysis demonstrates that exercise significantly improves cardiorespiratory fitness and disease-related fatigue in individuals with SLE, without adversely affecting disease activity. This review suggests that exercise may be safely prescribed in this population. Longitudinal studies examining the effects of exercise on CV risk factors in this population are recommended based on the promising findings of this meta-analysis.



Image 1



(16A131) Abstract 8 Oral Presentation 8 (Clinical Science)

Long Term Efficacy of Ustekinumab for the Treatment of Giant Cell Arteritis

Author(s): Richard Conway, Lorraine O'Neill, Phil Gallagher, Eileen O'Flynn, Geraldine M. McCarthy, Conor C Murphy, Douglas J. Veale, Ursula Fearon, Eamonn S. Molloy

Department(s)/Institutions: Centre for Arthritis and Rheumatic Diseases, Dublin Academic Medical Centre, St Vincent's University Hospital, Dublin, Ireland. University College Dublin, Ireland. Department of Molecular Rheumatology, Trinity College Dublin, Ireland. Royal Victoria Eye and Ear Hospital, Dublin, Ireland. Mater Misericordiae University Hospital, Dublin, Ireland

Introduction: Giant cell arteritis (GCA) requires treatment with high dose corticosteroids with attendant significant adverse events. There is a critical need for alternative therapies. Interleukins 12 (IL-12) and 23 (IL-23) stimulate Th1 and Th17 responses respectively, both hypothesized to be important in GCA pathogenesis.

Aims/Background: We have recently reported preliminary evidence of efficacy of IL-12/23 blockade with ustekinumab in 14 GCA patients. In this study we report outcomes in a larger cohort of 25 patients.

Method: We performed a prospective open label study of ustekinumab in patients with refractory GCA. Ustekinumab was administered subcutaneously at a dose of 90mg at week 1 and week 4 followed by every 12 weeks. Patients underwent standardized clinical assessments. Disease activity was based on a combination of clinical assessment, acute phase reactants (ESR, CRP) and available imaging studies. Descriptive statistics were reported as mean and standard deviation (SD), median and interquartile range (IQR) or number (n) and percentages as appropriate, Wilcoxon Signed Rank test was used to compare between group differences. Statistical significance was set at p<0.05. All patients gave written informed consent and ethical approval obtained.

Results: 25 patients commenced ustekinumab having failed to taper corticosteroids and a median of 1 other immunosuppressant, with a median (IQR) of 2 (1, 3) prior relapses of GCA. 84% had experienced significant corticosteroid side effects. Full demographic and clinical details are shown in Table 1. Median (IQR) duration of ustekinumab treatment at last

follow-up was 15 (6, 22) months. Efficacy outcomes are detailed in Table 2. Median (IQR) steroid dose decreased significantly from 15mg (5, 20) to 5mg (3.8, 10) (p=0.002). 7 patients with large vessel vasculitis had follow-up imaging performed with improvement of wall thickening in all and no new stenoses or aneurysms. No patients experienced a relapse of GCA during ustekinumab treatment. 11 adverse events were recorded, 2 respiratory tract infections, and 1 case each of pancreatitis with infected pseudocyst, bell's palsy, thyroid goitre, alopecia, parasthesia, tinea pedis, urinary tract infection, dental abscess, and cold extremities. 3 patients discontinued ustekinumab due to adverse events or personal preference, 2 subsequently had flares of polymyalgia rheumatica.

Conclusions: Ustekinumab led to significant reductions in steroid dose and acute phase reactants in patients with refractory GCA. The efficacy of ustekinumab in GCA warrants investigation in a randomized controlled trial.

Image 1

Table 1: Characteristics and prior treatment of 25 GCA patients treated with ustekinumab

Age, years, mean (SD)	70 (7.3)
Female, n (%)	20/25 (80)
Met 1990 ACR criteria for GCA, n (%)	21/25 (84)
Biopsy positive, n (%)	19/25 (76)
Temporal Artery Ultrasound positive, n (%)	6/18 (33)
CT Angiogram positive, n (%)	9/13 (69)
Cranial-Ischaemic complications, n (%)	5/25 (20)
Vasculitis Damage Index, median (IQR)	1 (0, 2)
Charlson co-morbidity index, median (IQR)	1 (1, 2)
Disease duration, months, median (IQR)	29 (11.5, 36.5)
Relapses, median (IQR)	2 (1, 3)
Clinical presentation at last relapse	
Cranial, n (%)	10 (40)
Polymyalgia rheumatica, n (%)	8 (32)
Constitutional, n (%)	9 (36)
Large vessel vasculitis, n (%)	9 (36)
Prior treatment	
Glucocorticoids, n (%)	25 (100)
Glucocorticoid adverse events, n (%)	21 (84)
Other immunosuppressant, n (%)	17 (68)
Other immunosuppressant's failed, median (range)	1 (0, 1)
Methotrexate, n (%)	16 (64)
Duration methotrexate, months, median (IQR)	15 (3.5, 44.5)
Dose methotrexate, mg/week, median (IQR)	20 (13.8, 20)
Azathioprine	3 (12)
Leflunomide	1 (4)
Adalimumab	1 (4)



Image 2

Table 2: Outcome measures pre-ustekinumab and at last follow-up (median follow-up of 15 months (range 6-22) after initiation of ustekinumab.)

Outcome	Pre-ustekinumab	Last follow-up	p-value
Prednisolone dose, mg, median (IQR)	15 (5, 20)	5 (3.8, 10)	0.002
ESR, mm/hr, median (IQR)	29 (11, 43)	12 (8, 20)	0.020
CRP mg/L, median (IQR)	12.9 (5.3, 42)	4.5 (2, 14)	0.001
BVAS, median (IQR)	1 (0, 2)	0 (0, 0)	<0.001
Stopped glucocorticoids, n (%)	-	5 (20)	-
Stopped other immunosuppressant, n (%)	-	15 (94)	-

IQR, interquartile range; ESR, erythrocyte sedimentation rate, normal range 0-30 mm/hr. CRP, C Reactive protein, normal range 0-5 mg/L.

(16A101) Abstract 9

Poster 1

Does use of ultrasound in the rheumatology department reduce requests for imaging by radiology?

Author(s): Claire Masih, Elizabeth Ball

Department(s)/Institutions: Department of Rheumatology, Musgrave Park Hospital, Belfast

Introduction: Musculoskeletal ultrasound is a widely accepted part of patient assessment by rheumatology and is used routinely within the Belfast rheumatology group. Previous audits have demonstrated benefit in terms of diagnostic accuracy, improved injections and patient satisfaction with low costs and avoidance of radiation.

Aims/Background: The rheumatology department in Musgrave Park Hospital consisting of 6 Consultant teams, 5.5 Registrars and 1 Specialty doctor was surveyed for their use of ultrasound in routine practice.

Method: This covered outpatient clinics, joint injection clinics, rheumatology inpatients, day ward attenders and on-call referrals over a 4 week period. We had a particular interest in seeing if ultrasound avoided the need for requests for departmental imaging by radiology, with implied financial savings.

Results: One-hundred and twenty-four scans were recorded. This reflects an underestimate of numbers of scans undertaken as outpatient clinics operate over three separate sites with audit returns only being complete in two sites and a rheumatology conference taking place during the period audited. Most patients were in the 50-69yr age group with 66% female. Hand/wrist was the most common area scanned. Diagnoses reflected the rheumatology population with seronegative arthritis, rheumatoid arthritis, osteoarthritis and patients with no prior diagnosis featuring prominently.

In nearly all cases ultrasound was reported by the operator to influence the management, in areas such as diagnosis, judging severity and aiding injections. Operators explained the ultrasound findings in nearly all cases and felt ultrasound improved the patients' understanding of their conditions. In more than half of cases when ultrasound was used the operators felt without ultrasound they would have requested

further imaging, particularly departmental ultrasound scans (22) or MRI scans (33), as well as Xrays (11). With the use of ultrasound in fact only 6 MRI scans were requested and no departmental ultrasound scans.

Conclusions: This implies clear benefits with the use of clinic-based ultrasound, avoiding the need for 22 departmental ultrasound scans and 27 MRI scans in a 4 week period with obvious benefit for waiting times and costs. These findings are in keeping with other studies on clinic-based ultrasound in rheumatology¹, including estimation of reduced costs². Costs to the health trust are estimated at £194 per basic MRI scan and £51 for ultrasound scans.

(16A104) Abstract 10

Poster 2

Sarcopenia – How significant a problem is it in patients with newly diagnosed rheumatoid arthritis?

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Introduction: The European Working Group on Sarcopenia in Older People (EWGSOP) defines sarcopenia as a progressive and generalised loss of skeletal muscle mass and strength. It is quantified as appendicular skeletal mass divided by height squared (ASM/H^2) and considered present if the calculated skeletal muscle mass index (SMI) is two standard deviations below the mean for young adults as based on the Rosetta study. The cut-off points for sarcopenic muscle mass are SMI of $<7.26 \text{ kg/m}^2$ for males and $<5.5 \text{ kg/m}^2$ for females. The cut-off points for sarcopenic muscle strength are handgrip strength of $<30 \text{ kg}$ for males and $<20 \text{ kg}$ for females. Inflammatory cytokines, especially $TNF-\alpha$, play a vital role in the pathogenesis of both rheumatoid arthritis (RA) and sarcopenia. Elevated $IL-1\beta$ and $TNF-\alpha$ levels increase patients' risk of sarcopenia in RA. Studies have shown increased incidence of sarcopenia in patients with RA.

Aims/Background: To identify the incidence and stages of sarcopenia in patients with newly diagnosed RA

To compare the incidence of sarcopenia in the newly diagnosed RA patient group with the incidence in the established inflammatory arthritis (IA) patient group

To identify the incidence of sarcopenia in patients with established IA being treated with and without biologic therapy

Method: Patients with newly diagnosed RA (N=81) attending the NWRU were invited to participate in a study analysing total body composition, muscle function and quality of life. In a separate database of patients with established IA (N=58), the incidence of sarcopenia was identified using the same EWGSOP criteria. The established IA group was further categorized based on their use of biologic therapy. Additional relevant information, such as age, weight, percentage tissue fat, and number of comorbidities, were noted. All data were analysed using SPSS version 22.0.

Results: In total, 14 (17.3%) males and 12 (14.8%) females in the newly diagnosed RA patient group were identified with sarcopenia based on the EWGSOP criteria. Within the



established IA group, 5 (8.6%) males and 16 (27.6%) females were sarcopenic. There were 9 (11.1%) pre-sarcopenic and 17 (21.0%) sarcopenic patients in the newly diagnosed RA group. There was no significant difference between the incidences of sarcopenia in patients with established IA being treated with and without biological therapy ($p=0.622$); however, a trend towards a lower incidence of sarcopenia in those on biologics was found. Pearson's correlation identified a significant positive correlation between weight and the SMI in females with newly diagnosed RA ($p=0.001$).

Conclusions: In conclusion, 26 (18.7%) patients with newly diagnosed RA were identified with sarcopenia using the EWGSOP criteria. While not statistically significant, the incidence of sarcopenia was lower in patients with established IA [21 (15.1%)]. This may be due to the use of biologic medication or due to the inclusion of psoriatic arthritis in the IA group. Substantial evidence suggests that sarcopenia is a reversible cause of disability, and that patients may benefit from interventions if implemented at the early stage. Therefore, prompt screening, assessment, and appropriate management is of the utmost importance.

(16A106) Abstract 11

Poster 3

Delay in Diagnosis of Ankylosing Spondylitis and its effect on prognostic outcomes

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Introduction: Delayed diagnosis is considered to be one of a number of factors affecting the prognostic outcomes in patients with AS. Furthermore it has been identified that AS has the longest diagnostic delay among other rheumatic diseases, i.e. approximately 5-10 years (1).

Aims/Background: to evaluate the effect if any of delay from onset of symptoms to diagnosis of Ankylosing spondylitis on specific outcome measures in patients with ankylosing spondylitis (AS) attending the NWRU.

Method: In collaboration with the Ankylosing Spondylitis Registry of Ireland (ASRI) data on patients attending the NWRU with a diagnosis of AS was routinely recorded on the ASRI database and included in the study analyses. In total 102 patients (92 males (83.6%) and 10 females (9.1%)), mean age 46.41 (± 13.3) were included. The main outcome variable (diagnostic delay) was defined as the interval between onset of first symptoms and diagnosis of AS and was divided into <5 yrs, 6-10 yrs and >10 yrs. Functional status and disease activity were measured using the BASDAI, BASFI, ASQoL and HAQ scores. Spinal and hip mobility were assessed using the Tragus to wall, cervical rotation, chest expansion, schobers test and lumbar flexion measures. The relationship between delay in diagnosis and extra-articular manifestations (EAMs) such as enthesitis, uveitis, dactylitis psoriasis, cardiovascular disease and inflammatory bowel disease were also assessed.

Results: The average time from symptoms to diagnosis was 9.18 yrs (± 9.68). Diagnostic delay between the 3 groups was not significantly correlated with BASDAI mean 4.01 (± 2.46), ($p=0.449$), BASFI mean 3.92 (± 2.75), ($p=.280$), ASQoL mean

6.29 (5.42), ($p=.467$), HAQ mean .605 ($\pm .606$) ($p=.716$). There was no significant correlation identified between delay in diagnosis between the 3 groups and measures of mobility : Tragus-to-wall (cm) mean 19.70 (± 8.36), ($p=.539$), cervical rotation (deg) 45.62 (± 35.32), ($p=.981$), chest expansion (cm) 2.42 (± 1.50), ($p=.923$), schober test (cm) mean 3.28 (± 2.21), ($p=.634$) and lumbar side flexion (cm) mean 11.19 (± 9.17) ($p=.677$). In total 76 (74.5%) of patients were treated with biologics. Furthermore delay in diagnosis did not correlate with the presence of extra-articular manifestations (EAMs) such as enthesitis, uveitis, dactylitis psoriasis, cardiovascular disease and inflammatory bowel disease in this patient group.

Conclusions: In our cohort surprisingly delay in diagnosis of AS was not significantly associated with measures of quality of life, functional status, disease activity in patients attending the NWRU. However further studies with larger numbers may be required to support these findings.

1. Sieper J, Rudwaleit M. How early should ankylosing spondylitis be treated with tumour necrosis factor blockers? *Ann Rheum Dis* 2005;64:61-4.

(16A107) Abstract 12

Poster 4

Seasonal changes in anthropometric characteristics, injury incidence and dietary assessment in senior inter county Gaelic players between 2013 and 2016

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Introduction: Ensuring that senior inter county gaelic players reach optimum physical condition while remaining injury-free throughout the competitive playing season is critical to team performance and results. Optimal body composition and in particular increases in lean mass have been associated with increases in players' speed, strength and agility in certain sporting groups and these changes have also been correlated with a decline in injury occurrence over a competitive playing season.

Aims/Background: To monitor trends in body composition changes, dietary assessment and injury occurrence in a senior inter county gaelic team over a three-year period from 2013-2016. 2) To identify a possible correlation between injury occurrence and body composition changes during the study period.

Method: A repeated measure, prospective longitudinal study over three competitive playing seasons was performed on a senior inter county gaelic men's team between 2013 and 2016 ($n=63$). Body composition analysis was performed using dual X-ray absorptiometry (DXA) scan at the pre and mid-season stages of each playing season. Dietary intake was assessed using the EPIC Norfolk food frequency questionnaire (FFQ) each year. Injury data was routinely collected and recorded by team physiotherapists in The National GAA Injury database.



Results: In total there were 63 players included in the study, mean age 25.83 years (\pm SD 4.21). The number of injuries per player was 1.83 (SD \pm 1.41). Lean mass increased at pre-season from 67.2 kg (SD \pm 6.1) to 67.9kg (SD \pm 6.0) at mid-season a statistically significant increase of 0.67kg (95% CI: 0.25, 1.19) ($t(62)=-3.166$, $p=0.002$) The average lean mass of uninjured players at pre-season 71.14 kg(\pm SD 4.10) was significantly higher than the injured players 65.82 kg (\pm SD 6.18), a statistically significant difference of 5.31(95% CI: 1.98, 8.63) ($t(61)=3.196$, $p=0.002$). There was a moderate negative relationship between lean mass at pre-season and the number of injuries sustained ($r=-0.299$, $p=0.017$) with lean mass accounting for 8.9% of the variability in the number of injuries sustained. The players reported a mean calorie daily intake of 2,215.18 (\pm SD 737.64) which is lower than the recommendations for normal active males aged between 18 and 50 (2400-2800). Reported dietary intake did not correlate with changes in body composition during the study.

Conclusions: The results of this study indicate that lean mass is protective of injury in elite gaelic footballers. Management of teams strive to adapt an appropriate balance of strength and conditioning training and suitable dietary intake of players tailored to optimise players physiological profile. Monitoring of body composition changes over the course of a playing season and identifying recommended values specific to elite gaelic players can provide valuable information for players and management in relation to players physiological response to training regimes and reduction in injury risk. In the non-recommended food groups studies have identified that athletic populations are more likely to under report nutritional intake.

(16A108) Abstract 13

Poster 5

Efficacy And Safety of Baricitinib (Bari) In Patients with Active Rheumatoid Arthritis (Ra) and Inadequate Response (Ir) To Tumour Necrosis Factor Inhibitors (Tnfi): Summary Results From The 24-Week Phase 3 Ra-Beacon Study

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Introduction: Baricitinib (BARI), an oral JAK1/JAK2 inhibitor, improved disease activity with an acceptable safety profile in the phase 3 RA-BEACON study of patients with moderate to severe active rheumatoid arthritis (RA) and inadequate response (IR) to tumour necrosis factor inhibitors (TNFi).

Aims/Background: A summary of efficacy and safety data up to week (wk) 24 in patients with IR/intolerance to ≥ 1 TNFi is presented.

Method: 527 patients with active RA despite previously using ≥ 1 TNFi were randomised to placebo (PBO) or BARI (2 or 4mg,QD). Primary endpoint was wk12 ACR20 (BARI 4mg vs PBO). Subgroup efficacy by prior biologic use, safety, and changes in total lymphocyte count (TLC) and NK-cells are reported.

Results: Wk12 ACR20 was higher with BARI 4mg vs PBO (55% vs 27%; $p\leq 0.001$). Improvements in ACR20/50/70, DAS28-CRP occurred with BARI 4mg (1 prior TNFi) at wk12/wk24; improvements in CDAI;SDAI;HAQ-DI were observed at wk24. A decrease ≥ 0.6 in DAS28 and ≥ 6 in CDAI at wk4 was observed in 79% and 80% of patients on BARI 4mg, respectively, associated with LDA/remission at wk12/wk24. More TEAEs occurred with BARI 2 and 4mg vs PBO, including infections. TLC changes in BARI groups were similar vs PBO at wk12/wk24. There were increases in T-cells, B-cells and NK-cells at wk4, and decreases in T-cells, NK-cells, and an increase in B-cells at wk12/wk24 for BARI groups (all TLC changes within normal range; NK-cell decrease was not associated with increased infection).

Conclusions: BARI showed clinical improvements wk4-wk24 with acceptable safety profile. Wk4 clinical response might predict later LDA/remission.

(16A109) Abstract 14

Poster 6

Efficacy and safety of baricitinib in patients with active rheumatoid arthritis (RA) and inappropriate response (IR) to conventional synthetic disease modifying anti-rheumatic drugs (csDMARDs): summary results from the 24-week phase 3 RA-BUILD study

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Introduction: Baricitinib, an oral JAK1/JAK2 inhibitor, has shown promising results in patients with active RA.

Aims/Background: We present efficacy, safety and patient-reported outcome (PRO) analyses from patients with active RA and IR to csDMARDs in the randomised 24-week phase 3 RA-BUILD study of baricitinib.

Method: Patients with active RA and IR to csDMARDs (N=684) received placebo or baricitinib (2 or 4mg,QD) for 24 weeks. Primary endpoint was ACR20 response at week 12 for baricitinib 4mg vs placebo. Safety and other efficacy analyses were also reported.



Results: Significant improvements in ACR 20/50/70, DAS28-ESR, SDAI remission, HAQ-DI, and faster decreases in morning joint stiffness, worst joint pain and tiredness were seen with baricitinib vs placebo at week 12 and week 24. At week 24, mTSS was reduced with baricitinib 4mg vs placebo. Baricitinib 4mg produced a significant rapid decrease (within 1 week) in DAS28-ESR and CDAI vs placebo. TEAE and SAE rates, including serious infections, were similar among groups. Increases in total lymphocyte count (TLC) including T, B and NK cells at week 4 for baricitinib were within the normal ranges. T-cells and NK-cells decreased and B-cells increased at week 12 and week 24 vs placebo.

Conclusions: Baricitinib 4mg resulted in significant improvement in structural progression and PROs at week 12 and week 24. Safety and infection rates were acceptable regardless of TLC changes.

(16A113) Abstract 15

Poster 7

Development of a Rheumatology Rapid Access Clinic in the Belfast Health and Social Care Trust- report on the pilot phase

Author(s): Maura McCarron, Anne Quinn

Department(s)/Institutions: Rheumatology Department, Belfast Health and Social Care Trust

Introduction: It was recognised that the rheumatology registrars in the Belfast Health and Social Care Trust were experiencing an increasing burden of referrals, frequently from multiple hospital sites. This inevitably resulted in delays for patients, particularly in the Emergency Department. A Rheumatology Rapid Access clinic was thus conceived and piloted from January to March 2016.

Aims/Background: Reduce burden on registrars by redirecting patients who did not need seen immediately. Reduce time spent by patients waiting in Emergency Department for registrar

Method: Rapid access clinic established- staffed by Staff Grade Rheumatologist and Rheumatology Nurse Specialist (RNS). One clinic per week with six slots. On-call registrar filtered referrals and booked appointments via RNS. Once pilot completed all attendances reviewed. Feedback survey completed by registrars.

Results: 9 clinics available, 2 of which had no referrals. 21 patients attended. Diagnoses as follows-

suspected Giant Cell Arteritis- 6	Gout- 3
Pseudogout- 1	Reactive arthritis- 2
New inflammatory arthritis- 3	Baker's cyst- 1
suspected vasculitis- 2	adult onset Stills disease- 1
Raynauds- 1	Pyrexia of unknown origin- 1

Positive feedback from registrars- all requested that clinic would continue after pilot stage.

Conclusions: Overall, the Rapid Access Clinic was a useful addition to our service. There was appropriate filtering of referrals by registrars. Patients preferred to be given a prompt clinic slot to waiting in the Emergency Department. Feedback from registrars was positive. Further technical and administrative support is required moving forward.

(16A114) Abstract 16

Poster 8

Promoting a Culture of Safety and Excellence- Optimisation of the Biologics Unit, Musgrave Park Hospital, Belfast Health and Social Care Trust

Author(s): Maura McCarron, Ursula Griffiths, Siobhan Graham, Mark Hoey, Kathryn Robinson, Louise McDonald, Adam Lowe

Department(s)/Institutions: Rheumatology Department, Musgrave Park Hospital, Belfast Health and Social Care Trust

Introduction: Patients attend the Biologics Unit for assessment and administration of biologic therapies.

In 2015 several issues impacting on the optimal operation of the unit were identified-

- Increasing number of patients on biologic drugs with complex co-morbidities
- Increasing number of biologic drugs available
- Frequent staff changeover
- Lack of structured, standardised assessment and documentation
- Inefficient paperwork process at clinic and significant delays with typing of letters causing potential safety issues

It was recognised that to ensure safe and efficient working, things had to change.

Aims/Background: The vision was for-

- Provision of succinct relevant information on therapies for new staff
- Development of a structured proforma for use in the Biologic Clinics to standardise assessment/documentation
- A proforma to be available online, linking to Electronic Care Record (ECR) thus-avoiding duplication of effort, delayed typing and reducing the burden on secretaries

Method: Our SMART (Specific, Measureable, Achievable, Realistic, Timely) aims as outlined below were achieved.

1. 'Develop a Biologic Handbook by March 2015'
2. 'Develop an online proforma linking to ECR for use in all patients attending Biologic Clinics in MPH by November 2015'
3. 'Institute an induction programme for incoming junior doctors from February 2016'

Results:

- A standardised, structured online patient assessment and documentation tool is being used in 100% of attendances at Biologic Clinics from October 2015
- Letters are instantly available for GP and ECR - cutting 80 letters per week from secretarial workload
- Provision of Biologic Handbook and specific induction now part of unit practice
- Feedback surveys of junior doctors/nurse specialist found high satisfaction with the Biologic Handbook (86%) and online proforma (100%) plus 86% had a Biologic Induction
- Audit was carried out to evaluate the online proforma. Problems were identified relating to filing and linkage of the letters to ECR (Cycle 1- 38% of letters were properly filed; 82% of letters linked appropriately to ECR)
- Balancing measures were undertaken and re-audit performed
- Cycle 2- letter in chart: 98%, in correct section of chart: 63%; 92% of letters linked appropriately to ECR

Conclusions: We have established a robust system to provide assurance that safety and quality are paramount. The education of staff and standardised assessment tool ensure that patients



receiving biologic drugs are optimally managed. The online proforma has improved the quality and efficiency of service provided by the unit. We have fostered a learning culture where the potential for error is identified and managed in a supportive, pre-emptive manner

(16A115) Abstract 17

Poster 9

Audit of an outreach Early Inflammatory Arthritis Clinic reveals 53% with newly diagnosed disease.

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Department(s)/Institutions: St Luke's Hospital, Kilkenny and St Vincent's University Hospital, Dublin

Introduction: To analyse the profile of patients who attended a new, outreach Early Inflammatory Arthritis Clinic (EIAC) over a 1 year period.

Aims/Background: Inflammatory arthritis requires early diagnosis and early treatment to have an impact on long term morbidity and mortality. Criteria for attendance at EIACs include: joint tenderness and/ or swelling, duration of symptoms < 2 years, and/or other history suggestive of EIA (e.g. presence of extra-articular features including psoriasis, inflammatory type back pain, and/ or suggestive family history), and investigations associated with EIA (elevated ESR/ CRP and/ or positive serology).

Method: GPs local to St Luke's Hospital, Kilkenny (SLK) were informed of criteria for referral to a newly established EIAC and were sent the ISR-recommended, national EIAC referral form, encouraging its use. An audit was conducted of the patients referred between January and December 2015. Data were collected for the following parameters as provided by the referring GP and by reviewing the SLK chart: date of referral and date seen, symptoms, duration of symptoms, physical findings, investigations, diagnosis, and medications prescribed. Results were analysed statistically using EZR software (Saitama Medical Center, Jichi Medical University, Japan).

Results: A total of 85 patients (pts) were referred over the one-year period. 52 pts (61%) were deemed suitable for the EIAC as they met the referral criteria. 49 pts (45%) attended the EIAC as a new pt; 3 did not attend. 28 pts (57%) were seen within 7 weeks of GP referral. 47% were referred using the National EIA referral form. 82% were women and the mean (SD) age was 54.9 (14.7) years.

The most common symptom was joint pain (94%) and joint swelling was observed by GPs in 40% of pts. The most frequent suggested diagnosis by GPs was rheumatoid arthritis (RA) (22%), followed by psoriatic arthritis (PsA) (8%), polymyalgia rheumatica (PMR) (6%), fibromyalgia (FM) (4%), osteoarthritis (OA) (4%) and axial spondyloarthritis (SpA) (2%). In 37% of referrals, a diagnosis was not suggested. 26 (53%) pts pre-process were diagnosed inflammatory arthritis at the EIAC. The most frequent diagnosis was RA (31%), followed by FM (20%), OA (14%), PsA (10%), PMR (4%) and SpA (2%). 47% of pts were given the same diagnosis by both GPs and consultant.

43 (91%) pts had duration of symptom < 2 years, and 60% of pts had duration < 6 months. The proportion with duration of symptoms < 6 months was significant higher in pts referred using the EIA referral form (78%) compared to those referred by standard letter (42%) ($p = 0.02$). However, 65% of pts referred using the EIA referral form required further investigation compared to those referred by standard letter (29%) ($p = 0.01$).

Pts were referred significantly earlier if they had joint swelling ($p = 0.014$) or an elevated inflammatory marker such as ESR or CRP ($p = 0.01$).

Conclusions: Although this EIAC is targeting EIA, 47% did not have EIA and 9% had symptoms >2 years. The most frequent diagnoses suggested by GPs and confirmed by consultant was rheumatoid arthritis. 47% were given the same diagnosis by both GPs and consultant. Finally, the detection of joint swelling or an elevated ESR and /or CRP were associated with earlier referral.

(16A119) Abstract 18

Poster 10

The "Forgotten Joint" Temperomandibular Corticosteroid Injections In Juvenile Idiopathic Arthritis

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Department(s)/Institutions: National Centre for Paediatric Rheumatology, OLCHC. University College Dublin, Dublin.

Introduction: The temperomandibular joint (TMJ) has long been recognised as one of the most frequently involved joints in Juvenile Idiopathic Arthritis (JIA), but is often not assessed and referred to as the "forgotten joint". TMJ arthritis is associated with significant morbidity, and can result in resulting disabling orofacial pain, joint dysfunction and micrognathia. Intra-articular corticosteroid injection (IACI) is well recognised as a treatment modality.

Aims/Background: This clinical audit aims to evaluate the effects of IACI on TMJ pain and function, as well as investigate the incidence of IACI-associated side effects.

Method: A retrospective observational study of all children attending the NCPR for IACI of TMJs over a ten year period from 2006-2016. JIA-subtype, concurrent medications and any adverse side effects were recorded. Pain self reported and /or induced, function as well inter-cisal distance at clinical examination prior to treatment (T1), and at two consecutive post-treatment assessments (T2) mean 114 days post-treatment, (T3) mean 334 days post-treatment were documented.

Results: A total of 38 patients with JIA were included (median age 13 years, IQR 9-14.5years). All patients reported significant pain on examination and 18/40 had functional impairment (clicking, locking, asymmetrical opening). All patients received TMJ IACI of triaminolone hexacetonide, (19 bilateral and 19 unilateral) up to a maximum of 40mg into each joint. The IACIs were carried out after an insufficient response to standard medical management (NSAIDs/Methotrexate). Significant pain reduction was observed at T2 in all, except 2. In 24/40 patients the inter-cisal distance was documented at both T1 and T2. In 20 of these, an increase of inter-cisal distance, with a mean of .63 patient's finger breadths was observed. An increase in TMJ tenderness for up to 36 hours after IACI was reported in 5, before complete resolution. Bruising was noted in 1, this was self-limiting. No other side effects were noted. At T3, 20 patients noted a return in orofacial pain, with a decrease in inter-cisal distance documented. However they still showed an improvement in function, when compared to T1. The other 18 patients still report pain reduction in the TMJ joint. At T3 50% of the cohort had commenced on a biologic agent.

Conclusions: Our results indicate a significant overall improvement with IACI of the TMJ, in pain and inter-cisal distance in particular in the short term measure. There is a more sustained response in terms of function after the procedure.



IACIs do not play a curative role but their localised effect can help avoid oral corticosteroid use and hence many of steroid systemic side effects. We acknowledge that the improvement may not be attributed to steroid injections alone as over 50% had begun a biologic agent at T3. We advocate that IACIs should be considered as a short-term bridging therapy when patients are progressing from methotrexate to a biologic agent.

Image 1



(16A120) Abstract 19

Poster 11

Detection of Inflammatory Heart Disease in Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg Strauss) Patients

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Introduction: EGPA has a 5-year survival rate of 90%. Cardiac involvement decreases 5-year survival to 78%, quadruples mortality risk and is the cause of a third of EGPA deaths. Patterns of cardiac involvement include myocarditis, myocardial fibrosis, cardiomyopathy, pericarditis, conduction abnormalities, intraventricular thrombus and sudden cardiac death.

Aims/Background: To define the detection and pattern of EGPA/Churg Strauss inflammatory heart disease and develop an algorithm for heart disease screening in EGPA patients.

Method: A retrospective review of all EGPA patients attending a specialist clinic was performed. EGPA patients variably underwent serum troponin, ECG, echocardiography and cardiac MRI with gadolinium enhancement along with their routine vasculitis evaluation.

Results: 131 EGPA patients (47% men) were identified of whom 96 (73%) had undergone cardiac evaluation. Median age was 50 years (38 - 58), 37% were ANCA +ve and asthma preceded diagnosis in most by a median of 97 months (36 - 240). 41/96 of those screened (43%) were symptomatic for heart disease with: dyspnoea (47%), chest pain (29%), limb oedema (24%), palpitations (13%), syncope (4%), abdominal discomfort (2%) and shock (2%). 27/96 (28%) patients had EGPA-related inflammatory heart disease: in 20 this was present at EGPA diagnosis, 5 developed cardiac disease at time of EGPA flare and in two, it preceded an EGPA diagnosis. 59% (24) of those who were symptomatic and 5% (3) of those who did not have cardiac symptoms had EGPA inflammatory heart disease. see table 1. Patients with inflammatory heart disease were younger (46 [28 - 52] V 50 [41 - 59]; p = 0.04), more frequently ANCA-negative (85% V 69%; NS), had higher BVAS scores (3 [1 - 4] V 1 [0.75 - 2]; p = 0.005), higher eosinophil counts (5.60 [1.44 - 11.57] V 1.60 [0.75 - 4.00] x10⁹/L; p = 0.029) and higher CRP levels (52 [30 - 100] V 15 [5 - 81] mg/L; p = 0.017). Troponin I was determined in 33 patients and was elevated in 75% patients with

EGPA inflammatory heart disease V 14% without (p = 0.001).

Conclusions: Twenty seven per cent of EGPA patients have inflammatory heart disease with nearly 60% of those symptomatic for heart disease and 5% of those without cardiac symptoms being affected. EGPA patients with inflammatory heart disease had more systemic disease and higher serum and clinical markers of inflammation. All EGPA patients should have ECG, troponin and echocardiography as screening investigations with progression to cMRI for patients with heightened suspicion for cardiac disease. see Figure 1. Head to head comparison of cMRI to echo for detection of EGPA inflammatory heart disease is awaited.

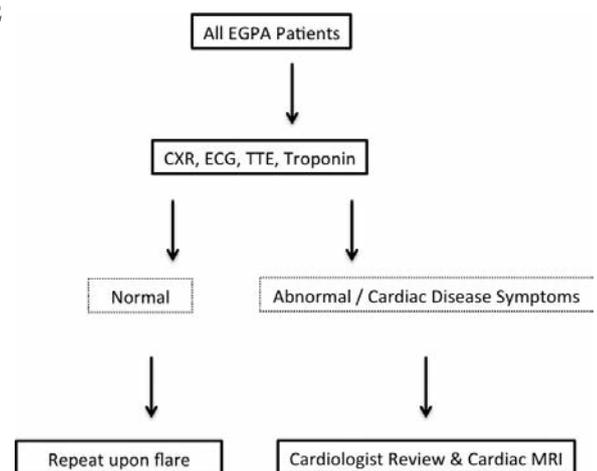
Image 1

Table 1: Incidence of pertinent heart abnormalities in EGPA patients symptomatic and asymptomatic for heart disease. (n=100; 4 patients originally screened in the asymptomatic group later became symptomatic and were again tested)

	Evaluated patients (n=100)	Asymptomatic patients (n=55)	Symptomatic patients (n=45)	p
Detected abnormalities	52/100 (52%)	25/55 (45%)	27/45 (60%)	0.09
ECG	70/100 (70%)	40/55 (73%)	30/45 (67%)	
Minor	16/70 (23%)	6/40 (15%)	10/30 (33%)	0.17
Major	9/70 (13%)	0/40	9/30 (30%)	<0.01
Holder	11/100 (11%)	0/55	11/41 (24%)	
TTE	82/100 (82%)	49/55 (89%)	33/45 (73%)	
Pericardial effusion	9/82 (10%)	3/49 (6%)	7/33 (21%)	0.09
Diastolic dysfunction	23/82 (28%)	12/49 (25%)	11/33 (33%)	0.63
LVEF < 55%	10/82 (12%)	2/49 (4%)	8/33 (24%)	0.02
Wall motion abnormality	10/82 (12%)	3/49 (6%)	7/33 (21%)	
Global	6/82 (7%)	1/49 (2%)	5/33 (15%)	0.08
Regional	4/82 (5%)	2/49 (4%)	2/33 (6%)	1
Dilated cardiomyopathy	4/82 (5%)	1/49 (2%)	3/33 (9%)	0.31
Cardiomyopathy	5/82 (6%)	1/49 (2%)	4/33 (12%)	0.16
MRI	37/100 (37%)	12/55 (22%)	25/45 (56%)	
Pericardial effusion	6/37 (16%)	2/12 (17%)	4/25 (16%)	0.51
Diastolic dysfunction	3/37 (8%)	2/12 (17%)	1/25 (4%)	0.28
LVEF < 55%	10/37 (27%)	2/12 (17%)	8/25 (32%)	0.15
Wall motion abnormality	11/37 (30%)	3/12 (25%)	9/25 (36%)	0.64
Global	3/37 (8%)	0/12	3/25 (12%)	0.27
Regional	8/37 (22%)	2/12 (17%)	6/25 (24%)	0.45
Dilated cardiomyopathy	4/37 (11%)	1/12 (8%)	3/25 (12%)	0.64
Cardiomyopathy	10/37 (27%)	2/12 (17%)	8/25 (32%)	0.41
LGE	12/37 (32%)	2/12 (17%)	10/25 (40%)	0.09
Endocardium	8/37 (22%)	2/12 (17%)	6/25 (24%)	0.27
Myocardium	3/37 (8%)	2/12 (17%)	1/25 (4%)	0.58
Epicardium	0/37	0/12	0/25	

ECG = Electrocardiogram, cMRI = Cardiac Magnetic Resonance Imaging, LGE = Late gadolinium enhancement, LVEF = Left ventricle ejection fraction, TTE = Transthoracic Echocardiography, p<0.05 was considered significant difference between those symptomatic and asymptomatic for heart disease.

Image 2



(16A122) Abstract 20

Poster 12

Documentation of musculoskeletal & rheumatic conditions on hospital discharge summaries – A Quality Audit from a tertiary care centre.

Author(s): Abuelmagd Abdalla, Ammar Ibrahim, John Carey

Department(s)/Institutions: Rheumatology Dept. Galway University Hospitals

Introduction: Musculoskeletal & rheumatic diseases are



common causes of disability, GP consultations & acute ED presentations, yet they are regarded as minor non serious conditions & their documentation had been poor, widely variable, non-standardized & non-specific.

Aims/Background: To examine the documentation of the established or newly diagnosed Musculoskeletal & rheumatic diseases among acute medical patients on their electronic discharge summaries (EDS). It also gives a point prevalence of rheumatic diseases among acutely admitted general medical patients. We used the National Standard for Patient Discharge Summary Information, developed by HIQA, July 3rd 2013 edition (Available online at www.hiqa.ie) as a standard tool.

Method: 128 consecutive medical patients admitted under rheumatology acute GIM take over 6-week period between Feb-Apr 2016 were included & their clinical histories & medical records were examined. Any underlying or newly diagnosed Musculoskeletal or rheumatic diseases were recorded & compared to their EDS when discharged from hospital. Local approval obtained by clinical audit department.

Results: 5 cases were excluded for absence of relevant data. 47 patients (38% of total medical patients) had an underlying or newly documented rheumatic or musculoskeletal diseases with mean age of 69.7 (female 53.2%). Of those, 18 patients (14.6% of total medical patients) were admitted for a reason directly related to their underlying rheumatic or musculoskeletal condition. Commonest conditions encountered were OA (31.5%), Osteoporosis (25.5%), Gout (17%) & PMR/GCA (8.5%). The commonest causes for direct acute rheumatology admission were acute gouty arthropathy & osteoporotic fractures (4% & 3% respectively). EDS was successfully completed on 85% of patients, however their Musculoskeletal & rheumatic conditions were documented on only 59.6% of cases.

Conclusions: This audit showed that around 40% or over of the medical patients they don't get their underlying Musculoskeletal or rheumatic conditions recorded on their EDS. This has a potential impact on their future multidisciplinary care & reimbursement. The audit also highlighted the high prevalence of Musculoskeletal & rheumatic diseases among medical patients (38%) & that acute rheumatology accounted for 14.6% of total medical admissions requiring specialist care. As per national standard on discharge summary, all the principal and additional relevant diagnoses should be recorded. Junior doctors on training need further awareness & education on the importance of documenting all relevant diagnoses on EDS with special emphasis on Musculoskeletal & rheumatic diseases.

Image 1

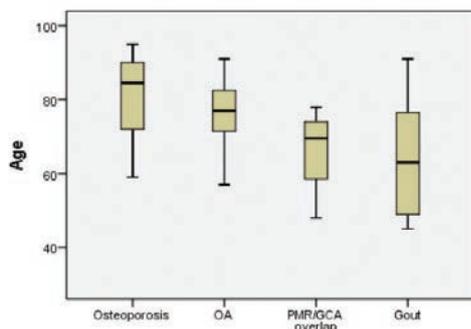


Figure.1 Mean age across common conditions

(16A123) Abstract 21

Poster 13

More Tendinopathy than Inflammatory Arthritis in a New Patient Rheumatology clinic. A retrospective review of 397 new patients.

Author(s): Kirwan P^{1,2}, French HP², Duffy T³

Department(s)/Institutions: 1Physiotherapy Department, Connolly Hospital, Blanchardstown, Dublin 15; 2School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin 2; 3Rheumatology Department, Connolly Hospital, Blanchardstown, Dublin 15.

Introduction: Tendinopathy is a common musculoskeletal complaint. A Recent Dutch study¹ has indicated that lower limb tendinopathy has a higher incidence (10.52 per person-years) than osteoarthritis (8.4 per 1000 person-years).

Aims/Background: The purpose of this review was to establish the number of patients with tendinopathy/tendon pain presenting to a general 'New Patient' rheumatology clinic.

Method: Data were collected consecutively on all patients assessed by one experienced Physiotherapist working in the 'New Patient' rheumatology clinic from Dec 2010 to May 2016. No triage of these patients was performed, therefore Doctors and Physiotherapist see similar patients. A retrospective review of the data collected and medical charts was undertaken. The number of patients diagnosed with tendinopathy by the Physiotherapist was noted, and descriptive statistical analysis was undertaken. The diagnosis of tendinopathy was made clinically.

Results: In total, 392 patients were assessed over the time period, 265 females and 127 males, representing a 2:1 ratio for females to males. The mean age was 49 ± 13.7 years. Tendinopathy was diagnosed in 134 patients, therefore 34% of all the patients assessed had tendon pain. Thirty-two patients, 8% of the total, had bilateral tendon pain. The total number of painful tendons was 166.

The most common tendinopathy was rotator cuff tendinopathy accounting for 12% of patients (n=46), followed by gluteal tendinopathy representing 10% (n=38), whilst lateral elbow tendinopathy accounted for 9% of patients (n=31).

Medial elbow, tibialis posterior, proximal hamstring, peroneal, patellar and Achilles tendinopathy accounted for the remaining 19 patients with tendinopathy. Plantar fasciopathy was diagnosed in 7% of patients (n=27).

An Inflammatory arthritis was diagnosed in 20% of patients (n=78).

Conclusions: Results show that there is more tendinopathy than inflammatory arthritis in a 'New Patient' rheumatology clinic. Tendon pain combined with plantar fascia pain (41%), accounts for double the number of patients seen who were diagnosed with inflammatory arthritis.

This review reveals the high proportion of those presenting to a 'New Patient' rheumatology clinic have clinically diagnosed tendinopathy. It highlights the importance of knowledge of differential diagnosis and evidence-based management of tendinopathy for doctors and other healthcare professionals working in rheumatology.

References: 1. Albers et al. BMC Musculoskeletal Disorders (2016) 17:16



(16A126) Abstract 22

Poster 14

Spinal Magnetic Resonance Imaging (MRI) manifestations in axial psoriatic arthritis patients with specific genotypes.

Author(s): Ali Al Shamsi, Natsumi Ikumi, Phil Gallagher, Eric Heffernan*, Oliver FitzGerald

Department(s)/Institutions: Department of Rheumatology and Diagnostic Imaging*, St Vincent's University Hospital, Dublin

Introduction: Our previous studies have shown that symmetrical involvement of the sacroiliac joints is associated with the presence of HLA-B27 whereas asymmetrical involvement is strongly associated with HLA-B08. Furthermore, McGonagle et al have previously shown that HLA-B27 positivity defines a group of PsA patients with more severe axial bone marrow edema that is likely related to the classic AS phenotype. Clinically, HLA-B27-negative PsA is more likely to be reported as a "negative" MRI examination result. In this study, we further examine and compare the clinical and MRI features of spinal involvement in our PsA patients defined by the presence of HLA-B27 or HLA-B08.

Aims/Background: To describe the clinical and spinal MRI features in axial PsA patients who have either HLA-B08 or HLA-B27 genotypes.

Method: 40 patients with PsA all meeting CASPAR criteria and who had previous evidence of sacroiliac disease from our recent cohort study, were divided into three groups: either HLA-B08, (n= 24), HLA-B27 (n=12) or both HLA-B08 and HLA-B27 (n=4) genotypes. Assessments detail in table 1. 37 patients underwent thoracolumbar spinal MRI evaluation; 3 further in progress. Scans were analyzed blind to the clinical or genetic data by consultant musculoskeletal radiologist. Features evaluated included presence/location of bone marrow edema (BME), syndesmophyte formation, and presence of enthesitis or synovitis. Spinal MRI findings were considered asymmetric when the ratio between right and left sided involvement of the spine is < 50%; findings were considered symmetric when the ratio is > 50%.

Results: Clinical features in patients with HLA-B08 and HLA-B27 genotypes were similar (Table1). Patients with HLA-B08 were older with more asymmetric sacroiliac involvement as previously described. While there was no difference in presence/location of bone marrow edema, syndesmophyte formation, and presence of enthesitis or synovitis, patients with HLA-B08 had more asymmetrical spinal involvement on MRI while HLA-B27 positive patients had more symmetrical disease (Table 2). Finally, there was no correlation observed between measures of clinical disease activity (defined as BASDAI >4) and activity on MRI defined by presence of BME (6 vs 9 in HLAB 08 and 3 vs 5 patients in HLAB 27 respectively); only 4 patients (3 HLAB 08; 1 HLAB 27) had a combination of both clinical activity and BME.

Conclusions: This study suggests that symmetry or asymmetry of spinal disease in PsA may be dependent on patient genotype. Furthermore, spinal MRI identifies spinal inflammation where clinical assessments suggest good disease control.

Image 1

	HLA B08	HLA B27	p value
Number of patients	24 (%)	12 (%)	
Male gender, n (%)	13 (54)	9 (75)	NS
Age (mean)	56.1	49.6	0.05
Nocturnal Back Pain, n (%)	10 (42)	5 (45)	NS
Schober (mean)	4.64	5.16	NS
BASDAI (mean)	3.4	3.03	NS
BASMI (mean)	2.94	2.94	NS
CRP (mean)	3.43	5.18	NS
Asymmetrical SI X ray, n (%)	22 (92)	4 (33)	0.0006
Symmetrical SI X ray, n (%)	2 (8)	8 (67)	0.0002

Table1. Clinical features in HLA B08 and HLA B27 patients. NS: not significant.

SI : sacroiliitis, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index. BASMI: Bath Ankylosing Spondylitis Metrology Index. CRP: C-Reactive Protein

Image 2

Genotype	Spinal MRI		
	Symmetrical	Asymmetrical	Normal
HLAB08 (21)	6	10	5
HLAB27 (12)	7	3	2
HLAB08 and HLAB27 (4)	3	1	0

Table 2. Spinal MRI findings in patients with HLA B08 or HLA B27.

(16A128) Abstract 23

Poster 15

Clinical features and treatment of patients with Behcet's disease in Musgrave Park Hospital, Belfast

Author(s): Mark Hoey, Elizabeth Ball. Claire Masih, Kathryn Robinson

Department(s)/Institutions: Musgrave Park Hospital, Belfast Trust, Belfast, Northern Ireland

Introduction: Behcet's disease is a rare condition with an estimated 1000 – 2000 people affected in the UK. As a result it is less well characterized than other rheumatological conditions.

Aims/Background: There is limited data on the prevalence or phenotype of Behcet's disease in Northern Ireland. Our aim was to quantify the number of patients with Behcet's disease treated within the Belfast Trust and to gain a better understanding of this cohort of patients in terms of their demographics, phenotypes and current/previous treatments.

Method: Patients were identified from discharge diagnoses, a biologics database, activity statistics from the administration team and discussion with consultants. For each patient demographics at diagnosis, clinical features, past/present treatments were recorded and comparison with Eular standards was carried out (ref Hatemi G, Silman A, Bang D, et al. EULAR recommendations for the management of Behcet's disease. Ann Rheum Dis 2008;67:1656–1662.)

Results: 35 patients were identified. 7 were excluded due to uncertain or evolving diagnosis, or incomplete records. There were 8 males and 20 females. Mean age was 46yrs (Range 21-79), Mean age at diagnosis 32 yrs (Range 12-66). Clinical features are outlined in Figure 1. The most common was aphthous/genital ulceration. Current and previous treatments are outlined in Figure 2. 27/28 (96.4%) had been treated with steroids and the majority 18/28 (64.3%) were still taking them. 11/28 (39.3%) were currently treated with an anti-TNF agent; Infliximab and Adalimumab were the most common.

Conclusions: There are a relatively high number of patients with



Behcet's disease treated at Belfast compared to the rest of the UK. We now have a better understanding of this cohort of patients in terms of their demographics, clinical features and treatment. This may be helpful when counseling patient's on their condition and discussing treatment.

Image 1

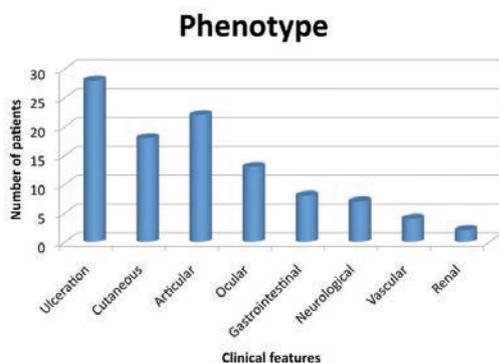
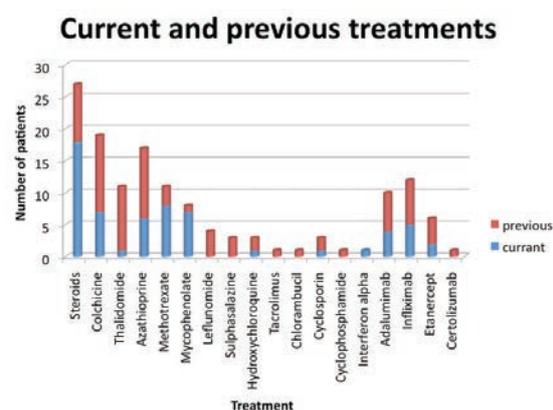


Image 2



(16A129) Abstract 24

Poster 16

Platelet Activation, As Measured By Plasma Soluble Glycoprotein VI, Is Not Associated with Disease Activity or Ischaemic Events in Giant Cell Arteritis

Author(s): Richard Conway, Anne Madigan, Laura Helbert, Niamh Redmond, Eimear Dunne, Eamonn S. Molloy, Dermot Kenny, and Geraldine M. McCarthy

Department(s)/Institutions: Department of Rheumatology, Mater Misericordiae University Hospital, Dublin, Ireland. Centre for Arthritis and Rheumatic Diseases, Dublin Academic Medical Centre, St. Vincent's University Hospital, Dublin, Ireland. University College Dublin, Ireland. Royal College of Surgeons in Ireland

Introduction: Patients with Giant Cell Arteritis (GCA) have an increased risk of devastating cranial ischaemic complications including vision loss and stroke. The BSR guidelines recommend platelet inhibition with aspirin to reduce the risk of ischaemic complications in GCA. Thrombosis occurs following platelet activation. The glycoprotein VI (GPVI) receptor is found exclusively on platelets and megakaryocytes. The proteolytic cleavage of GPVI occurs following platelet activation and is detectable in the plasma as soluble GPVI (sGPVI). Therefore elevated plasma sGPVI is a marker of platelet activation and risk marker for adverse cardiovascular outcomes.

Aims/Background: Enhanced platelet activation is observed in inflammatory arthritis. We hypothesized that GCA would also be associated with platelet hyperreactivity which might support the

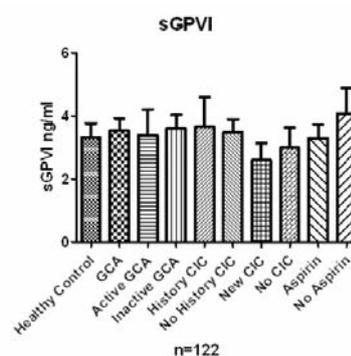
rationale for aspirin use in GCA.

Method: Following ethics approval and informed consent, blood samples were taken from patients with GCA. Healthy control samples were obtained from volunteers. Demographic and clinical data were collected for all participants. Blood samples were processed as double spun platelet poor plasma. sGPVI levels were measured using ELISA. sGPVI levels were compared between patients with GCA and healthy controls, between active and inactive GCA, and between those with and without cranial ischaemic complications. Mann-Whitney U test was used to compare groups. Spearman's Rank Correlation Coefficient was used to assess for associations between sGPVI levels and demographic and clinical markers. GraphPad Prism and SPSS were used for data analysis.

Results: 122 patients were included in the study, 70 with GCA and 53 healthy controls. Of the GCA patients, 19 had active disease and 19 had had cranial-ischaemic complications. There was no difference in sGPVI levels between GCA and healthy controls, median (IQR) 2.32 ng/ml (1.60, 4.21) vs 2.19 ng/ml (1.72, 3.31) (p=0.76). sGPVI levels were similar in GCA patients with active and inactive disease, median 2.31 ng/ml (1.86, 4.21) vs 2.33 ng/ml (1.57, 4.21) (p=0.93). sGPVI levels were similar in GCA patients with and without a history of cranial ischaemic complications, median 2.04 ng/ml (1.33, 4.21) vs 2.37 ng/ml (1.88, 4.21) (p=0.85). sGPVI levels taken from patients at initial presentation with and without cranial ischaemic complications were no different, median 2.31 ng/ml (1.33, 4.21) vs 2.27 ng/ml (1.72, 3.22) (p=0.91). Aspirin therapy did not significantly affect sGPVI levels, median 2.22 ng/ml (1.40, 4.20) vs 2.74 ng/ml (2.01, 4.64). There was no correlation between sGPVI levels and CRP (r=0.16), ESR (r=0.10), or prednisolone dose (r=-0.21).

Conclusions: We found no evidence of increased platelet activation in patients with GCA. There was no association between platelet activation and disease activity or cranial ischaemic complications in GCA.

Image 1



Ref: (16A130) Abstract 25

Poster 17

Interleukin-23 Stimulates Inflammatory and Proliferative Pathways in Giant Cell Arteritis

Author(s): Richard Conway, Karen Creevey, Michelle Trenkmann, Geraldine M. McCarthy, Conor Murphy, Douglas J. Veale, Ursula Fearon, Eamonn S. Molloy

Department(s)/Institutions: Centre for Arthritis and Rheumatic Diseases, Dublin Academic Medical Centre, St Vincent's University Hospital, Dublin, Ireland. University College Dublin, Ireland. Department of Molecular Rheumatology, Trinity College Dublin, Ireland. Royal Victoria Eye and Ear Hospital,



Dublin, Ireland. Mater Misericordiae University Hospital, Dublin, Ireland

Introduction: Giant cell arteritis (GCA) is the most common form of systemic vasculitis. The pathogenesis of GCA remains incompletely understood. Current evidence suggests that dendritic cells are key regulators of the inflammatory pathways involved in GCA. Dendritic cells secrete the T-cell regulating cytokine interleukin-23 (IL-23) which stimulates Th17 cells. The aim of this study was to evaluate the effect of IL-23 on inflammatory and proliferative pathways in GCA.

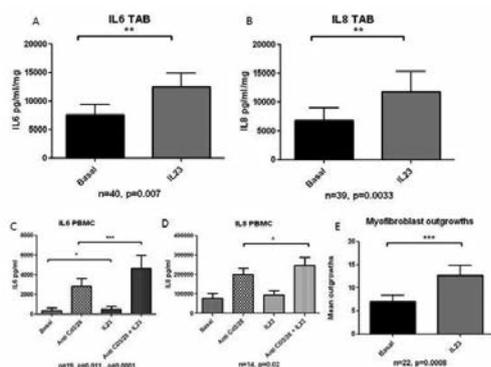
Aims/Background: The aim of this study was to evaluate the effect of IL-23 on inflammatory and proliferative pathways in GCA.

Method: Temporal artery (TA) explant, peripheral blood mononuclear cell (PBMC), and myofibroblast outgrowth models were established from patients with GCA. All patients met the ACR classification criteria for GCA. TA explants were stimulated for 24 hours with recombinant IL-23 (10ng/ml). PBMCs were stimulated with recombinant IL-23 (10ng/ml) after priming with anti CD3 (0.5µg/ml) and anti-CD28 (1µg/ml). Levels of the pro-inflammatory cytokines IL-6 and IL-8 were quantified by ELISA. Myofibroblast outgrowths were established from TAs embedded in Matrigel, stimulated with IL-23 (10ng/ml) with media changed every 3 days, and number of outgrowths per high-power field (hpf) counted after 28 days. Data were reported as mean (standard deviation (SD)). Wilcoxon Signed Rank test was used to compare between group differences. Statistical significance was set at $p < 0.05$. Analyses were performed using SPSS.

Results: IL-23 stimulated IL-6 from TA explants from a basal level of 7595 (11726) to 12468 (15194) pg/ml/mg ($p=0.007$, $n=40$), and IL-8 from a basal level of 6859 (13454) to 11820 (21685) pg/ml/mg ($p=0.003$, $n=39$). IL-23 stimulated IL-6 from PBMCs from a basal level of 2830 (3568) to 4637 (5739) pg/ml ($p=0.0001$, $n=19$), and IL-8 from a basal level of 201075 (116367) to 248228 (152195) pg/ml ($p=0.02$, $n=14$). IL-23 significantly increased the number/hpf of myofibroblast outgrowths compared to basal conditions from 7.01 (6.66) to 12.71 (10.55) ($p=0.0008$, $n=22$). Results are demonstrated in Figure 1.

Conclusions: IL-23 upregulated pro-inflammatory cytokines in temporal artery explants and PBMCs from GCA patients, including IL6, suggesting that IL23 may be upstream of IL-6 in the pathogenesis of GCA. IL-23 may play a central role in stimulating inflammatory and proliferative pathways and constitutes a therapeutic target in GCA.

Image 1



(16A132) Abstract 26

Poster 18

Increased Platelet Reactivity in Gout: Relationship to Tophus Burden and Colchicine Use

Author(s): Richard Conway, Claire-Louise Murphy, Anne Madigan, Patricia Kavanagh, Liz Geraghty, Niamh Redmond, Laura Helbert, John J. Carey, Eimear Dunne, Dermot Kenny, Geraldine M. McCarthy

Department(s)/Institutions: University College Dublin, Ireland. Centre for Rheumatology Research, UCL Division of Medicine, London, United Kingdom. Mater Misericordiae University Hospital, Dublin, Ireland. UCD Clinical Research Centre, Ireland. Galway University Hospitals, Ireland. Royal College of Surgeons in Ireland

Introduction: Patients with gout have an increased risk of cardiovascular events. The presence of tophi is associated with enhanced cardiovascular risk. Increased platelet reactivity is a risk marker for cardiovascular events. The glycoprotein VI (GPVI) receptor is found exclusively on platelets and megakaryocytes and is the predominant platelet receptor for collagen. It remains intact on platelets under resting conditions. The proteolytic cleavage of GPVI occurs upon specific activation of platelets and is detectable in plasma as soluble GPVI (sGPVI). Therefore elevated plasma sGPVI is a marker of platelet activation and a risk marker for adverse cardiovascular outcomes.

Aims/Background: The aim of this study was to assess platelet activation, as measured by plasma sGPVI level in gout.

Method: Following ethics approval and informed consent, blood samples were taken from patients with gout. Control samples were obtained from healthy volunteers. Demographic and clinical data were collected for all participants. Blood samples were processed as double spun platelet poor plasma. Plasma sGPVI levels were measured using ELISA. Mann-Whitney U test was used to compare groups. Spearmans Rank Correlation Coefficient was used to assess for associations between sGPVI and demographic and clinical markers. IBM SPSS Statistics Version 20 was used for data analysis.

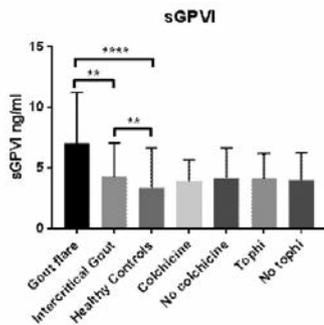
Results: 121 patients were included, 27 during gout flare, 41 with intercritical gout, and 53 healthy controls. There were no significant differences in demographic details between the groups. Median (IQR) sGPVI levels were 6.51 ng/ml (4.52, 8.41) in gout flare, 3.58 ng/ml (2.11, 5.55) in intercritical gout, and 2.19 ng/ml (1.72, 3.31) in healthy controls. Plasma sGPVI levels in both gout groups were significantly increased compared to healthy controls ($p < 0.005$ for each) (Figure 1). sGPVI levels were significantly increased in gout flare compared to intercritical gout ($p=0.001$). There was no significant difference in sGPVI levels in gout patients with and without tophi, median (IQR) 3.58 (2.26, 6.08) vs 2.94 (1.91, 6.01) ($p=0.441$), or in those prescribed colchicine, median (IQR) 3.60 (2.19, 6.06) vs 3.12 (2.12, 6.49) ($p=0.773$). There was moderate correlation between sGPVI levels and VASpain ($r=0.40$), and VASQOL ($r=0.33$). There was a weak correlation with CRP ($r=0.23$) and no correlation with ESR ($r=0.049$). sGPVI level did not correlate with presence of tophi ($r=0.115$) or colchicine use ($r=0.042$).

Conclusions: Patients with both tophaceous and non-tophaceous gout exhibit platelet hyperactivity as demonstrated by elevated plasma sGPVI levels. Platelet activation is exacerbated during acute gout flares. Colchicine therapy does not influence plasma sGPVI levels. Platelet activation probably contributes to the



elevated cardiovascular risk in gout patients and antiplatelet therapy warrants consideration in this patient population.

Image 1



(16A133) Abstract 27

Poster 19

Smoking Prevalence in a Cohort of Patients with Ankylosing Spondylitis and its Association with Disease Outcomes.

Author(s): Ú. Lannin, F. O’Shea

Department(s)/Institutions: Rheumatology Department, St. James’s Hospital, Dublin

Introduction: The impact of smoking on disease outcomes in patients with ankylosing spondylitis (AS) is increasingly recognised (1)

Aims/Background: 1. Estimate smoking prevalence among a cohort of Irish patients with AS 2. Explore the association between smoking status and disease outcomes.

Method: Outpatients with AS were evaluated according to their smoking status, medications and disease duration. The following disease outcomes were measured: Bath AS Disease Activity Index (BASDAI) Bath AS Functional Index (BASFI), total back pain, AS quality of life score, Fatigue and Patient Global Disease Activity Score. Mean disease indices were compared across two distinct groups. The first group comprised active and ex smokers. The second group comprised lifelong non smokers only. Data were collected using an anonymised questionnaire and analysed using IBM SPSS.

Results: In total, 61 patients were enrolled in the study. Patient demographics are outlined in attached table.

Mean BASFI score was higher in the ever smoked compared to the lifelong non smoker group (4.31 versus 3.66, p=not sig). There was no significant difference between mean scores of BASDAI fatigue, BASDAI and ASQoL in the ever smoker compared to the lifelong non smoker group.

Conclusions: In this study, it was found that subjects who currently smoke or had previously smoked demonstrated poorer functional outcomes but not disease activity scores.

Image 1

Gender N (%)	
Male	46 (75.4%)
Female	15 (24.6%)
Mean age in years (SD)	45 (11.8)
Mean disease duration in years (SD)	14.5 (12.4)
Smoking status N (%)	
Current/ex smoker	36 (59%)
Life long non smoker	25 (41%)
Biologic agent use N (%)	37 (60.6%)

Table 1: Patient demographics

(16A135) Abstract 28

Poster 20

The transformation of inpatient rheumatology services in a post-biologics era

Author(s): S McDonald, G Wright

Department(s)/Institutions: Musgrave Park Hospital, Belfast, N.Ireland

Introduction: Over the last 15 years the rapid development of an armory of biological drugs has revolutionised the management of inflammatory arthritis and other rheumatological conditions. In the past Rheumatology inpatient wards were largely occupied with patients with difficult rheumatoid arthritis and associated extra-articular disease, with little option bar synthetic DMARDS, corticosteroid, respite and physiotherapy.

Aims/Background: In 1996 we audited inpatient services for the month of February within the Belfast Rheumatology Unit and a report was issued as a result of this to help plan service development. Twenty years later we repeated the audit.

Method: We audited the inpatient admissions between 5th October 2015 and 5th November 2015. Data was collected contemporaneously by reviewing the medical notes whilst the patients remained on the ward and any omissions filled in retrospectively using our local database NIECR. Information collected included age, gender, method of admission, diagnosis on discharge, duration of admission, procedures carried out, allied health professionals inputting, radiology services required and onward referral as inpatient to other specialities. We compared this to the audit report from 1995.

Results: The audit discovered that there was some similarities between the two eras including;

- 1) Inpatients remain predominantly female - 77% in February 1996 compared with 88% in October 2015.
- 2) Emergency admissions remain in the minority- 17% in February 1996 compared with 25% in October 2015.
- 3) 59 patients were admitted to the ward in February 1996 compared with 44 in October 2015.

4) The mean age of our inpatients was 56 years. The commonest age interval in 1996 in both males and females was 45-64.

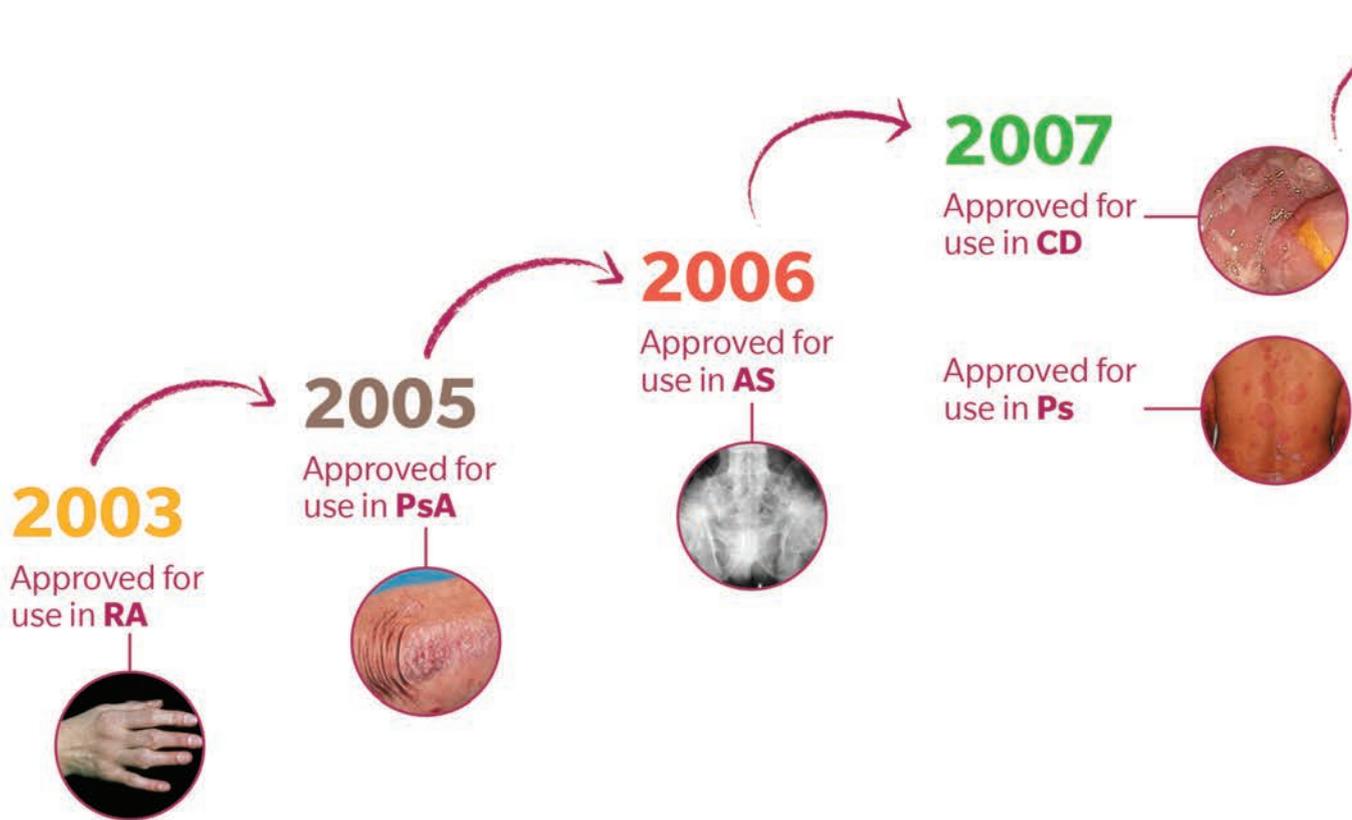
Conversely there are a few notable differences including;

- 1) In 1996 there were 44 beds in the department compared with 16 beds currently.
- 2) In 2015 21/44 patients were elective admissions to the ward for administration of Iloprost or Flolan. Other common reasons for admission included multiple joint injections (5/44) and flares of inflammatory arthritis (4/44). In 1996, 23/49 patients were admitted for the management of flares of inflammatory arthritis. This represents a 38% reduction in admissions for disease flares.
- 3) Less patients required access to the multidisciplinary team (MDT). In 1996 85% of patients were reported to access inpatient physiotherapy, compared with 52% in 2015. 80% of patients in 1996 were said to access OT, but it was 18% in 2015.
- 4) The mean length of stay in 1996 was 11.8 days, compared with 7.1 days in 2015.

Conclusions: Our ward serves a comparable number of patients nowadays, as it did in 1996. However the inpatient population has certainly evolved. Better treatments for inflammatory arthritis have reduced the number of admissions to manage flares. Those patients that are admitted, stay for a shorter time and require less MDT input, perhaps due to less acquired disability.

Trust in HUMIRA

HUMIRA has 12 approved indications¹



Rheumatoid Arthritis (RA)

HUMIRA in combination with methotrexate, is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. HUMIRA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

Psoriatic Arthritis (PsA)

HUMIRA is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. HUMIRA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

Ankylosing Spondylitis (AS)

HUMIRA is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Crohn's Disease (CD)

HUMIRA 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.

Date of Preparation: August 2015 IREHUM140419a(2)



Psoriasis (Ps)

HUMIRA is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

Polyarticular juvenile idiopathic arthritis

HUMIRA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. HUMIRA has not been studied in patients aged less than 2 years.

Paediatric Crohn's Disease (Paed CD)

HUMIRA is indicated for the treatment of severe active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

Hidradenitis Suppurativa (HS)

HUMIRA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

Full prescribing information is available upon request from AbbVie Limited, Immunology Division, 14 Riverwalk, Citywest Business Campus, Dublin 24, D24 XN32.

Legal category: POM. **Marketing Authorisation Numbers:** EU/1/03/256/001-005, EU/1/03/256/007-010. **Marketing Authorisation Holder:** AbbVie Ltd., Maidenhead, Berkshire SL6 4UB, UK.

Reference: 1. HUMIRA [summary of product characteristics]. AbbVie Ltd.

Paediatric plaque psoriasis (Paed Ps)

Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age with an inadequate response to or who are inappropriate candidates for topical therapy and phototherapies.

Ulcerative Colitis (UC)

HUMIRA 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.

Axial Spondyloarthritis Without Radiographic Evidence of AS (nr-axSpA)

HUMIRA is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and / or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

Enthesitis-related Arthritis (ERA)

HUMIRA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

HUMIRA[®]
adalimumab
destination you[™]



Image 1



(16A136) Abstract 29

Poster 21

Vitamin D levels among Behçet's disease patients in a Northern European population

Author(s): Fahd Adeeb^{1,2}, Khairunnisa Mohd Idris¹, Alwin Sebastian¹, Maria Usman Khan^{1,2}, Mary Brady¹, Siobhan Morrissey¹, Joseph Devlin¹, Austin Stack^{2,3}, Alexander Fraser^{1,2}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick 2. Graduate Entry Medical School, University of Limerick 3. Renal Department, University Hospital Limerick

Introduction: Besides its well-known role in calcium homeostasis, current literature suggests that vitamin D plays a significant role in immune modulation and functioning¹⁻². Many studies have revealed a higher rate of vitamin D deficiency among patients with autoimmune or rheumatological diseases³⁻⁴.

Aims/Background: The aim of this study is twofold: first, to evaluate the serum 25-hydroxyvitamin D (25(OH) D) levels of Behçet's disease (BD) patients attending our rheumatology service, and secondly to correlate the levels with the disease activity.

Method: All BD patients fulfilling the ISGBD criteria and attending our service were matched with healthy controls and included in the study. Any subjects who were on vitamin D supplement were excluded. The serum was measured by enzyme-linked immunosorbent assay (ELISA) method; vitamin D levels lower than 20ng/ml were defined as vitamin D deficient, and between 20-40ng/ml as vitamin D insufficient.

Results: A total of 19 BD were included in the study (4 male, 15 female, median age of 41.26 years, range, 19-82 years). The mean serum 25(OH)D levels of BD patients were 47.68ng/ml (range, 21-76ng/ml). The mean 25(OH)D levels were relatively lower in active BD patients in comparison to inactive patients 35ng/ml (range, 21-49ng/ml) and 51.07ng/ml (range, 26-76ng/ml) respectively. Overall, none of the patients had vitamin d deficiency, however 6 patients had vitamin d insufficiency.

Conclusions: In contrast to previous studies⁵⁻⁷ in other BD cohorts and other autoimmune diseases, our study suggests that the mean 25(OH)D levels are higher in the BD group. In active patients however, the serum levels are relatively lower compared to the inactive BD patients, which is in concordance with the literature. Our findings suggest vitamin D as a potential suppressor of inflammatory response in BD, however more studies are needed to support this and conclusively understand its role in the inflammatory pathway.

References: 1. Hamzaoui K, Ben Dhifallah I, Karray E, Sassi FH, Hamzaoui A. Vitamin D modulates peripheral immunity in patients with Behçet's disease. *Clin Exp Rheumatol*. 2010 Jul-Aug;28(4 Suppl 60):S50-7
2. Bscheider M, Butcher EC. Vitamin D immunoregulation through Dendritic Cells. *Immunology*. 2016 Apr 3. Review.
3. Jeffery LE, Raza K, Hewison M. Vitamin D in rheumatoid

arthritis-towards clinical application. *Nat Rev Rheumatol*. 2016 Apr;12(4):201-10.

4. Andreoli L, Piantoni S, Dall'Ara F, Allegri F, Meroni PL, Tincani A. Vitamin D and antiphospholipid syndrome. *Lupus*. 2012 Jun;21(7):736-40.

5. Gatenby P1, Lucas R, Swaminathan A. Vitamin D deficiency and risk for rheumatic diseases: an update. *Curr Opin Rheumatol*. 2013 Mar;25(2):184-91

6. Karatay S1, Yildirim K, Karakuzu A, Kiziltunc A, Engin RI, Eren YB, Aktas A. Vitamin D status in patients with Behçet's Disease. *Clinics (Sao Paulo)*. 2011;66(5):721-3.

7. Can M, Gunes M, Haliloglu OA, Haklar G, Inanç N, Yavuz DG, Direskeneli H. Effect of vitamin D deficiency and replacement on endothelial functions in Behçet's disease. *Clin Exp Rheumatol*. 2012 May-Jun;30(3 Suppl 72):S57-61

(16A137) Abstract 30

Poster 22

A Review of Pneumocystis Pneumonia in Rheumatology Patients in the Northern Health and Social Care Trust

Author(s): Dr A McShane (St5 Rheumatology), Dr A Millar (Cons Rheumatologist NHSCT)

Department(s)/Institutions: Rheumatology Department, Antrim Hospital, Northern Health and Social Care Trust (NHSCT)

Introduction: Formerly known as pneumocystis carinii and more recently pneumocystis jiroveci, pneumocystis pneumonia is a potentially life threatening opportunistic infection that occurs in immunocompromised patients. In rheumatology our patients are immunocompromised both due to their underlying condition and drug treatments required. With advancements in available drug treatments we are becoming more aware of the need for prophylaxis and early recognition of opportunistic infection.

Aims/Background: To determine the incidence of Pneumocystis in Rheumatology Patients within our Trust

Method: Retrospective analysis of all positive virology samples for pneumocystis in the Northern Health and Social Care Trust between February 2011- September 2015.

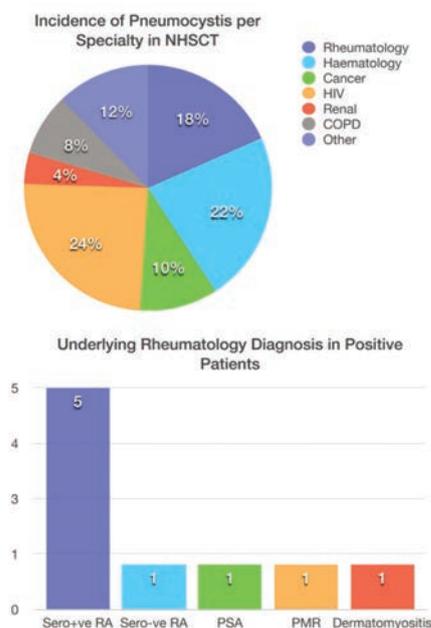
Results: 2498 samples were received from the Trust in total. 90 of these were positive for pneumocystis pneumonia. 38 were paediatric patients and 52 adults. 1 adult was not identifiable and therefore excluded, resulting in 51 positive adults. Of these 9 were primary rheumatology patients (17.6%). 6 patients had rheumatoid arthritis (4 seropositive, 1 seronegative, 1 unknown). The remaining patients had psoriatic arthritis, polymyalgia rheumatica and dermatomyositis.

At the time of diagnosis all but one of the patients were on immunosuppressive medications. None of the patients had received biologic treatments. 7 of the patients were receiving oral Prednisolone or had received intra-muscular depomedrone within 4 weeks of diagnosis. 6 of the patients were receiving Prednisolone plus a DMARD (5 Methotrexate, 1 Salazaparin). One patient was receiving Methotrexate mono therapy (dose 15mg) and one patient had no active rheumatology treatment for 6 months prior to diagnosis due to recurrent infections (previously having received Leflunomide for several years). The minimum dose of oral prednisolone at time of diagnosis was 7mg, with the maximum dose being 25mg. The minimum dose of Methotrexate was 15mg with maximum dose being 22.5mg. Mortality rate for rheumatology patients was 44.4% compared to overall mortality rate of 43% for all positive patients.



Conclusions: Rheumatology patients are at risk of opportunistic infections and accounted for 17.6% of Pneumocystis pneumonia within our Trust. The mortality rate is high and was higher in our group of patients than the general population affected. There are currently no guidelines available to advise on prevention or prophylaxis of pneumocystis. Biologics had not been used in our cohort of patients however there is concern that with the increased availability and usage of biologics we may see an increase in incidence of opportunistic infections. This study highlights the need for more investigation and guidance on pneumocystis prophylaxis in rheumatology patients.

Image 1



(16A138) Abstract 31

Poster 23

CVD Risk Management on RA patients: A Multicentre Audit in the Mid-West Region of Ireland.

Author(s): Maria Usman Khan^{1,3}, Usman Azhar Khan^{2,3}, Eoghan Meagher³, Alwin Sebastian¹, Mary Brady¹, Siobhan Morrissey¹, Mary Gillespie¹, Fahd Adeeb^{1,3}, Joseph Devlin¹, Alexander Fraser^{1,3}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick, Limerick. 2. Cardiology Department, University Hospital Limerick, Limerick. 3. Graduate Entry Medical School, University of Limerick, Limerick

Introduction: Rheumatoid arthritis (RA) is known to be associated with increased risk of morbidity & mortality from cardiovascular disease (CVD). The high prevalence of traditional CVD risk factors (tCVD-RF) & systemic inflammation play an important role in accelerated atherosclerosis¹. EULAR recommendations for CVD risk management include annual cardiovascular risk assessments (CRA) for RA patients.

Aims/Background: The aim of the audit is three-fold: To determine the prevalence of tCVD-RF (DM, hypertension, hyperlipidaemia, long term steroid use, smoking) & the efficiency of recording them, to assess the management of CVD risk in RA patients if in concordance with EULAR recommendations, & to identify whether RA disease activity is adequately controlled.

Method: This multicentre study involved Croom Hospital &

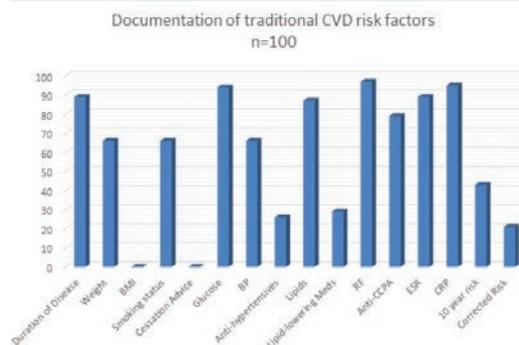
University Hospital Limerick. 100 consecutive patients with definite RA were recruited & proforma was completed based on medical notes & electronic record. Data recording efficiency was assessed based on following information at any time since diagnosis of RA: demographic data, disease duration & activity, extra-articular manifestations, RF/ACPA measurement, most recent ESR, CRP & DAS28 (< 1 year), tCVD-RF, past history of IHD & related co-morbidities (TIA, CVA, PVD, aortic aneurysm), drug history (current RA medications, BP and lipid lowering agents), smoking cessation & lifestyle advice. Data on blood pressure (BP), full lipid & glucose profile (random, fasting or HbA1c) were sought in preceding 4-years & if treatment were commenced as per guidelines accordingly. 10-year risk of fatal CVD was calculated using the SCORE chart: total cholesterol/HDL ratio as measure of lipid profile & risk was multiplied by 1.5 if patient had 2 of these 3 criteria: RA duration >10 years, positive RF/ACPA, presence of severe extra-articular manifestations.

Results: 100 RA patients were audited (F:M ratio=3:1). The efficiency of recording the CRA indices is summarised in Figure 1. 25% patients were still actively smoking, despite this, there was no documentation of smoking cessation advice. 66 patients had their BP monitored: 22 (33.3%) with BP of ≥ 140/90 but only 10 patients were on anti-hypertensives. Blood glucose & lipid monitoring were well documented in 94 & 87 patients respectively. Due to lack of required data, only 43 patients were able to have their 10-year CVD risk SCORE model calculated. 31/43 patients (72%) were considered to be at least of moderate risk to develop fatal CVD within 10 years.

Conclusions: Measurement of tCVD-RF is suboptimal and requires improvement. Rheumatologists should actively look for tCVD-RF in RA patients & be aware that tight control of risk factors is essential due to the high incidence of IHD in this population.

Reference: 1. Rheumatoid arthritis: A disease associated with accelerated atherogenesis. Semin Arthritis Rheum. 2005;35:8-17

Image 1



(16A139) Abstract 32

Poster 24

Pre Biologic screening in Inflammatory arthritis patients. Are we doing enough?

Author(s): Shama Khan, Ausaf Mohammad, Angela Camon, Aine Gorman, Killian O'Rourke

Department(s)/Institutions: Rheumatology Department, Midland Regional Hospital Tullamore

Introduction: The British society of Rheumatology (BSR) established and updated guidelines for the use of Anti-TNF in 2001, 2005 and 2010. It produced recommendations on the



safety aspects and appropriate use of biologics in Rheumatoid arthritis, and the precautions that need to be taken in advance of their prescription [1]. The risk of infection in Rheumatoid arthritis is estimated to be twice that of general population, and is further increased with these medications [2]. These patients should be screened for exposure to TB and other infections, prior to commencement, and closely monitored afterwards for a new infection or reactivation [3]. Several case reports highlights risk of reactivation in patients treated with Anti-TNF [4].

Aims/Background: The aim of the audit was to establish our adherence to the BSR guidelines prior to biologic prescription

Method: A retrospective study of 94 inflammatory Arthritis patients on Biologics, which had a Rheumatology outpatient electronic record available, were reviewed. The following parameters were included.

1. History of Tuberculosis (TB)
2. History of contact with TB
3. A baseline Chest X-Ray (CXR)
4. Mantoux test / Quantiferon Test
5. Methotrexate prescription
6. History of Multiple sclerosis
7. Hepatitis B and C serology
8. Varicella Zoster serology

Results:

AUDIT

PARAMETER AUDIT

QUESTION NUMBER OF PATIENTS (%)

1. History of TB Enquired / Question asked 94 (100%)
No history of TB 91 (94.8%)
Positive history of TB 3 (5.2%)
2. Contact with TB Enquired 94 (100%)
History of contact 16 (17.6%)
No contact 75 (82.4%)
3. CXR Performed Yes 93 (98.8%)
No 1 (1.1%)
4. Mantoux / Quantiferon Test Performed 89 (94.6%)
No record 5 (5.4%)
5. Methotrexate Prescribed Yes 28 (31.1%)
No 66 (68.9%)
6. History of Multiple sclerosis No 94 (100%)
Yes 0 (0%)
7. Hepatitis B&C serology Tested 68 (72.3%)
Not recorded 26 (27.6%)

Conclusions: The audit has demonstrated that we are performing well with regards to TB screening. Patients who had not had their Mantoux or Quantiferon test, have now had this rectified. However there is significant room for improvement with regards to the documentation of Hepatitis B&C and Varicella Zoster status, and a plan to address this is currently on-going.

(16A140) Abstract 33

Poster 25

Diabetes Mellitus in Rheumatoid Arthritis: Treating to Target Two Independent Cardiovascular Risk Factors in a single Rheumatology Department

Author(s): Maria Usman Khan^{1,2}, Fahd Adee^{1,2}, Usman Azhar Khan^{2,3}, Alwin Sebastian¹, Eoghan Meagher², Mary Brady¹, Siobhan Morrissey¹, Mary Gillespie¹, Joseph Devlin¹, Alexander Fraser^{1,2}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick

2. Graduate Entry Medical School, University of Limerick
3. Cardiology Department, University Hospital Limerick

Introduction: Current evidence show that the risk of myocardial infarction and stroke could be reduced significantly in patients with rheumatoid arthritis (RA) if interventions including optimizing glycemic control are implemented accordingly at a timely manner. In RA, glucose metabolism is affected either directly via systemic inflammation, association with other autoimmune disorder producing antibody affecting insulin-producing β -cells in the pancreas, or by the treatment used such as corticosteroids to manage the disease.

Aims/Background: The aim of our study is to calculate the prevalence of diabetes mellitus (DM) in our RA cohort, and to evaluate the care provided and management of DM among these patients according to EULAR¹ and ESC(European Society of Cardiology) Guidelines.

Method: This multicenter study involved 2 teaching hospitals (Croom hospital & University Hospital Limerick). 100 consecutive patients with definite RA were recruited between May and June 2016. A proforma was completed for each patient based on medical notes and electronic record, which include basic demographic details, past medical history of ischaemic heart disease and related co-morbidities (TIA, stroke, PVD, aortic aneurysm), blood glucose reading (random, fasting or HbA1c) in proceeding 4-years and if treatment were commenced accordingly as per guidelines. Since there is no mention on the ideal targets for the control of diabetes by the EULAR guidelines, the recommendations by the "2016 European guidelines on cardiovascular disease prevention in clinical practice" have been used as a gold standard in the audit. These recommend that the target HbA1c for the prevention of cardiovascular disease in diabetes is <7%.

Results: Out of the 100 patients, 6 patients (6%) were found to have DM and were already on anti-diabetic treatment. Among the 6 patients, 3 (50%) were recorded to have at least one ischaemic event. Evaluating the care provided for DM patients in our cohort, 5 out of the 6 diabetic patients (83%) had their Hb1Ac checked within the past 12 month. Among them, 3 patients (60%) had their HbA1c $\geq 7\%$ however none had optimization of their anti-diabetic medication or documented dietary advice based on their elevated Hb1Ac levels. None of the patients were referred to the endocrine/diabetic service for optimization of their diabetic management.

Conclusions: Despite good documentation of patients' blood glucose levels, interventions such as dietary advice or optimization of patient's anti-diabetic treatment and/or referral to the appropriate specialty are poor. Awareness that DM is a key mortality predictor in RA is important among rheumatologists, and merits more attention in the outpatients clinic.

Refernce: 1.Peters M JL, Symmons D PM, McCarey D, Dijkmans B AC, Nicola P, Kvien T K et al. EULAR evidence-based recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis. Ann Rheum Dis, Feb 2010; 69: 325-33.

(16A141) Abstract 34

Poster 26

Treat to Target in Gout

Author(s): K. Osman, M. Carolan, B. Stafford, B. Murphy, S.A. Ramakrishnan, S. Chavrimootoo

Department(s)/Institutions: Regional Rheumatology Department, Our Lady's Hospital Navan Co Meath



Introduction: The tertiary management of gout patients can be a challenging but rewarding experience. Treat to target (T2T) is known to improve outcomes in many Rheumatic diseases including Gout. A specialised, nurse-led T2T clinic for the assessment and management of patients with uncontrolled Gout started in May 2014 at the regional department of Rheumatology, Our Lady's Hospital Navan. Assessment and management of cases followed the American College of Rheumatology (ACR) guidelines 2012.

Aims/Background: To assess the achievement of goals set up for the Gout T2T clinic, namely. 1- Control of gout flare ups off prophylaxis. 2- Serum Uric Acid below 360 $\mu\text{mol/l}$

Method: The Audit included all patients enrolled to T2T clinic in the period May 2014 till the end of July 2015. Medical charts were systematically analysed in December 2015. All patients were started or continued on Urate lowering therapy (ULT) with allopurinol or febuxostat at the start of T2T. Prophylaxis with Colchicine, NSAIDs or Steroids was also co-prescribed. Patients were followed on a 4-6 weekly basis for escalation of treatment if required.

Results: Thirty eight patients were included in the audit. The number of cases who continued T2T follow-up with the Rheumatology nurses was 36 (95%). The majority of enrolled patients were males (n=34, 90%). The mean age of patients in years was (males=58.8, females=62.2). The mean level of uric acid at the start of T2T was 492 $\mu\text{mol/l}$. The mean number of acute episodes of gout prior to T2T was 2.4. The mean duration of gout symptoms was 6.7 years. The number of patients who successfully achieved both goals of the T2T clinic was 25 out of 38 enrolled, (65.7 %). The mean duration of follow up of this group of patients was 5.9 months.

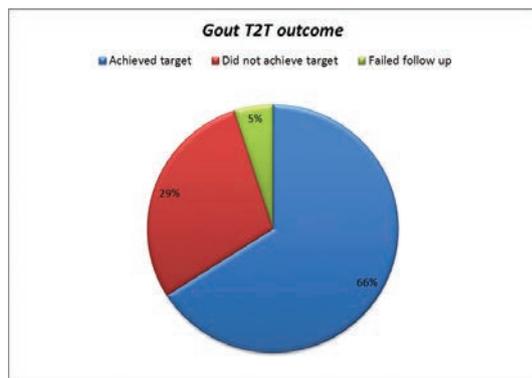
The number of patients who failed to achieve either one of the above goals was 9 (23.6%), with mean duration of follow up being 10.8 months at the time of data analysis.

Two patients failed to achieve both goals. One of them had a rash with angioedema due to Allopurinol and subsequently Febuxostat. He has since been started on Probenecid. In the other case, it was due to lack of adherence to medications.

Conclusions: There was a high proportion of patients who completed T2T for gout. The majority achieved the T2T targets and were successfully discharged to Primary care within a 6 month period.

The establishment of an early arthritis clinic for gout followed by a T2T approach in management has better outcomes as shown by this audit.

Image 1



(16A142) Abstract 35

Poster 27

An audit to assess the relationship between timing of influenza vaccination and infection rates in patients on rituximab with rheumatic disease in Musgrave Park Hospital.

Author(s): Dr Ursula Laverty, Dr Mark Leith, Dr Claire Benson

Department(s)/Institutions: Musgrave Park Hospital, Belfast

Introduction: Patients on rituximab are at an increased risk of hypogammaglobulinaemia and an increased risk of infection. EULAR guidelines recommend that vaccines should ideally be administered before B cell depleting biological therapy is started or when patients are on such a treatment already, at least 6 months after the start but 4 weeks before the next course. The aim of this project is to raise awareness of timely influenza vaccination and improve practice.

Aims/Background: 1. To investigate the temporal association of influenza vaccination and rituximab infusions measuring rates of delayed infusions and ineffective vaccination. 2. To measure IgG levels in patients on rituximab and associated rates of infection.

Method: Patients were identified on the rituximab database (255 patients) in Musgrave Park Hospital. Data was collected retrospectively with the use of a proforma. Patient records were reviewed on the electronic care record (ECR) to obtain the date of rituximab infusion, immunoglobulin G (IgG) levels and infection rates. Each patient's GP surgery was contacted for the date of influenza vaccination.

Results: IgG levels were low in 12 % of patients receiving rituximab in MPH. Rituximab was given in 83% patients with low IgGs. 45% of patients with low IgG level who were given rituximab needed antibiotics within 6 months, compared with 26% of those with normal IgG levels. The rate of uptake of influenza vaccine in patients on rituximab was 79%. Rituximab treatment was delayed in 2% of patients because influenza vaccine had not been given. Of those receiving the influenza vaccine, 8% of rituximab doses should have been delayed until 4 weeks after vaccine. 30% of patients received flu vaccine within 6 months of rituximab doses and therefore their humoral response is likely to be less effective.

Conclusions: The results show that we are not currently meeting the standards in EULAR recommendations. We are sending a letter to each patient and GP to advise them to attend for influenza vaccination at least 4 weeks before their next dose of rituximab, aiming to ensure rituximab is not delayed and vaccines are effective. There was an increased risk of infection in patients on rituximab in this group of patients, particularly if IgG levels were low. However we cannot conclude if there is a direct association between immunoglobulin levels and infection rates as infection risk is likely to be multifactorial given co-morbidities and demographics. Education of physicians and patients about the association of rituximab with infections, monitoring of immunoglobulin levels and identification of high-risk groups for the development of infectious complications is important.



(16A144) Abstract 36

Poster 28

Audit of waiting time for imaging investigations ordered from a rheumatology outpatient department

Author(s): A. Sebastian¹, S. Clifford¹, R. McCafferty¹, C. McCarthy^{1,2}

Department(s)/Institutions: 1. Mater Misericordiae University Hospital, Dublin. 2. University College Dublin

Introduction: Timely access to a wide variety of imaging modalities is essential in Rheumatology for diagnosis and management. It is useful to be able to predict the length of time a patient will be awaiting a particular scan, as some treatments may be delayed until after a radiological diagnosis has been made.

Aims/Background: This study aims to show the average wait times for MRI, CT, DEXA, US and X-Ray investigations requested by the rheumatology out-patient department of our institution over a three year period, to assess allocation of resources.

Method: Data was collected using the computerised database at our institution. The details and waiting times of 1230 requested scans (MRI, CT, X-ray, DEXA and US) during 2011-2014 were analysed. The mean wait times were compared using ANOVA and paired student's t-tests. A target maximum wait time of 60 days for non-urgent MRI, CT and DEXA scan and 30 days for non-urgent X-Ray and US was decided upon following literature review to look at the target maximum wait times for imaging modalities in other countries, including the UK and Canada. The percentage of scans that were performed within this target wait time was analysed.

Results: Outpatient wait times were longest for MRI scans, with a mean of 306 days. This was followed by DEXA (mean 155 days), CT (mean 89 days), ultrasound (mean 66 days) and X-Ray (mean 7 days). The difference between the wait times between modalities were statistically significant (p<0.001). Only 10% of MRIs, 46% of CTs and 9% of DEXAs were done within the target period of 60 days. 98% of DEXAs and 33% of ultrasounds were done within the target period of 30 days.

Conclusions: Imaging studies play a crucial role in the diagnosis of rheumatic disease. This audit showed that for the majority of patients in our rheumatology service, the wait for radiological investigation is in excess of internationally recommended targets. More appropriate use of resources could result in improved patient diagnosis and management for rheumatology out-patients.

Image 1

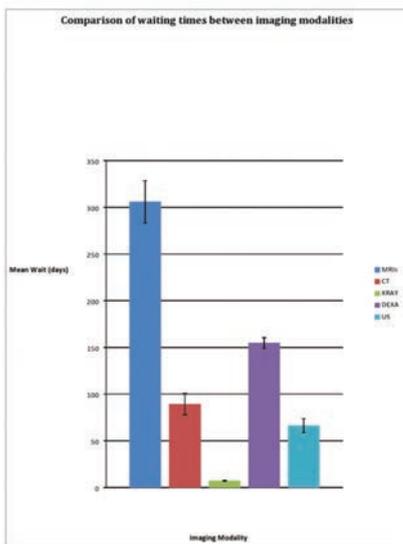


Image 2

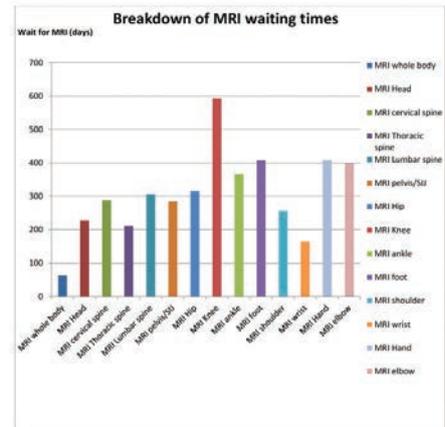
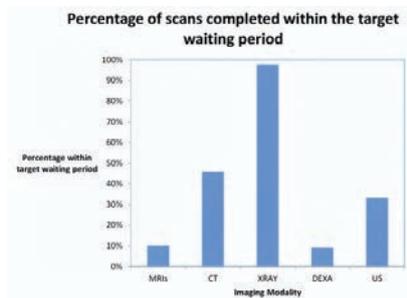


Image 3



(16A145) Abstract 37

Poster 29

Response rates to a second Tumour Necrosis Factor (TNF)-alpha inhibitor in axial spondyloarthritis.

Author(s): McKnight J, Gordon E, Pendleton A.

Department(s)/Institutions: Rheumatology Department, Musgrave Park Hospital, Belfast.

Introduction: TNF-alpha inhibitor therapies have a proven benefit in patients with axial spondyloarthritis. There has been a recent change to NICE guidelines recommending the use of TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. NICE now recommend treatment with another TNF - alpha inhibitor for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF - alpha inhibitor, or whose disease has stopped responding after an initial response.

Aims/Background: We sought to assess the response rates of patients with axial spondyloarthritis to a second TNF-alpha inhibitor in the clinical setting. Also, we assessed whether the initial reason which prompted the trial of a second TNF-alpha inhibitor had any effect on response rates.

Method: Using the local biological therapy database in Musgrave Park Hospital Belfast, we retrospectively identified 49 patients with axial spondyloarthritis who had trialled a second TNF-alpha inhibitor. We examined the response rates after three months of switching to a second TNF-alpha inhibitor; reduction in BASDAI >2 and VAS>2 compared with baseline counted as an adequate response.

Results: The overall response rate at three months to a second TNF-alpha inhibitor was 51%. In the subgroup of patients who switched due to primary inefficacy 37% responded, of those switched due to secondary inefficacy 52% responded. In those who switched due to side effects, 78% responded without further side effects at three months.



Conclusions: This clinical review suggests that a significant proportion of patients with axial spondyloarthritis will respond adequately to a second TNF-alpha therapy, especially if the initial reason for switching was secondary inefficacy or side effects.

(16A148) Abstract 38

Poster 30

Repeated Osteoporosis screening in Rheumatoid Arthritis: Are we complying with guidelines?

Author(s): A. Gorman, V. Sullivan, S. Khan, A. Mohammad, A. Khan, K P. O'Rourke.

Department(s)/Institutions: Department of Rheumatology, Midlands Regional Hospital, Tullamore.

Introduction: Osteoporosis rates are higher in patients with rheumatoid arthritis (RA). Patients with RA diagnosed with osteoporosis have a 30% increased risk of major fracture.¹ Monitoring response to osteoporosis treatment is recommended however there is no consensus on how frequently this should be performed. The International Society for Clinical Densitometry (ISCD), National Osteoporosis Foundation (NOF) and the American Association of Clinical Endocrinologists (AACE) all recommend repeat Bone Mineral Density (BMD) assessment within two years after initiating osteoporosis treatment to assess response to treatment.^{2,3,4} Furthermore, the NOF and AACE recommend repeat screening every two years after diagnosis.^{3,4}

Aims/Background: To identify patients with RA and osteoporosis. To identify if international guidelines are being achieved for reassessment of BMD within two years of treatment commencement in keeping with international guidelines.

Method: A database of patients with a diagnosis of RA and osteoporosis who attend the Rheumatology department of the Midlands Regional Hospital, Tullamore since January 2013 was reviewed. Outpatient summaries, date of diagnosis, radiology investigations (DEXA scanning), pharmacological treatment and follow up investigations and treatment were documented.

Results: As of August 2016, 770 patients were identified as having RA. 90% of patients had attended the department since 2013. 117 (16.7%) patients were identified as having osteoporosis. Of these, 52.14 % of patients were prescribed bisphosphonate therapy, 31.62% denosumab, 9.4% calcium / vitamin D alone, 0.85% other treatment (teriparatide / strontium) and 5.1% were on no treatment. Only 11.9% of these patients had a repeat DEXA scan within two years of starting or changing treatment. 11.1% of patients had repeat DEXA scans booked. The average length of time since a patient's most recent DEXA is 35 months.

Conclusions: Repeat DEXA scanning to assess the response to osteoporosis treatment in people with RA within the timeframe recommended by international guidelines has not been achieved. Patients who fail to respond to osteoporotic treatment are not being identified in a timely manner and therefore are at an increased risk of fractures. The results of this audit will make us more vigilant to identify those patients who are treated for osteoporosis that need repeat DEXA scanning to ensure that treatment is efficacious.

References: Kanis JA, Johnell O, Oden A, et al. FRAX and the assessment of fracture probability in men and women from the UK. *Osteoporos Int* 2008; 19:385.
2013 ISCD Official Postions - Adult

<http://www.iscd.org/official-positions/2013-iscd-official-positions-adult/> (Accessed on December 02, 2013).

Cosman F1, de Beur SJ, LeBoff MS, et al. *Clinician's Guide to Prevention and Treatment of Osteoporosis* *Osteoporos Int*. 2014 Oct;25(10):2359-81

Watts NB, Bilezikian JP, Camacho PM, Greenspan SL, et al. *American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the diagnosis and treatment of postmenopausal osteoporosis*. *AACE Osteoporosis Task Force Endocr Pract*. 2010 Nov;16 Suppl 3:1-37.

(16A155) Abstract 39

Poster 31

A less common differential for Rheumatoid Nodules

Author(s): Dr. R Valea, Dr. S Chavrimootoo, Dr. SA Ramakrishnan

Department(s)/Institutions: Our Lady's Hospital Navan

Introduction: Tumoral calcinosis is an uncommon, benign condition described for the first time in 1943 by Inclan et al. characterized by deposition of calcific masses in the soft tissue. Decades after it has been first described the etiology is still uncertain though an agreement has been reached regarding the classification for diagnostic purposes. According to the presence or absence of underlying calcifying disease tumoral calcinosis can be classified as primary - hyperphosphatemic or normophosphatemic, and secondary, the most common association of the later being CKD and hyperparathyroidism. Diagnosis is established by imaging studies, x-ray showing multilobulated periarticular calcifications, CT/MRI for establishing the extent of lesions and as a guide for surgical planning.

TC can be mistaken for osteosarcoma, chondrosarcoma, myositis ossificans, and other conditions [2,4]. As this case demonstrates, TC should be considered in the differential diagnosis of any soft tissue calcification.

Treatment of tumoral calcinosis can be divided in medical and surgical, removal of deposits being associated with high recurrence rate.

We report the case of a 36yrs old Colombian woman with a background of Hypothyroidism who was referred by our Orthopaedic colleagues with suspected Rheumatoid nodules of her elbows. She reported multiple subcutaneous nodules located on both elbows and lower limbs since the age of 11. These were associated with a history of arthralgia involving the knees, elbows, left hip and low back which had improved in the years prior to referral. She also had symptoms suggestive of Raynaud's phenomenon.

Clinical examination revealed evidence of soft tissue nodules over elbows and knees with no evidence of synovitis. Laboratory investigations revealed normal routine bloods, including serum calcium level. RF, anti-CCP antibodies, ANA and ENA were all negative. X-rays of affected areas showed calcified deposits which were consistent with a diagnosis of tumoral calcinosis.

Surgical excision of lesions was not recommended at present as the patient was not significantly symptomatic.

This is an important but rare differential to consider when evaluating patients with potential Rheumatoid Arthritis.



(16A156) Abstract 40

Poster 32

Is the traditional way (Cyclophosphamide) or the modern biologic (Rituximab) to induce remission in GPA?

Author(s): Alwin Sebastian¹, Maria Usman Khan^{1,2}, Alexander Fraser^{1,2}, Joe Devlin^{1,2}, Fahd Adeeb^{1,2}

Department(s)/Institutions: 1. University Hospital Limerick. 2. University of Limerick

Introduction: Granulomatosis with polyangiitis (GPA) is a rare blood vessel disease. GPA is a systemic vasculitis that typically involves small and medium vessels. This is a complex and potentially serious disease. However, with prompt diagnosis, GPA can be treated effectively. Treatment options for remission induction include corticosteroids and cyclophosphamide or corticosteroids and Rituximab

Aims/Background: We present this interesting case to prove that biologic therapy is not always superior to traditional way of treatment to induce remission of GPA

Method: 62 years old male presented with 2 weeks history of purpuric rash in his legs and extensive maculopapular rash on his trunk, face and neck. He was diagnosed with GPA in 2009 and treated with Rituximab until 2011 and on maintenance therapy with Methotrexate 25 mg weekly. He was in remission with negative cANCA until this presentation.

He was afebrile and his vital signs were normal. He had residual peripheral neuropathy. His Urine dipstick and CXR was normal. His bloods showed CRP-112, cANCA and PR3 positive. He was started on pulsed IV Methylprednisolone 1 gram for 3 days followed by 1 gram of Rituximab infusion along with oral Prednisolone 60mg OD.

On day 12, he was desaturated. CXR showed bilateral extensive pulmonary hemorrhage which was confirmed by the CT Thorax and bronchoscopy. He was treated with another course of IV methylprednisolone. His bronchial washing confirmed the presence of pneumocystis jirveci and for this he was commenced on Septrin.

On day 30 he was discharged from the hospital with PO steroids and MTX. Unfortunately 2 months later he was readmitted with increasing SOB. His CXR suggested possible pulmonary hemorrhage and he was in respiratory distress. He was admitted to HDU and received pulse methylprednisolone for 3 days followed by IV Immunoglobulins for 5 days along with PO prednisolone 60 mg OD. He was started on IV Cyclophosphamide 1 gram. He is clinically much improved.

Results

Our patient ultimately required Cyclophosphamide treatment as a 2nd line after previous remission with Rituximab.#

Conclusions: Cyclophosphamide is a well-known used medication to treat GPA, however considering the use of limitations of this and the introduction of Rituximab is a welcome alternative therapy. This strategy is still debatable in certain conditions such as the availability, accessibility and the cost

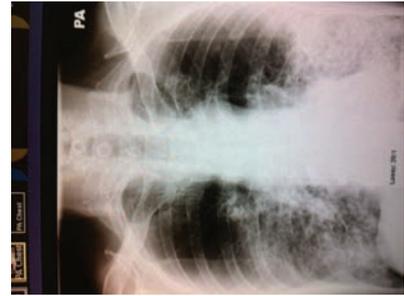
Image 1



Image 2



Image 3



(16A157) Abstract 41

Poster 33

A Survey in Two Continents on Management of Gout Among Final Year Medical Students and Medical Interns

Author(s): Khairunnisa Mohd Idris¹, Fahd Adeeb^{2,3}, Orla Ni Mhuircheartaigh², Maria Usman Khan^{2,3}, Alwin Sebastian², Joseph Devlin², Manal Tayel¹, Alexander Duncan Fraser^{2,3}

Department(s)/Institutions: 1. Rheumatology department, Alexandria University Hospital, Alexandria, Egypt. 2. Rheumatology department, University Hospital Limerick, Ireland. 3. Graduate Entry Medical School, University of Limerick, Ireland

Introduction: Hippocrates first described gout as the "unwalkable disease" in the 5th century BC, but it was actually the Ancient Egyptians who were the first to identify uric acid in 2640 B.C. Despite being among the oldest recognized disease known for thousands of years and with current excellent therapies, gout remains to be one of the most poorly managed conditions. Final year medical students & junior medical doctors undertaking housemanship are expected to demonstrate reasonable competence in the understanding & management of this condition.

Aims/Background: The aim of the study were to evaluate the understanding, rate of variability, & identifying the areas of deficiency in the management of gout among final year medical students in Alexandria University, Egypt & medical interns in University Hospital Limerick, Ireland.

Method: This is a cross-sectional study involving 21 final year medical students and 21 medical interns from Alexandria University & University Hospital Limerick respectively. Participants were randomly chosen prior to their scheduled tutorial to answer a set of short, structured questionnaire on acute and chronic management of gout. Results were compared with the European League Against Rheumatism (EULAR) guidelines. Participants were asked to anonymously fill the questionnaire within a time frame of ten minutes.

Results: All 42 participants answered & returned the questionnaire, giving a 100% response rate. 4 participants (9.5%)



knew uric acid levels could be high or normal during an acute attack whereas 29 (69%) thought it would only be high, while nine (21.5%) were unsure. In the treatment of acute gout, 38 participants (90.5%) knew NSAIDs was the first line therapy, 33 (78.6%) knew low-dose colchicine could be used & 26 (61.9%) suggested steroids as an option. On commencement of urate-lowering therapy (ULT), only three (7%) participants realized it should be initiated concomitantly with prophylaxis treatment (NSAIDs, colchicine or steroids) to prevent flares. 22 (52.4%) mentioned Allopurinol, two (4.8%) mentioned Febuxostat & five (11.9%) mentioned probenecid as the first line ULT, however none knew the doses. Nineteen (45.2%) knew thiazide is one of the commonest drugs that exacerbate gout. Eight (19%) knew the target serum urate levels should be <360µmoles/liter or <6mg/dl. Majority (92.2%) knew regarding other recommendation & advice including modification of dietary, lifestyle habits & compliance.

Conclusions: Overall, the understanding of gout management among the final year medical students and medical interns were suboptimal when compared to EULAR recommendations, however there is plenty of room to improve. To overcome this, there was a session with the medical students & interns respectively to discuss the results of the questionnaire, an agreement that results were suboptimal & a literature review lunch meeting was arranged to discuss further on management of gout.

(16A159) Abstract 42

Poster 34

Chart review after New Rheumatology patient assessment significantly reduces demand for follow up appointments

Author(s): K. Osman, Q. Shah, S. Chavrimootoo, S. A. Ramakrishnan

Department(s)/Institutions: Regional Department of Rheumatology, Our Lady's Hospital, Navan Co. Meath

Introduction: Rheumatology outpatient clinics in the country are overstretched with ever increasing demand. A large number of new patient referrals are seen in each department on a continual basis which increases demand for follow up slots for these patients in an already stretched service. The average time to find a follow up slot in most hospitals is 3 to 6 months that causes delay in treatment after assessment and also places further demands in the system.

Aims/Background: Our aim was to reduce the number of follow up appointments generated after new patient assessment by chart review and discharge suitable patients to primary care with appropriate recommendations. This will facilitate smooth functioning of existing follow up clinics for inflammatory conditions.

Method: All new patients who attended Department of Rheumatology at Our Lady's hospital Navan between December 2016 to May 2016 were included in this study. After assessment, appropriate investigations were requested on the day. Charts of these patients were reviewed by Rheumatology team in a non-clinical session each week led by consultants 3-5 weeks after attendance. Where appropriate, patients were discharged with detailed advice. A note was sent to patient of this arrangement. Other patients were offered follow up as appropriate.

Results: A total of 522 new patients were seen in the 6 month period. The number of patients seen in early arthritis clinic was

148(28.35%) and General Rheumatology clinic was 374(71.65 %).

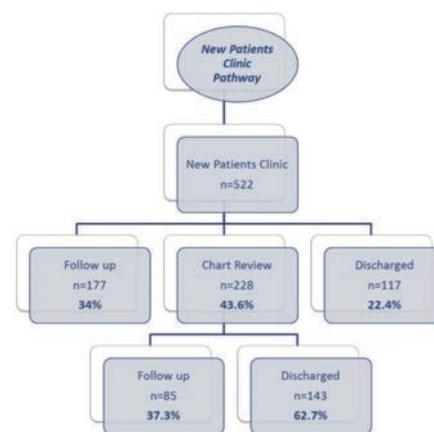
The number of patients discharged to primary care after first assessment was 117(22.4%).The diagnoses for these were Osteoarthritis (n=33, 28.2%), Soft tissue rheumatism (n=27, 23%), Fibromyalgia (n=24, 20.5%), Nonspecific symptoms (n=14, 11.9%), Osteoporosis (n=6, 5%) and other conditions 13 (11.1%). The total number of patients given follow up appointment after first assessment was 177 (34 %).

The number of patients booked for chart review session was 228 (43.6 %).Of these 143 (62.7) were discharged to primary care. This constitutes 27% of the total number of new patients seen in the period of six month. The diagnoses of these were Osteoarthritis (n=53, 37%), Nonspecific symptoms, (n=28, 19.6%), Soft tissue rheumatism (n=15, 10.4%), Osteoporosis (n=15, 10.5%), Fibromyalgia (n=10, 7%) and others (n=22, 15.4%).

The total number of patients discharged to primary care after first visit was 260 out of 522 (49.8%) which is a significant number.

Conclusions: Chart review session is an efficient way to reduce the number patients requiring follow up. It also facilitates early initiation of management after first assessment. In addition it provides opportunity for members of rheumatology team to interact and participate in clinical decision making.

Image 1



(16A162) Abstract 43

Poster 35

Screening for the Development of Pulmonary Hypertension in patients with Systemic Sclerosis in Beaumont Hospital

Author(s): Dr. Conor Magee, MB BAO BCh; Dr. Adam Roche, MB BAO BCh; Dr. Paul G O'Connell, MB, FRCPI; Dr. Donough Howard, MB BAO BCh, FRCPI; Dr. Grainne Kearns, MD

Department(s)/Institutions: Department of Rheumatology, Beaumont Hospital, Dublin 9

Introduction: The purpose of this audit was to check whether patients with scleroderma attending Beaumont Hospital were being appropriately investigated for the development of pulmonary hypertension.

Aims/Background: Pulmonary Arterial Hypertension (PAH) is one of the most serious complications and a leading cause of death in patients with systemic sclerosis. Detection of the development of PAH facilitates earlier treatment and better outcomes for patients with this condition. The DETECT algorithm was developed to facilitate a stepwise approach to screening for the development of PAH.



Method: We looked at whether patients with systemic sclerosis who had attended Beaumont Hospital within the past 2 years had had pulmonary function testing performed within that time. We also looked at whether these patients had had an ECHO performed during this time and whether these patients had had a urate level and BNP checked (as these were found to be significant variables in the DETECT algorithm for the development of pulmonary hypertension).

Results: Of the 42 patients who had attended the outpatient service in the past 2 years 81% (34/42) had had pulmonary function testing within that time frame. We found that 57% (24/42) had had an ECHO during that time. We also found that 67% (28/42) had had a urate level checked and 83% (35/42) had had a BNP checked.

Conclusions: We found a high percentage of patients attending the Rheumatology service in Beaumont Hospital had had pulmonary function testing performed within the previous 2 years. However, a significantly smaller percentage had had either an ECHO performed within that time frame or had had all of the DETECT criteria checked (which would enable the prioritization of ECHOs for particular patients within this cohort).

(16A163) Abstract 44

Poster 36

Management of Hyperlipidaemia in Rheumatoid Arthritis patients

Author(s): Maria Usman Khan^{1,2}, Fahd Adeb^{1,2}, Usman Azhar Khan^{2,3}, Eoghan Meagher², Joseph Devlin¹, Alexander Fraser^{1,2}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick. 2. Graduate Entry Medical School, University of Limerick. 3. Cardiology Department, University Hospital Limerick

Introduction: Rheumatoid arthritis (RA) is a recognized independent risk factor of accelerated atherosclerosis. The 2016 Joint European Society of Cardiology (ESC) guidelines on cardiovascular disease (CVD) prevention in clinical practice recommended a systematic CVD assessment as a screening tool in individuals at increased cardiovascular risk including targeted high-risk subpopulation such as RA, using the SCORE system that gives an estimate of the 10-year risk of a first fatal atherosclerotic event.

Aims/Background: The aim of the study is twofold: To determine the efficiency of screening for hyperlipidaemia in our RA cohort and secondly, to evaluate the initiation or optimization of lipid lowering therapy among the indicated RA patients.

Method: This multicenter retrospective cohort study involved 2 teaching hospitals (Croom hospital & University Hospital Limerick). 100 consecutive patients with definite RA were recruited. A proforma was completed for each patient based on medical notes and electronic record data. In those patients where data on age, gender, smoking, blood pressure and lipid profile were complete, the 10-year risk of fatal CVD was calculated using the SCORE chart. The patients were stratified into 4 risk categories, and together with measurement of target LDL-cholesterol (LDL-c) levels, recommendations for lipid lowering measures were adapted: Ideal LDL-c for low (SCORE <1%) and moderate risk patients (SCORE ≥1- <5%) should be <3.0 mmol/L, <2.6mmol/L for high risk (SCORE ≥5- <10%) & <1.8mmol/L for very high risk patients (SCORE ≥10%). Statins were the recommended treatment due to potential anti-inflammatory effects¹.

Results: Among the 100 patients, full lipid profile was performed in 87 patients within the last 4-years. 57 of the 87 patients (65.51%) had their full lipid profile checked within the last 12 months. 43 patients had adequate data to calculate the 10-year risk of fatal CVD. 32 out of 43 patients (74.41%) had indication to be on lipid-lowering therapy. 7 patients in low risk category had an indication for statins but were not on therapy. Out of 27 patients in moderate risk group, 12 pts were on statins with 3 of them at suboptimal control (at inadequate dose). 9 patients were not on statins despite fulfilling the above-mentioned criteria. 2 of 3 high-risk patients were suboptimally controlled on statins and 1 of the 2 patients in very high-risk category was a candidate for statin. Overall 17/43 patients were candidates for de novo statin therapy and lipid control was suboptimal in 6/43 patients on statin therapy.

Conclusions: Despite sufficiently having adequate indication to be on lipid lowering therapy, majority of the RA patients remained untreated or on sub-therapeutic doses. To address this issue, we recommend annual screening using the latest Joint ESC guidelines of the 10-year risk of fatal CVD in combination with target LDL-c measurement, with regular audit to see if this is achieved.

Reference: 1. Okamoto H, Koizumi K, Kamitsuji S, et al. Beneficial action of statins in patients with rheumatoid arthritis in a large observational cohort. *J Rheumatol* 2007;34:964–8.

(16A165) Abstract 45

Poster 37

Gout: Treat to Target - Are We On Target?

Author(s): Gillian Corbett, John Stack, Geraldine McCarthy

Department(s)/Institutions: Rheumatology Department, Mater Misericordiae University Hospital

Introduction: Pharmacological management of gout, or monosodium urate deposition disease, is centred on establishing a normo-uricaemic patient who is asymptomatic of disease. Of all patients with hyperuricaemia, only one third will manifest symptomatic disease. These cases of asymptomatic hyperuricaemia have been associated with both crystal deposition and multiple non-MSK manifestations.

Aims/Background: The aims of this study was to (i) estimate the number of gout patients with hyperuricaemia and (ii) to ascertain the underlying causes of hyperuricaemia.

Method: A cohort of gout patients attending the MMUH Rheumatology out patient department (OPD) was randomly selected from the patient database. Details for each case were elicited by examining past consultation notes as of December 2015. The uric acid level deemed on target was <360 umol/L. The uric acid level used was the most recent one known at the time of the last OPD consultation. It was noted whether the patient had an on-target uric acid level, whether they were symptomatic, the urate lowering therapy agent(ULT) the patient was on and whether action was taken at last OPD (increase the dose or switch to alternative agent). The consultation notes were then examined for a cause of hyperuricaemia.

Results: Overall, 35/60 (58.33%) patients included were on-target, while 25/60 (41.66%) were off-target. In the on-target group, the mean uric acid level was 283 umol/L, with minimum and maximum values of 132 and 360 umol/L, respectively. 6/35 of this group were symptomatic, with action taken on the last OPD in 4 of these cases. In the off-target group, the mean uric



acid level was 479 umol/L, with minimum and maximum values of 366 and 694 umol/L, respectively. 9/25 of this group were symptomatic, with action taken in 7/35. Of note, the uric acid level was detailed in the consultation note in 26/35 (74.3%) in the on-target group versus 13/25 (52%) in the off-target group. There was a similar usage of allopurinol in on and off target groups (65% and 68% respectively) but Colchicine use was higher in the off target group (76% versus 57%) and Febuxostat use was higher in the on target group (33% versus 24%). The underlying causes identified in the off-target groups is detailed in Table 1.

Conclusions: This study of the gout cohort at MMUH has shown that 41.66% of patients have off-target uric acid levels. Causes for this include compliance, patients lost to follow up, attending with other rheumatological diagnoses, no recent uric acid levels, patients not attending OPD appointments or phlebotomy and pharmacological diuresis. In consultation notes, the uric acid level was detailed in 74.3% in the on target group and 52% of the off target group. There was a higher use of febuxostat in the on target group. The results of this audit was discussed at multidisciplinary meeting to highlight the importance of raising the dose of ULT or switching to an alternative in patients who are off target. The results may be re-audited in six to twelve months.

Image 1

Table 1.

Cause of hyperuricaemia	Number affected	% Affected
Attending for >1 Rheum Dx	4/25	16%
Patient adherence issues	11/25	44%
Lost to follow up	5/25	20%
No recent urate	4/25	16%
Did not attend OutPatient Apt	2/25	8%
Did not attend phlebotomy	1/25	4%
Diuretics	1/25	4%

(16A166) Abstract 46

Poster 38

A prospective, open-label treatment trial to compare the effect of corticosteroids for Inflammatory Lower Back Pain in patients with Psoriatic arthritis and Ankylosing Spondylitis

Author(s): Muhammad Haroon, Muddassar Ahmad, Sujil Jacob, Nouman Baig, John Rice

Department(s)/Institutions: Division of Reumatology, Department of Medicine, and Department of Orthopaedics, University Hospital Kerry, Tralee, Ireland

Introduction: At present there are no approved therapies for treatment of axial PsA (AxPsA). Overall, the most data about axial involvement in SpA come from ankylosing spondylitis (AS) studies, while data about the axial involvement in PsA is limited. The efficacy of corticosteroids in psoriatic arthritis (PsA) patients with inflammatory back pain has not been studied to date.

Aims/Background: To investigate the comparative performance of depot corticosteroids for active axial-PsA (defined as patients with inflammatory back pain-IBP) versus those with active AS.

Method: In this open-label controlled trial, patients with active AxPsA (n=10) and AS (n=10) despite taking NSAIDs were recruited. The active disease was defined as patients with IBP (fulfilling ASAS Expert Criteria) with spinal pain score (numerical rating scale 0-10) of ≥ 4 and BASDAI score ≥ 4 . All patients received a depot intra-muscular steroid injection (Triamcinolone Acetonide 80mg), one dose only. Intra-muscular

steroid option was used to overcome the compliance and adherence issues. Clinical outcome assessments were made at following time points: baseline, week 2, and week 4, and included BASDAI, Bath AS Functional Index (BASFI), patient global assessments (numeric rating scales 0–10), number of swollen joints (66/68-joint score) and number of enthesitic sites (Leads Enthesitis Score). Laboratory outcome assessments included C reactive protein (CRP) level and HLA-B27 status. The ASAS 40 response was calculated. Achieving ASAS 40 response at week-2 was chosen as primary outcome parameter, and a 50% improvement of the initial BASDAI (BASDAI 50) at week 2 was also considered as secondary outcome measure.

Results: Age and gender matched patients with AxPsA and AS were recruited (10 patients in each group with mean age of 36.7±9 years and 55% of the entire cohort was female). Among Ax-PsA patients at week-2 and week-4, spinal pain score, patient global, ASQoL, BASFI, BASDAI improved significantly (p<0.001). However, among patients with AS, at week-2 and week-4, only spinal pain score and patient global assessments improved (p=0.01) but other indices remain unchanged. Primary end point, ASAS 40 response, was achieved by 60% and 20% of Ax-PsA and AS patients respectively. However, at week-4, ASAS 40 response was achieved by 70% and 40% of Ax-PsA and AS patients respectively. Secondary outcome measure, BASDAI 50 response, was achieved by 50% and 10% of Ax-PsA and AS patients, respectively. However, at week-4, BASDAI response was achieved by 40% and 10% of Ax-PsA and AS patients, respectively.

Conclusions: AxPsA patients respond significantly better to corticosteroids than patients with AS. This furthers the argument and adds to the growing evidence that AxPsA and AS are distinct entities. This is the first study to date which has shown a differential therapeutic response to corticosteroid Therapy for inflammatory back pain among patients with PsA and AS. Recruitment of patients in the control arm is underway.

(16A167) Abstract 47

Poster 39

Mono-therapy is effective in inducing remission in an Early Rheumatoid Arthritis population using Treat to Target (T2T) protocol.

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Department(s)/Institutions: 1.Rheumatology Department, Manoramilton 2.Department of Medicine, NUIG.

Introduction: Reaching the therapeutic target of remission or low-disease activity has improved outcomes in patients with rheumatoid arthritis (RA) significantly.

Aims/Background: To analyse the effectiveness of DMARD mono-therapy in an Early Rheumatoid Arthritis population.

Method: 48 patients with Early Rheumatoid Arthritis were included. Data was collected prospectively on these patients. Clinical Disease Activity Index (CDAI) was used to assess disease activity.

Results: Of 48 patients 47 reached the target of CDAI LDAS (N=8), Or remission (N= 39) .In the LDAS group 4 were on methotrexate monotherapy,2 were on biologics,2 were on combination DMARDS. Monotherapy group consisted of patient on methotrexate(N=22),plaquanil (N=1) salazopyrin (N=4).Combination therapy included 10 patient on combination



c DMARDs and 11 on biologics. Mean CDAI in the monotherapy group on remission was 2.07 v 3.00 in combination group (p .241) Mean age with monotherapy was 54.85 versus 51.85 in combination therapy (p .546). In addition , the mean duration in weeks of symptoms before referral in monotherapy was 20.81 versus 29.85 in combination therapy (p .200). 23.1% of smokers needed combination therapy to achieve remission as compared to 26.7% of non smoker (p.496). Erosion on Xray was found in 45.8% of patients on monotherapy versus 54.2% at presentation.

Conclusions: Our experience showed that monotherapy is effective in achieving remission in a large number of patients treated according to a T2T protocol. Trends of use of combination DMARDs needed in younger age, increased duration of symptoms before referral, non smoker, erosion on xray at presentation. Although none of above data is statistically significant we continue to add patients to the group and review outcome data for significant association.

(16A169) Abstract 48

Poster 40

Behçet's disease and HLA-B51 in Ireland

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3. Renal Department, University Hospital Limerick

Introduction: Behçet's disease (BD) is a type of vasculitis with distinctive clinical manifestations and multifactorial immunopathogenesis. Association of HLA-B51 (which belongs to the HLA-B5/B35 cross-reacting group) is well recognized as the strongest genetic susceptibility gene so far in BD.

Aims/Background: The aim of this study is to determine the association of HLA-B51 in our BD cohort.

Method: Patients meeting the ISGBD and the ICBG criteria for BD were identified from our institutional database. Medical charts and electronic data were reviewed retrospectively to document the HLA antigen profile of the patients, which were carried out by a same recognized lab in London, using Gen-Probe Lifecodes HLA-SSO Typing kits based on Luminex xMAP technology.

Results: Of the 22 Irish descent patients identified satisfying the diagnosis for BD, 16 patients were HLA typed. The group consisted of 5 males and 11 females. The HLA-B51 antigen was found in only one of the 16 patients (6.3%) with a higher frequency of HLA-B35, B44 and B57 (5 patients each; 31.2% each) and B27 (12.5%).

Conclusions: The overall frequency of HLA-B51 is not increased in this series and our study didn't reveal any association between HLA-B51 and our cohort of BD patients.

(16A170) Abstract 49 Poster 41

Clinical and Demographic Profiles of Patients with Osteoporosis and Paget's Disease treated with IV Zoledronic Acid; Single Centre Study

Author(s): S. Saripella², R. Visevic¹, S. Al Qatari¹, J. Ryan¹, G. Murphy¹

Department(s)/Institutions: 1Department of Rheumatology, Cork University Hospital, Cork, 2Medical Student, Poznan University of Medical Sciences, Poznan, Poland.

Introduction: Osteoporosis represents significant burden for health systems worldwide. With over 200 million people affected worldwide including 300,000 people in Ireland. Anti-resorptive therapies such as bisphosphonates are commonly used to treat both osteoporosis and paget's disease. Adherence to oral bisphosphonates is known to be low, with some studies suggesting rates as low as 20% after 24 months, intravenous agents may ensure compliance in selected patient groups.

Aims/Background: To define and describe the patient population treated with iv zoledronic acid who attend the Rheumatology department at Cork University Hospital.

Method: We reviewed patients' notes for iv zoledronic acid doses given over a three year period and assessed DEXA scans and NMR data. We excluded patients with anorexia nervosa, multiple myeloma and bone metastatic disease. We identified patients diagnosed with inflammatory arthropathies, connective tissue diseases and paget's disease receiving iv ZA once a year since 2010. Data sets were analyzed using SPSS nonparametric tests.

Results: At total of 41 patients met inclusion criteria with diagnoses of IA/CTD (30) and paget's disease (11). Average age of IA/CTD group was 64.9 yrs and 73.3 yrs in paget's disease. In IA/CTD group (23.3%) have been prescribed steroids while treated with ZA. Prior to iv ZA administration, 12 /41 (29.3%) patients were on other osteoporosis drugs. Eight patients had oral bisphosphonates, three denosumab and one PTH analog therapy. At baseline 53.3% of IA/CTD patients and 18% for paget's patients had a documented fracture. In the paget's group ZA was the initial therapy for 9 patients of the 11 patients. While on therapy one patient with paget's reported a new fracture due to trauma - at a site unaffected by paget's. Compliance was 100%. Side effects were not reported in any of the patients. It was not possible to identify a trend in BMD as assessed by DXA- this was attributed to the small sample size and variations in repeat DXA frequency among the patient group.

Conclusions: ZA is infrequently used in our center. It would appear to be used preferentially for paget's disease. Side effects appear low with adherence rates high in our experience. Infusion capacity constraints and the availability of oral or subcutaneously administered agents appear to limit its attractiveness as an osteoporosis treatment. Adverse events such as atypical or jaw osteonecrosis were not identified in any of the 41 patients. Patients currently on the iv ZA only reported one new fracture that could have been a result of trauma. Concerns regarding side effects are perceived to limit use of IV bisphosphonates, however our small sample suggest it is well tolerated and remains an attractive therapy in ensuring adherence in selected patients.

Note. Special thanks to the Professor Molloy and Celia Berry at the UCC Department of Medicine Bone densitometry unit.



(16A171) Abstract 50 Poster 42

A short, easily readable, only 3-item tool - Bristol Rheumatoid Arthritis Fatigue scale (BRAFF) - is valid in patients with Psoriatic Arthritis

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Department(s)/Institutions: Division of Rheumatology, Department of Medicine, University Hospital Kerry, and Department of Rheumatology, St Vincent's University Hospital, Dublin

Introduction: Fatigue is a very common and important symptom in patients with chronic inflammatory arthropathies, and it can potentially be quite disabling. Fatigue is now increasingly recognised as important measure to assess among patients with psoriatic arthritis (PsA). Although, fatigue is not included among the 6 core domains that should be included in randomised controlled trials and longitudinal observational cohorts in patients with PsA, this was considered important and was suggested as a preferable assessment.

Fatigue in PsA is very little studied. Recently, an instrument, the Functional Assessment of Chronic Illness Therapy (FACIT), has been validated in PsA. The FACIT Fatigue Scale is a relatively long, 13-item, instrument which measures an individual's level of fatigue during their usual daily activities over the past week. An alternative instrument, the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales (BRAFF-NRS), is an easily readable, much shorter, 3-item tool which aims to identify the important domains of fatigue: severity, effect on daily life, and coping ability. The BRAFF-NRS has been studied and validated in rheumatoid arthritis population; however, this has not been validated in patients with PsA.

Aims/Background: The purpose of this study was firstly to determine the internal consistency, test-retest reliability, criterion validity of the BRAFF-NRS in patients with PsA.

Method: A consecutive cohort of 70 PsA patients (fulfilling CASPAR criteria) completed the 3-item BRAFF-NRS scale and 13 items of the FACIT-F scale, alongside laboratory testing and disease activity assessment. Moreover, all these patients completed BRAFF-NRS questionnaires twice, one day apart. Internal consistency was measured by Cronbach's alpha; test-retest reliability by the intra class correlation coefficient (ICC); and validity by the correlation of the BRAFF-NRS results with validated FACIT-F measures. Exclusion criteria included patients diagnosed with cancer, a history of other immune-mediated diseases, who were pregnant, or those who had concomitant fibromyalgia.

Results: 67 patients had the complete assessments [mean age 52±9 years, 54% female, mean PsA duration of 5±3 years). The mean BRAFF-NRS score was 14±8. The internal consistency of the 3 items BRAFF-NRS questionnaire as measured by Cronbach's alpha was 0.92. Test-retest reliability as measured by the intraclass correlation coefficient between the first and repeat questionnaires was 0.98. The BRAFF-NRS scores were compared with the FACIT fatigue scores. There was an excellent correlation between the BRAFF-NRS and FACIT fatigue ($r=-0.83$ ($p<0.001$, 95% CI -0.74 to -0.91)). The negative sign reflects that higher scores on the FACIT fatigue scale indicate less fatigue whereas higher scores on the BRAFF-NRS scale indicate more fatigue.

Conclusions: BRAFF-NRS provides a reliable, reproducible and valid instrument of measuring fatigue in PsA. This short assessment tool can be especially valuable in the context of a busy clinic, and also in large epidemiological studies when other core domains warrant assessment.

(16A172) Abstract 51

Poster 43

A Serum Proteome Assay to Monitor Anti-TNF Response in Rheumatoid Arthritis

Author(s): Niamh E. Callan¹, Stephen R. Pennington¹, Cathy M McGeough², Philip V Gardiner³, Gary D. Wright⁴, Anthony J. Bjourson, David S. Gibson²

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2. Northern Ireland Centre for Stratified Medicine, Ulster University, C-TRIC Building, Londonderry, United Kingdom.
3. Department of Rheumatology, Altnagelvin Area Hospital, Londonderry, United Kingdom.
4. Department of Rheumatology, Musgrave Park Hospital, Belfast, United Kingdom.

Introduction: Biologic drugs have revolutionised the treatment of Rheumatoid Arthritis (RA), however these therapies are expensive and exhibit a high non-response rate (30%). Currently there are no specific biological markers which distinguish non-response early after initiating treatment.

Aims/Background: The aim of this study was to identify serum protein levels which change when disease activity score is reduced by biologic drug treatment. These proteins may give mechanistic insight into molecular events after failed therapeutic intervention.

Method: Sera and disease activity scores (DAS28-ESR) were collected from n=25 RA patients at baseline and six months after anti-tumour necrosis factor alpha treatment. EULAR response criteria were used. Untargeted (unbiased) label free LC-MS/MS based proteomics was used initially to discover sera proteins differentially expressed at six months in responders and non-responders. Multiple reaction monitoring (MRM) assays were designed and tested on a triple quadrupole mass spectrometer.

Results: Over 500 proteins were identified in each of the pooled serum samples using the untargeted label free LC-MS/MS approach. Statistical analysis of the data revealed a list of 155 proteins that were significantly differentially expressed between good and non-responders ($p<0.05$). 55 of these proteins were shortlisted for development of targeted MRM assays, and assays were successfully developed for 47 proteins.

Conclusions: The approach outlined here and the initial results obtained indicate the power of a combined mass spectrometry strategy for comprehensive serum proteome analysis to determine quantitative changes, discover novel protein signatures and develop a multiplexed protein assay capable of monitoring response to biologic treatments. Such biologic drug response markers could minimise the use of expensive biologic drugs in patients who do not gain benefit and reduce adverse side effects.



(16A176) Abstract 52

Poster 44

Management of Hypertension in Patients with Rheumatoid Arthritis

Author(s): Maria Usman Khan^{1,2}, Fahd Adeeb^{1,2}, Usman Azhar Khan^{2,3}, Eoghan Meagher², Joseph Devlin¹, Alexander Fraser^{1,2}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick. 2. Graduate Entry Medical School, University of Limerick. 3. Cardiology Department, University Hospital Limerick

Introduction: In rheumatoid arthritis (RA), hypertension (HTN) doubles the risk of a composite cardiovascular outcome that includes myocardial infarction, heart failure & cardiovascular death. Many mechanisms may contribute to the high prevalence of HTN in RA including systemic inflammation & medications used such as corticosteroids and NSAIDs. Current guidelines provide evidence-based indications for when to initiate therapeutic interventions & set target blood pressure (BP) goals.

Aims/Background: To determine the prevalence of HTN in our RA cohort & evaluate BP management among these patients according to EULAR guidelines.

Method: This multicenter retrospective study involved 2 teaching hospitals (Croom hospital & University Hospital Limerick). 100 consecutive patients with definite RA were recruited. A proforma was completed for each patient based on medical notes & electronic record data. Concordant with current guidelines from American Heart Association, HTN is defined as a BP of $\geq 140/90$ mmHg. According to EULAR guidelines, ACE inhibitors (ACE-I) & angiotensin II (AT-II) blockers are preferred agents when indicated as they may have a favourable effect on inflammatory markers & endothelial function in RA.

Results: 1. 66 of 100 patients had their BP recorded within last 4-years & 22 patients (33.3%) had their BP record $\geq 140/90$ mmHg. Among the 22 patients, 10 (45.45%) were on antihypertensive treatment as mono or combination therapy i.e. ACE-I constituted 46.15%, AT-II blockers 7.69%, Diuretics 23.07%, calcium channel blockers (CCB) 15.38% & alpha blockers 7.69% [Fig 1]. 12 of 22 patients (54.5%) were not on antihypertensive medication (element of white coat hypertension not excluded).

2. 44 patients (66.6%) had BP $< 140/90$ mmHg: 16 patients (36.3%) were already on antihypertensive treatment as mono or combination therapy i.e. ACE-I constituted 6.4%, AT-II blockers 25.80%, Diuretics 19.35%, CCB 32.25% and beta blockers 16.12% [Fig 2].

3. Among 66 patients with available BP record, CCB (27.27%) were most widely used, followed by equivocal use of AT-II blockers & diuretics (20.45%), ACE-I (18.18%), beta blockers (11.36%) & alpha blockers (2.27%).

Conclusions: Management of HTN in our RA cohort is strikingly low & suboptimal. Awareness is important among rheumatologists as tertiary care physicians to be more actively involved in recording & managing HTN in RA patients with possible referral consideration to the relevant specialty for further management including a 24-hour BP monitoring if in doubt regarding the diagnosis of HTN.

Image 1

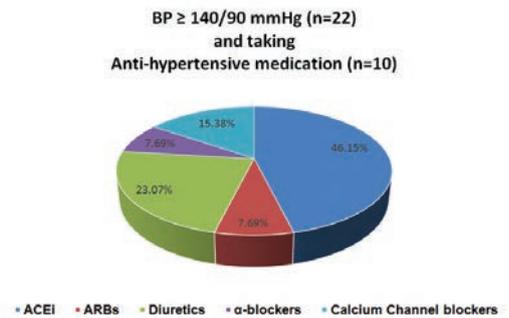
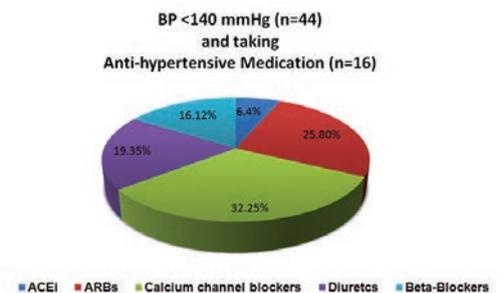


Image 2



(16A177) Abstract 53

Poster 45

Voriconazole-induced Periostitis; a novel cause of severe arthralgia and bone pain with a distinctive radiologic appearance.

Author(s): Hafiz Bajwa¹, Azhar Abdullah¹, Sarah Cormican², Declan de Freitas², Niamh Adams³, Aoife McErlean³, P O'Connell¹.

Department(s)/Institutions: Departments of Rheumatology¹, Nephrology², and Radiology³, Beaumont Hospital, Dublin 9, Ireland.

Introduction: Voriconazole is an oral antifungal agent with potent action against aspergillus which is now used chronically in lung transplant patients and increasingly in other settings. It contains high levels of fluoride (16%).

Aims/Background: Longterm use is associated with a newly recognised syndrome of extensive periostitis with distinctive radiology.

Method: A 61 year old man was readmitted from a rehabilitation facility for failure to improve despite intensive therapy. A major factor was severe pain and marked limitation of movement in both shoulders and hips and pain and swelling of both hands. Ten months earlier he had been admitted with renal failure due to PR3 positive ANCA vasculitis complicated by sepsis requiring a laparotomy for acute bowel perforation. He developed a ventilator associated pneumonia. Respiratory secretions grew *Aspergillus Fumigatus*. He was treated with 300mg voriconazole PO BD. Microbiology advised continuing this long term (almost 10 months). He was transferred after a complicated course to a rehabilitation facility. On re-admission, he was in severe pain with any attempt to move shoulders or hips, most joints were tender and fingers were swollen. ESR and CRP were raised. Bilateral hand (Figure 1), elbow, shoulder (Figure 2), chest, pelvic, knee and lower leg radiographs were performed showing exuberant bilateral periosteal reaction involving all bones, most prominent in the hands, shoulders and hips. An NM Bone SPECT-CT demonstrated increased radiotracer uptake (Fig 3). Plasma fluoride level was 278 μ g/L (NR $< 50\mu$ g/L). A



diagnosis of voriconazole induced periostitis deformans was made. Discontinuation led to rapid clinical improvement with normalised fluoride levels.

Results: Figure 1 – Florid periosteal reaction in the proximal phalanges bilaterally with involvement of the distal radius, carpal bones, metacarpals and middle phalanges.

Figure 2 – There is extensive periosteal reaction on the scapula, distal clavicle and humeral shaft

Figure 3 - Bone scan demonstrates extensive multifocal increased tracer uptake in the upper limbs and hip girdle in a pattern consistent with periostitis.

Further images will be shown in full presentation.

Conclusions: Rheumatologists need to be aware of this new syndrome and recognise it in the appropriate clinical setting.

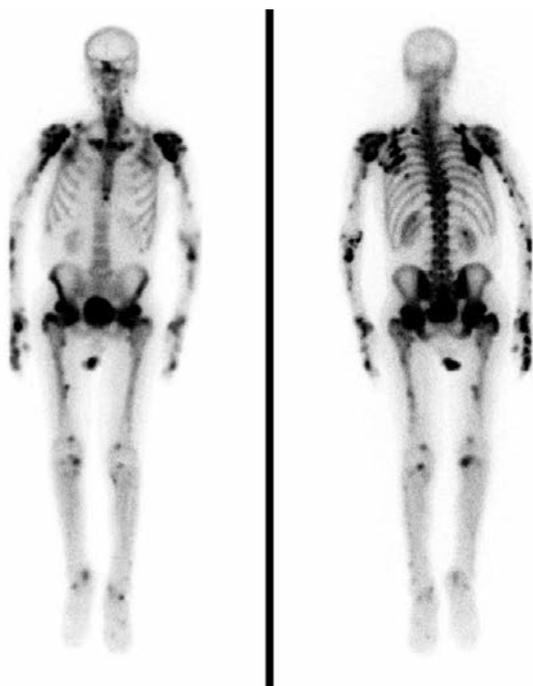
Image 1



Image 2



Image 3



(16A178) Abstract 54

Poster 46

Management of Traditional Modifiable Cardiovascular Risk Factors including Hyperlipidemia, Hypertension, Diabetes Mellitus and Smoking among Rheumatoid Arthritis patients in the Midwest region of Ireland

Author(s): Maria Usman Khan^{1,2}, Fahd Adeeb^{1,2}, Usman Azhar Khan^{2,3}, Joseph Devlin¹, Alexander Fraser^{1,2}

Department(s)/Institutions: 1. Rheumatology Department, University Hospital Limerick. 2. Graduate Entry Medical School, University of Limerick. 3. Cardiology Department, University Hospital Limerick

Introduction: Rheumatoid Arthritis (RA) is known to be associated with a substantially increased risk of cardiovascular disease (CVD). Although inflammation has been shown to be a key component in the development of CVD in RA patients¹, there is also a high prevalence of traditional modifiable CVD risk factors in this group. Recording of these risk factors is a cornerstone in CVD risk management in RA patients.

Aims/Background: The aim of this study is to evaluate the existing cardiovascular risk reduction practice in patients with RA by assessing the efficiency of recording and management of traditional modifiable cardiovascular risk factors including hyperlipidemia, hypertension, diabetes mellitus and smoking.

Method: This multicenter retrospective cross-sectional study involved 2 teaching hospitals (Croom hospital & University Hospital Limerick). 100 consecutive patients with definite RA were recruited between May and June 2016. A proforma was completed for each patient based on medical notes and electronic record data.

Results: 1. 87 patients (87%) had their full lipid profile screening in last four years. 43 patients had adequate data (age, gender, smoking, blood pressure and lipid profile) to calculate the 10-year risk of fatal CVD based on SCORE model. 17/43 patients (39.53%) were candidates for de novo statin therapy and lipid control was suboptimal in 6/43 patients (13.95%) on existing statin therapy.

2. Blood pressure (BP) record was available in 66 patient (66%). 10 out of 22 patients (45.45%) in BP range $\geq 140/90$ mmHg were already on anti-hypertensive treatment, representing suboptimal control while another 12 patients (54.54%) in the same BP record category were potential candidate for de-novo anti-hypertensive therapy.

3. 6 patients (6%) were found diabetic in medical notes. 5 out of 6 diabetic patients (83.33%) had recent HbA1c (< 1-year), which demonstrated suboptimal diabetic control (HbA1c > 7%) in 3 patients (60%).

4. 66 patients (66%) had their smoking status documented and 25 (37.87%) of them were active smoker. None of the patients had documentation of smoking cessation advice in their medical notes.

Conclusions: Traditional cardiovascular risk factors including hyperlipidemia, hypertension, diabetes mellitus and smoking are highly prevalent, under-diagnosed, and poorly controlled in patients with RA, despite appreciation that these conditions are associated with an increased burden of cardiovascular disease. The implementation of effective recording and management of these traditional modifiable risk factors in daily clinical rheumatological practice is an important first step in the process of augmenting the prevention of CVD in RA patients.

Reference: 1. C. S. Crowson, K. P. Liao, J. M. Davis III et al., "Rheumatoid arthritis and cardiovascular disease," *The American Heart Journal*, vol. 166, no. 4, pp. 622–628, 2013.

TAPENTADOL PALEXIA® SR

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FOR SEVERE CHRONIC PAIN

PALEXIA® SR Tablets are indicated for the relief of **severe chronic pain** in adults, which can be adequately managed only with opioid analgesics.¹



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Refer to the Summary of Product Characteristics (SmPC) before prescribing. **PRESENTATION:** 50 mg (white), 100 mg (pale yellow), 150 mg (pale pink), 200 mg (pale orange) and 250 mg (brownish red) prolonged-release tablets contain 50 mg, 100 mg, 150 mg, 200 mg and 250 mg of tapentadol (as hydrochloride) respectively. **INDICATION:** Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. **DOSEAGE AND METHOD OF ADMINISTRATION:** Individualise according to severity of pain, the previous treatment experience and the ability to monitor the patient. Swallowed whole with sufficient liquid, not divided or chewed, with or without food. Initial dose 50 mg twice a day. Switching from other opioids may require higher initial doses. Titrate in increments of 50 mg twice a day every 3 days for adequate pain control. Total daily doses greater than 500 mg not recommended. **Discontinuation of treatment:** Taper dose gradually to prevent withdrawal symptoms. **Renal/hepatic impairment:** Not recommended in patients with severe cases. Caution and dose adjustments with moderate hepatic impairment. **Elderly:** May need dose adjustments. Children below 18 years: Not recommended. **CONTRAINDICATIONS:** Hypersensitivity to ingredients, suspected or having paralytic ileus, acute intoxication with alcohol, hypnotics, centrally acting analgesics or psychotropics. Not for use when mu-opioid receptor agonists are contraindicated (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia). **SPECIAL WARNINGS AND PRECAUTIONS:** At risk patients may require monitoring due to misuse, abuse, addiction or diversion. At high doses or in mu-opioid receptor agonist sensitive patients, dose-related respiratory depression may occur. Caution and monitoring required with impaired respiratory function. Should not use in patients susceptible to intracranial effects of carbon dioxide retention (e.g. increased intracranial pressure, impaired consciousness or coma). Use with caution with head injury, brain tumours, moderate hepatic impairment, biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures or with severe renal or hepatic impairment. Care should be taken when combining with mixed mu-opioid agonists/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine). Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **INTERACTIONS:** Use with benzodiazepines, barbiturates and opioid analgesics, antitussive drugs and substitutive treatments may enhance the risk of respiratory depression. Central nervous system (CNS) depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect and impair vigilance. Consider dose reduction with respiratory or CNS depressant agents. In isolated cases, serotonin syndrome has been reported with Palexia SR in combination with serotonergic medicinal products (e.g. serotonin re-uptake inhibitors). Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia SR. Risk of decreased efficacy or adverse events if used with strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort). Avoid use in patients who have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days, due to cardiovascular events. **PREGNANCY AND LACTATION:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Not recommended during and immediately before labour and delivery. Do not use during breast feeding. Driving and using machines: May have major effect on ability to drive and use machines, especially at the beginning or change in treatment, in connection with alcohol or tranquilisers. **UNDESIRABLE EFFECTS:** *Very common* (≥1/10): dizziness, somnolence, headache, nausea, constipation. *Common* (≥1/100, <1/10): decreased appetite, anxiety, depressed mood, sleep disorder, nervousness, restlessness, disturbance in attention, tremor, involuntary muscle contractions, flushing, dyspnoea, vomiting, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema. Other important undesirable effects: palpitations, heart rate increased/decreased (*uncommon* ≥1/1000, <1/100), drug hypersensitivity including angioedema, anaphylaxis and anaphylactic shock (*uncommon* ≥1/1000, <1/100), respiratory depression (*rare* ≥1/10,000, <1/1000), convulsion (*rare* ≥1/10,000, <1/1000). No evidence of increased risk of suicidal ideation or suicide with Palexia SR. Additional information is available on request. **OVERDOSE:** Seek specialist treatment (see SmPC). **LEGAL CLASSIFICATION:** POM, CD (Schedule II). **MARKETING AUTHORISATION NUMBERS AND PACK SIZES:** 50 mg: PA 1189/7/4, 28 and 56 packs; 100 mg: PA 1189/7/5, 56 pack; 150 mg: PA 1189/7/6, 56 pack; 200 mg: PA 1189/7/7, 56 pack and 250 mg: PA 1189/7/8, 56 pack. **MARKETING AUTHORISATION HOLDER:** Grünenthal Ltd, Regus Lakeside House, 1 Furze Ground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK. **DATE OF PREPARATION:** November 2013. IRE/P13 0025b. **REFERENCE:** 1. Palexia SR Summary of Product Characteristics



Case Submissions – Autumn Meeting

Ref	Authors	Titles
16A100	Claire Masih	A case of transient Raynaud's Phenomenon
16A110	Hasan Tahir	Baricitinib, Methotrexate, or Baricitinib Plus Methotrexate in Patients with Early RA
16A112	Subhashini Arthanari	Baricitinib Versus Placebo or Adalimumab in Patients with Active RA
16A117	Anne McShane	Diastematomyelia- An unusual presentation to Rheumatology
16A118	Kamal Osman	Calcinosis in Systemic Sclerosis can mimic other common rheumatologic manifestations
16A121	Kamal Osman	A young man with severe localized pain syndrome
16A125	Maria Usman Khan	A Rare case of rheumatoid vasculitis leading to digital ulceration and gangrene
16A127	Claire Masih	Spinal abscesses following tocilizumab therapy
16A134	Stephen McDonald	A case of voriconazole induced adrenal suppression in a patient with polyarteritis nodosa
16A143	Abuelmagd Abdalla	2 CTD cases of young patients with rare severe form of DM associated aggressive lung disease
16A149	Shakeel Anjum	Granulomatosis with Polyangiitis presenting with clubbing and lung hilar mass in a heavy smoker male.
16A152	Rachel Flood	Shrinking Lung Syndrome - A rare complication of Systemic Lupus Erythematosus
16A154	Eva McCabe	An unusual case of certolizumab and movicol anaphylaxis
16A160	Len Harty	Necrobiotic xanthogranuloma (NXG) complicating Cogan's syndrome (CS)
16A161	Omer Hussein	Body tightness in a young man
16A174	Anne McShane	Continued use of Infliximab in PSA despite the development of MS on Treatment
16A180	Ramona Valea	Rare association of Systemic sclerosis with Gastric Antral Vascular Ectasia (GAVE)
16A181	Colm Kirby	Varicella Zoster Virus Encephalitis in a patient treated with Infliximab for Rheumatoid Arthritis
16A182	Peter Browne	Sciatica? Hard to stomach
16A183	Rachel Cole	Case Report
16A184	Shama Khan	Granulomatosis with Polyangiitis and co existent Rheumatoid Arthritis in a patient, a rare clinical entity
16A185	Sinead Maguire	A Complex Case of Subcutaneous Sweet's Syndrome
16A186	Sinead Maguire	Biopsy Proven Unilateral Sarcoid Sacroiliitis
16A187	Wan Lin Ng	A case of third nerve palsy in a patient with scleroderma

Efficacy still going strong five years on

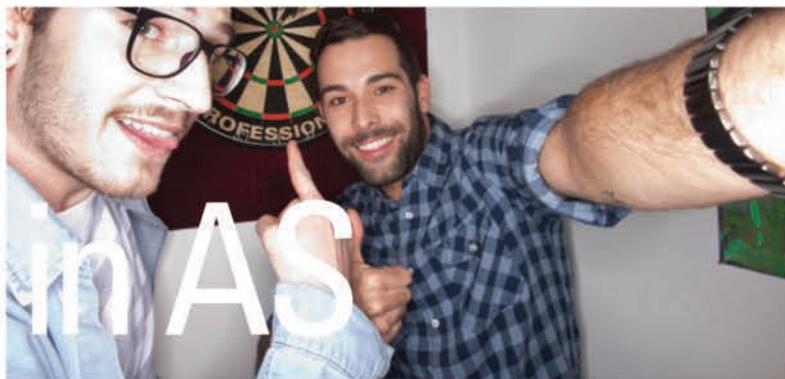
monthly 
Simponi[®]
golimumab



Indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients in combination with MTX when response to DMARDs therapy, including MTX, has been inadequate.



Indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to DMARDs has been inadequate.



Indicated for the treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.

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

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

Indications: *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs *Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Dosage and administration:** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA or UC. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. *RA:* Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. *PsA:* Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. *AS and nr-Axial SpA:* Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. *UC:* Patients weighing < 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. Patients weighing ≥ 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). Missed dose: If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. *Elderly patients (> 65 years):* no dose adjustment required. *Paediatric patients (<18 years) and patients*

with renal and hepatic impairment: Simponi is not recommended in these populations. **Contraindications:** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. 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 (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-blocking agents) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart Failure:** Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. **Neurological events:** Use of anti-TNF therapy,

The GO studies

Recently presented five-year data confirm good persistence, sustained efficacy and predictable tolerability across indications with Simponi¹⁻³

Persistence with Simponi at 5 years

(Simponi 50mg and 100mg)



GO-FORWARD¹

70%

n=444



GO-REVEAL²

69%

n=405



GO-RAISE³

71%

n=356

including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery:** Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations:** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. **Excipients:** Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **Interactions:** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **Pregnancy and Lactation:** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **Side-effects: Refer to SmPC for complete information on side effects.** **Vary Common (≥ 1/100):** upper respiratory tract infection; **Common (≥ 1/1000):** 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, thrombocytopenia, pancytopenia, aplastic anaemia, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. *Observed with other TNF-blocking agents, but not

observed in clinical studies with golimumab **Package quantities:** 1 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 1 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 1 100 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 Lelid, The Netherlands. **Date of Revision of Text:** December 2015. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. **Date of preparation:** March 2016.

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

References

1. Keystone EC, et al. *J Rheumatol*. 2016 Feb;43(2):298-306.
2. Kavanaugh A, et al. *Ann Rheum Dis*. 2014 Sep;73(9):1689-94.
3. Deodhar A, et al. *Ann Rheum Dis*. 2015 Apr;74(4):757-61.



Red Oak North, South County Business Park,
Leopardstown, Dublin 18 X5K7 Ireland





IRHPS Autumn 2016 Update

Welcome to the Autumn Conference 2016

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

A very warm welcome to our keynote speakers this year. Dr. Anita Banerjee, Obstetric Physician from Guy's and St. Thomas's London who will be presenting on pregnancy management and rheumatic disease. Dr. Helen Mitchell, clinical psychologist from De Monfort University, Leicester will discuss the challenges associated with parenting/grand parenting in rheumatic disease. Finally, Dr. Caitriona Cunningham lecturer and B. Physio from University College Dublin will present on exercise and bone health.

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. Thanks must go to Abbvie, MSD, Roche, Janssen, UCB and Pfizer. Full details on this and all our bursaries are available on our website www.irhps.ie.

I do hope you enjoy this year's conference and that you will find the discussions educational and beneficial to your everyday practice.

The IRHPS committee's support and dedication over the past year has been invaluable. My sincere thanks to you all especially now as I step down as chair and hand over to Eileen Shinnors from Our Lady's Hospice and Care Services, Harolds Cross. I wish Eileen and the Society every success in the future.

Best wishes,
DEREK DEELY
IRHPS Chair



Abstract 1

Oral Presentation 1

The Development and Evaluation of a Multi-disciplinary Team (MDT) Programme for the Management of Osteoarthritis (OA) of the Thumb

Author(s): Martina Fitzpatrick, Trish Fitzgerald and Norma Ferris

Department(s)/Institution(s): Rheumatology Department, St. Vincent's University Hospital

Introduction: In November 2014 an MDT programme for the management of OA of the thumb was developed and facilitated by a senior occupational therapist (OT), physiotherapy clinical specialist and clinical nurse specialist in the rheumatology department at SVUH. This programme was developed in line with the National Institute for Health and Care Excellence (NICE) guidelines which propose that the care and management of OA may potentially be improved by self-management programmes (NICE, 2014). This development is supported by the European League against Rheumatism (EULAR) recommendations that joint protection and hand exercises are offered in the management of hand OA (EULAR, 2015).

Method: A care pathway with inclusion criteria and patient screening tool were designed.

An evidence based programme consisting of two weekly sessions of ninety minutes with six to eight participants in each programme was developed.

Outcome Measures included the Arthritis Self Efficacy Scale Short Form (ASES-SF2) and a post-programme participant evaluation form. All participants who completed the programme between November 2014 and May 2015 were included (n=21). Data collection and analysis were completed by the OT and Physiotherapist who facilitated the programme.

Results: Mean scores of the ASES-SF2 identified positive changes for self-efficacy in pain management, function and symptom management. All participants who completed the evaluation form strongly agreed that they would recommend the programme to others and the material presented had practical relevance.

Conclusion: An MDT programme including joint protection, training in activities of daily living and hand exercises constitutes a potentially effective intervention for the management of OA of the thumb.

Ethical Approval: Clinical Audit Department, SVUH.

References: European League against Rheumatism (2015) A textbook of rheumatic diseases (2nd Edition). Switzerland: BMJ. National Institute for Health and Care Excellence (2014). Osteoarthritis: Care and Management in Adults. Available at <http://www.nice.org/> (Accessed 19 May 2016).

Abstract 2

Oral Presentation 2

Prevalence of co-morbidities in newly diagnosed rheumatoid arthritis patients followed up in a Registered Advanced Nurse practitioner (RANP) clinic.

Author(s): Noreen Harrington, Carmel Silke, Bryan Whelan

Department(s)/Institution(s): Northwestern Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim.

Introduction: Co-morbidities reduce the life span of patients with RA (1). Among RA patients there is a high prevalence of cardiovascular events and risk factors such as tobacco smoking, obesity, hyperlipidaemia, hypertension, and diabetes (2).

Osteoporosis related fractures are also more commonly observed and significantly affect long term prognosis for functional decline (3, 4). High incidence of depression and malignancies is reported but prevalence varied widely among countries (5).

Aim: 1. To evaluate the prevalence of co-morbidities in an Irish setting among newly diagnosed RA patients. 2. To estimate detection of co-morbid risk factors and newly diagnosed co-morbidities during 12 month follow up in an RANP clinic.

Method: Following consultant diagnosis of new RA, patients were referred to the RANP for 12 month follow up. At initial assessment a history of co-morbidities from review of medical records or patient report was input into SPSS for analysis. Detection of new co-morbidities was added. Demographics collected included: age, gender, body mass index (BMI), smoking status, lipademia (HDL, LDL), glucose and blood pressure.

All patients had a DEXA scan to assess for osteoporosis and were screened for vitamin D deficiency.

Results: A total of 92 patients (56% female) were analysed, Mean age was 55(sd15) min19 maximum 88. The mean number of co-morbidities was (2.3) min 0 maximum 7.

The most common co morbidities, DEXA, Vit D and BMI results as well as smoking status is listed in Table 1

Hypertension	26 (28%)	3 pt newly detected
Hypercholesterolemia	22 (24%)	7 pt newly detected
Anxiety,depression, mental disorders	16 (17%)	
Hypothyroidism	16 (17%)	1 pt newly detected
Cancer	10 (11%)	
Diabetes	9 (10%)	1 pt newly detected
Asthma	6 (7%)	
DEXA	Osteopenia	Osteoporosis
	29 (32%)	12(13%)
Vitamin D	Deficiency	Inadequate levels
	deficiency (<30 nmol/L)	48(52%)
Inadequate Vit D levels (30-50 nmols/L).		
Smoker	Current Smokers	Ex smokers
	30 (33%)	13 (14%)
Body Mass index (BMI)	Overweight	Obese
	40 (43%)	18 (19%)

Conclusion: There is a high prevalence of co morbidities and their risk factors detected in early RA patients. Implementing more rheumatology nurse specialist clinics in early inflammatory arthritis would provide the ideal opportunity to provide brief intervention and address risk factors for co-morbidities as well as early detection and preventative screening.

References: 1.Gabriel SE, Michaud K. Epidemiological studies in incidence, prevalence, mortality,and comorbidity of the rheumatic diseases. Arthritis Res Ther 2009;11:229. 2)Liao KP, Solomon DH. Traditional cardiovascular risk factors, inflammation and cardiovascular risk in rheumatoid arthritis. Rheumatology (Oxford) 2013;52:45-52. 3)Coulson KA, Reed G, Gilliam BE, et al. Factors influencing



fracture risk, T score, and management of osteoporosis in patients with rheumatoid arthritis in the Consortium of Rheumatology Researchers of North America (CORRONA) registry. *Journal Clinical Rheumatology* 2009;15:155–60.

4)Gullick NJ, Scott DL. Co-morbidities in established rheumatoid arthritis. *Best Practice Research Clinical Rheumatology* 2011;25:469–83.

5)Dougados M, Soubrier M, et al .Prevalence of comorbidities in rheumatoid arthritis and evaluation of their monitoring: results of an international, cross-sectional study (COMORA). *Annals Rheumatic Disease* . 2014 Jan;73 (1):62-8..

Abstract 3

Poster Presentation 1

Addressing Work Participation in Inflammatory Arthritis: Irish Rheumatology Clinicians Experiences and Perspectives.

Author(s): Yvonne Codd¹, Tadhg Stapleton¹, Ronan Mullan², David Kane²

Department(s)/Institution(s): Discipline of Occupational Therapy, School of Medicine, Trinity College Dublin¹. Rheumatology Departments, Naas and Tallaght Hospitals²

Introduction: Inflammatory arthritis (IA) strongly correlates with work disability; 40% of people with rheumatoid arthritis exit the workforce within five years of diagnosis (Bevan et al 2009).

Aim: To explore the extent of work support within the current organisation and delivery of rheumatology services for people with IA.

Method: A questionnaire was distributed via online survey to medics, nurses and physiotherapists working in clinical rheumatology.

Results: Response rate of 22% was achieved and total sample of 73 analysed. Responders indicated that 71% of service users were of working age and the majority of respondents (95%) agreed that addressing employment retention was within the remit of rheumatology services. 55% of respondents estimated that 25-49% of their caseload had work needs. Factors influencing addressing work included: client raising work concerns (94%), client reports work absenteeism (83%), client's work involved manual component (75%). Barriers to addressing work were: limited time in clinical setting to address work (92%); unfamiliarity with best practice for work support (91%); lack of perceived competency to assess complexities of work (82%). Occupational therapy (OT) was identified as the most appropriate profession to address work (78%). However, 51% respondents reported not routinely referring to OT for work support due to: limited availability of OT (13% of responders having no access to OT); uncertainty regarding optimum timing for work intervention; uncertainty as to what OT offer.

Conclusion: Addressing work was recognised as multifaceted and multidisciplinary. Work needs tend to be addressed within current rheumatology services only when the client themselves initiate the issue. There is opportunity to improve the quality of services to address work early in the disease trajectory in line with international standards including through implementation of a clinical pathway for employment retention.

References: Bevan, S., McGee, R. and Quadrello, T. (2009) *Fit For Work? Musculoskeletal Disorders and the Irish Labour Market*, London: The Work Foundation.

Abstract 4

Poster Presentation 2

Experiences of adults with inflammatory arthritis who have completed an occupational therapy led vocational rehabilitation programme: A qualitative study

Author(s): Fitzgerald, T; Corcoran, O;

Department(s)/Institution(s): Occupational Therapy Faculty of Health and Life Sciences, Oxford Brookes University; Occupational Therapy Department, St. Vincent's University Hospital; Occupational Therapy Department, University Hospital Waterford

Aim/Introduction: The 'Working Successfully with Arthritis' (WSA) programme is an occupational therapy led vocational rehabilitation programme. The WSA programme was developed to offer early, accessible vocational rehabilitation intervention to employed adults with inflammatory arthritis experiencing work instability. This study aims to explore the experiences of adults with inflammatory arthritis at risk of work instability following participation in the WSA programme.

Method: A qualitative study utilised one-to-one semi-structured interviews. Data collected consisted of participant's personal narratives obtained from the interviews; these narratives provided rich descriptions of participants' individual experiences of attending the WSA programme. Seven participants were included in the study. Thematic analysis was used to synthesize the data and summarise the findings.

Results: The participant's interviews revealed the perceived positive impact of attending the WSA programme through improvement in confidence in symptom management which included joint protection, improved ergonomics in the work place, fatigue and stress management. An increased understanding of their employment rights, group support and peer exchange were found to be factors in maintaining work participation. Barriers experienced in accessing support in the workplace in Ireland were also identified.

Conclusion: The WSA programme was perceived by participants to have contributed to improvement in the overall management of their condition at work. Increased knowledge of physical and psychological tools were identified as factors in maintaining work participation. Educating participants on employment rights increased confidence in disclosure of their condition. The findings also promote service development in an area of clinical practice requiring progression in Ireland.

Abstract 5

Poster Presentation 3

Irish Rheumatology Health Professional Society (IRHPS) Telehealth Project.

Author(s): Shona Lee, Eileen Shinnors, Angela Camon, Helen Reynolds, Una Martin

Department(s)/Institution(s): Irish Rheumatology Health Professional Society (IRHPS)

Aim/Introduction: Pilot Study to trial use of telephone follow for review rheumatology patients. Secondary aim to highlight quantify statistics on telephone work carried out by Clinical Nurse Specialist. To distinguish telephone contacts (number to calls to service) from Telephone assessments – which lead to clinical assessment, decision making and plan of care. To highlight the need for a more structured approach to telephone



work and assessment especially in the importance of managing a cohort of patients with inflammatory arthritis.

Method: Funding was sought to facilitate a national study with 4 pilot sites involved. Invitations were sent via email and at National yearly IRHPS conference inviting national centres to participate in study. 4 national rheumatology centres expressed interest in participating Tallaght hospital, Tullamore hospital, Our Lady's Hospital Manorhamilton and Waterford Regional hospital. Decision on statistics to be collected was made and plan for completion of project. Proposal made to offer appropriately screened review patients follow up in telephone clinic. Current process for patients accessing rheumatology services was outlined, with some centres moving to have structured telephone clinics fully supported by the use of an electronic record,

Results: Telephone review of rheumatology patients governed by guidelines and trained clinical nurse specialists working within scope of practice proved an efficient and effective service to manage this cohort.

Total savings offered by utilization of Telephone Clinics
228 review patients

€29,184 (initial savings) + €20,736 (Reduction in DNA) =
€49,920

Conclusion: Telephone clinics create a significant saving financially and through efficient utilization of resources

Abstract 6

Poster Presentation 4

Development and Outcomes of Rheumatology Clinical Nurse Specialist Telephone Clinic, Tallaght Hospital.

Author(s): Shona Lee

Department(s)/Institution(s): Department of Rheumatology, Tallaght Hospital, Dublin 24

Aim/Introduction: To demonstrate development of a safe, efficient and effective telephone clinic review service managing a cohort of inflammatory arthritis patients at a Dublin teaching hospital.

Method: Pilot study over 6 months with one structured clinic per week. Telephone clinic set up on hospital administration system (Pims) coded TELRHU. Telephone booking option added to medical OPD outcome booking form. Development of telephone assessment pages in the rheumatology electronic patient record (Cellma). Patients deemed suitable were pre booked into a telephone clinic follow if condition was deemed stable by rheumatology doctor.

Results: To date 419 patients have had either a 1/12, 3/12 or 6/12 month telephone review in the rheumatology telephone clinic. Telephone assessment is completed on electronic record with assessment, investigation results, actions taken and plan of care documented. Letter created electronically when call complete. Fast track back to treat to target clinic (TTT) if medical review required. Service report with further results on time spent per review and other outcomes from electronic record has been requested.

This process frees up medical review patient appointments for unstable disease control and urgent review visits. It also produces a significant financial cost saving to the service.

Conclusion: Fully integrated telephone clinical assessment, documentation, actions and recommendations through use of

electronic patient record (EPR) Cellma. Efficient effective care and patient satisfaction has been demonstrated. Effort will now be invested seeking payment for telephone reviews as currently none available in ROI. UK telephone reviews attract a £24 /31 euro payment per call.

Abstract 7

Poster Presentation 5

Development of Young Adult Care Clinic Tallaght Hospital.

Author(s): Shona Lee Ronan Mullan

Department(s)/Institution(s): Department of Rheumatology, Tallaght Hospital, Dublin 24

Aim/Introduction: To develop a seamless patient centred 1st time and follow up visit pathway, to provide partnership in care for young adult rheumatology patients moving from paediatric to adult services.

Method: Change management approach involving both hospital sites and interdisciplinary teams. Meetings to discuss transition patient needs when moving to adult care services. Training undertaken by adult rheumatology clinical nurse specialist by attendance at Paediatric rheumatology course in Great Ormond Street, London.

Pre entry of diagnosis and current medication onto rheumatology electronic record to as per referral letter from paediatric rheumatology prior to clinic appointment.

Results: To date the rheumatology clinic at Tallaght hospital have held 6 young adult clinics total 36 patients. At each clinic in attendance are 1 paediatric and 1 rheumatology consultant and 1 Clinical nurse specialist from paediatric and 1 from adult services present. Time spent with young adult advising of who their named contact in adult services is and contact details and education material provided including medication information. Information on how to request repeat high tech prescription advised should the need arise. Telephone helpline number given. Toolkit resource being sourced. Efforts made to minimise differences between adult and paediatric care most notably 1. Move to seeing a doctor without a parent, 2. Having a joint injection under local anaesthetic and not general or gas as in paediatric care.

Conclusion: Feedback from both young adult patients and their parents has been noted and included in an action plan for future.

Abstract 8

Poster Presentation 6

Development of Care Pathway for Patients with Ankylosing Spondylitis.

Author(s): Shona Lee, Ronan Mullan David Kane

Department(s)/Institution(s): Department of Rheumatology, Tallaght Hospital, Dublin 24

Aim/Introduction: To provide a structured streamlined care pathway for patients newly diagnosed with Ankylosing Spondylitis. To have patient access to education, drug monitoring, physical assessment and treatment one diagnosis has been made. This involves set up of nurse specialist and physio managed clinic RHUAHS which alternates with medical review appointments. Secondary aim to systematically record and measure outcomes specifically associated with this chronic condition. Pathway aimed at right people, right place, and right time.



Method: Change management project involving all of the rheumatology interdisciplinary team.

Structured appointments and outcome measurements performed and repeated at specified timed intervals. As a result of service participation in the Irish national AS registry a decision was made to include a core set of patient reported outcome measures (PROMS) into the electronic patient record. These are all completed electronically and can be mapped over time.

Results: To date 133 patients have followed this care pathway following diagnosis. Outcome measures collected include BASDAI, BASFI, BASMI, ASQOL, spinal measures, chest expansion, pain, fatigue. Patients have rapid access back to treat to target (TTT) clinic for reassessment in the event of worsening symptoms or who may need a treatment change. Inclusion of cardiovascular risk and osteoporosis risk also documented at baseline and yearly follow up.

Conclusion: Care pathway for patients with Ankylosing Spondylitis provides structure of care and access to interdisciplinary team members at appropriate time points. Patients very satisfied to have nurse and physiotherapist visit on same day. Plan to include other inflammatory back pain conditions in this pathway.

Abstract 9

Poster Presentation 7

Exercise and mental health in people who have Rheumatoid Arthritis: A systematic review

Author(s): Seán McKenna¹, Alan Donnelly², Alexander Fraser³,⁴, Norelee Kennedy¹

Department(s)/Institution(s):

1. Department of Clinical Therapies, University of Limerick, Limerick, Ireland 2. Department of Physical Education and Sports Sciences, University of Limerick, Limerick, Ireland 3. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland 4. Graduate Entry Medical School, University of Limerick, Limerick, Ireland

Aim/Introduction: People with Rheumatoid Arthritis (RA) have significant mood disturbances therefore, addressing depression and anxiety through exercise may have an important impact on their quality of life. The aim of this review was to systematically search for the availability of evidence for exercise and depression and anxiety in people who have RA.

Method: The review comprised three phases:- (i) search of academic databases using combinations of key terms and phrases. Grey literature and reference lists of the studies were also manually checked; (ii) potentially suitable papers were screened for eligibility; (iii) authors were contacted if required. Inclusion criteria were: quantitative studies involving exercise. Study strength was assessed using the Cochrane bias assessment tool for randomised controlled trials (RCTs) and Newcastle-Ottawa Quality Assessment Scale for non-RCT's. Two reviewers' were involved in the search, extraction and quality assessment.

Results: Eleven studies were included: 4 RCT's; 2 pilot RCT's and 5 sample of conveniences including 899 people with RA. Studies included were difficult to assess due to the heterogeneity of study designs and interventions (4 different types of Yoga, 2 dance based and 1 Tai-chi). A number of mental health outcome measures were included however, efforts to compare were hampered due to conversion issues. Overall studies had a high

risk of bias. There was tentative evidence for exercise impacting positively on depression and anxiety.

Conclusion: Exercise may have positive benefits on depression and anxiety in RA. Further studies with improved study designs, using subjective and objective measures, are needed to confirm this finding.

Abstract 10

Poster Presentation 8

Implementation of a Registered Advanced Nurse Practitioner (RANP) led Treat to Target (T2T) in early Rheumatoid Arthritis (RA) patients.

Author(s): Noreen Harrington, Bernie McGowan, Carmel Silke, Bryan Whelan

Department(s)/Institution(s): North Western Rheumatology Unit (NWRU), Our Lady's Hospital, Manorhamilton, Co Leitrim

Introduction: Treat to target (T2T) is an international initiative endorsed by the European League against Rheumatism (EULAR) in 2010 and updated in 2015 (1).

Aim: The aim was to develop, implement, and evaluate the treat-to-target strategy aimed at achieving remission in newly diagnosed RA in an autonomous nurse led practice.

Method: Following consultant diagnoses of RA, patients were referred to the RANP for 12 month follow up from diagnosis. Ongoing data collection includes patient demographics, disease history, management & outcomes at each visit. Disease activity was assessed using clinical disease activity index (CDAI) and Functional limitations assessed using HAQ-DI.

Results: A total of 105 patients with a diagnosis of RA were referred to the RANP. 13 patients were excluded from the analysis (4 choose private consultant follow-up, 7 had diagnosis reclassified/ outside nurse scope/ required medical management and 2 patients died).

Data analysed in 92 patients as per Table 1
Table 1: Baseline patient data: Total 92 pts

Table 1: Baseline patient data: Total 92 pts	
Gender female	57%
Age	Mean Age 55yrs (sd 15, min 19, max 88)
RF	Sero +ve 61 (66%)
Anti CCP positive	CCP positive 59 (64%)
Target set agreed with patient	Remission 86(93%) Low disease activity(LDA) 6 (7%)
Joint erosions on baseline xray	24 (26%)
Baseline CDAI	Mean 21 (min2, max67)
Baseline Disease Activity using CDAI assessment	40 (43%) had high disease activity, (HDA)
	44 (48%) had moderate disease activity, (MDA)
	8 (9%) patients had baseline LDA or remission following recent steroid use
Health assessment questionnaire	Mean 1.30 (min 0.125, max 2.75) indicating significant functional limitations
HAQ-DI	
Score 0-3	

A total of 48 pts have completed 12 months follow up. The mean CDAI was 2.49 and the mean HAQ was 0.32. There was 40(83%) in clinical remission. A further 7 (15%) achieved LDA. 1 patient was referred back with MDA. Medication to achieving final target was methotrexate monotherapy n=21 (44%), Methotrexate +HCQ n=8 (17%), MTX + SZP 3(6%). SZP monotherapy 4(8%),



11 (23%) required biologic medication in combination with traditional DMARDs.

Conclusion: Initiation of this autonomous nurse led T2T has led to significant improvement outcomes for newly diagnosed RA at this unit. At 12 month follow up HAQ show significant improvement in function correlating with improved disease activity.

References: 1) Smolen JS et al (2015). Annals of Rheumatic Diseases.; EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs.

Abstract 11 **Poster Presentation 9**

Osteoporosis Fracture Risk Profile in Patients with Newly Diagnosed Inflammatory Arthritis

Author(s): Rachel Burke¹, Ronan Mullan², David Kane²

Department(s)/Institution(s): Physiotherapy Department, Naas General Hospital¹, Rheumatology Department, Naas General Hospital²

Aim/Introduction: To determine the osteoporosis (OP) fracture risk profile in patients with newly diagnosed inflammatory arthritis (IA), including rheumatoid arthritis and psoriatic arthritis.

Method: Participants filled out the International Osteoporosis Foundation One-Minute OP Risk Test at their first physiotherapy appointment. BMI (height and weight) data was also elicited. The World Health Organisation Fracture Risk Assessment Tool (FRAX) 1 was then used to determine the 10-year probability of major OP fracture, and the 10-year probability of hip fracture. The National Osteoporosis Guideline Group (NOGG) management algorithm² was subsequently employed to classify individuals into low, intermediate or high risk fracture categories.

Results: Twenty-nine patients with a new diagnosis of IA were referred to physiotherapy in the first quarter of 2016. Sixteen subjects were excluded for the following reasons; incomplete data provision (n=6), did not attend a physiotherapy appointment in the hospital (n=4), aged less than 40, which precluded a valid FRAX calculation (n=4), or on an established treatment regime for OP (n=2). The OP fracture risk categories of 13 patients were subsequently analysed. The mean age of the group analysed was 56 years (range: 41-72 years), and comprised of 6 males and 7 females. The breakdown of FRAX scores and NOGG risk categories are outlined in Table 1.

Conclusion: This study highlights the need for formal bone health monitoring in this patient cohort. It also identifies the requirement for fracture prevention strategies in those identified as at risk.

References: 1. World Health Organisation Fracture Risk Assessment Tool <<https://www.shef.ac.uk/FRAX/tool.jsp>>
2. National Osteoporosis Guideline Group management algorithm <<https://www.shef.ac.uk/NOGG/index.html>>

Appendix:

	Overall	Males	Females
FRAX 10-Year Major OP Fracture Risk (%)			
Mean	8.5	6.6	13.6
Standard Deviation	4.1	3.9	3.8
Range	2.9-15	2.9 – 12	4.3- 15
FRAX 10-Year Hip Fracture Risk (%)			
Mean	2.5	2.4	5.7
Standard Deviation	2.2	2.7	1.9
Range	0.1-6.5	0.1 – 6.5	0.5 – 5.5
NOGG Risk Categories (%)			
Low risk	15	33	0
Intermediate risk	85	66	100
High risk	0	0	0

Table 1: FRAX scores and NOGG risk category stratifications

Abstract 12 **Poster Presentation 10**

Implementation of European League Against Rheumatism (EULAR) and British Society of Rheumatology (BSR) Guidelines for the assessment and management of Spondylothropathy (SpA); audit of a local SpA clinic

Author(s): Eileen O’Flynn, Nimmi Abraham, Phil Gallagher, Mairead Dockery, Oliver FitzGerald.

Department(s)/Institution(s): Rheumatology Unit, Bone & Joint, St Vincent’s University Hospital, Elm Park, Dublin 4.

Aim/Introduction: This audit was conducted to assess if current practice at the Rheumatology unit of St Vincent’s University Hospital are meeting the recommendations and guidelines set by Eular and BSR to assess and manage patients with Spondylothropathy (SpA) and Psoriatic arthritis (PsA).

Background: Guidelines are key to modern health and medical practice. Their recommendations are evidence-based and cover a wide range of topics - managing specific conditions, use of medicines in different settings or services and interventions to improve health, (British Society of Rheumatology, N.D.)

Method: A questionnaire was developed addressing Eular and BSR recommendations and guidelines. The questionnaire had two sections; one for completion by the patient and one by the health care professional. Patients attending the weekly SpA clinic were invited to participate in the audit. 120 patients were recruited with the following diagnosis: PsA 49%, Radiographic axial SpA 26%, Non Radiographic axial SpA 22%, SpA Undifferentiated 3%.

Results: Respondent’s ages ranged from 20-79 years. 7% had diagnosis confirmed <1 year. 45% confirmed >10years. Smoking status established; 18% current smokers, 13% ex smokers. Employment status revealed: 58% currently in employment, 12% on disability, 11% retired, 6% students, 30% of patients were on Synthetic DMARD, and 66% on Biologic DMARD. Comorbidities included Hypertension(19%), Obesity(16%), Hyperlipidaemia(7%) Diabetes Type 1&2(7%) Ischaemic Heart Disease(2%) and Osteoporosis(0.8%)

Conclusion: > The audit yielded some mixed results. There was a high level of patient satisfaction in the responses, specifically regarding: identifying and managing a flare, and support in “self-management”. Areas which need to be improved include in particular the level of information and support



received on the impact of disease on employment.

Patient Responses when asked to rate the following:				
Excellent	Very Good	Good	Satisfactory	Poor
Quality of information given on patient's condition				
33%	34%	25%	7%	2%
Information on the disease impact on ability to work				
12%	29%	14%	15%	12%*
The level of support received to remain in employment				
18%	32%	17%	18%*	16%*
Opportunities to discuss your care				
25%	37%	21%	14%	3%
Written information on flare management				
15%	27%	19%	16%*	23%*
Overall review of diagnosis and problems				
35%	35%	20%	7%	3%

Table 1. Audit Results of Patient's Experiences of the Service
Note: * denotes areas which need to be addressed

Abstract 13

Poster Presentation 11

Health Related Quality of life and Work Impairment Amongst Active Workers with Musculoskeletal Pain Referred for Assessment from Primary Care.

Author(s): Andy Cochrane¹, Niamh M Higgins¹, Conor Rothwell¹, Oliver FitzGerald², Pamela Gallagher³, Jennifer Ashton⁴, Roisin Breen⁵, Aisling Brennan⁶, Oriel Corcoran⁷, Deirdre Desmond¹.

Department(s)/Institution(s): 1 Department of Psychology, Maynooth University, Ireland. 2 School of Medicine and Medical Sciences, University College Dublin, Ireland. 3 School of Nursing and Human Sciences, Dublin City University, Ireland 4 Physiotherapy Services, Beaumont Hospital, Ireland. 5 Royal College of Physicians in Ireland. 6 Physiotherapy Services, AMNCH, Ireland. 7 Rheumatology Services, Waterford Regional Hospital, Ireland

Aim/Introduction: To examine the impact of MSDs on work impairment and health related quality of life (HRQoL) among workers referred from primary care.

Method: New referrals to musculoskeletal assessment clinics in five hospitals, in paid employment or off work for less than six months completed a battery of self-report questionnaires including the SF-12 and an assessment of work-ability (Work Ability Index; WAI).

Results: The participants (n = 164, 52.4% female, mean age 46.3 years) presented with a range of musculoskeletal disorders, the largest category related to pain in the lower limbs (29.9%). 82% were working at the time of assessment (n = 134); Over half (n = 86; 52.8%) reported poor to moderate work ability. Participants scored significantly lower on the Physical (p < 0.001) and Mental (p = 0.003) components of the SF-12 compared to population norms; there was no effect for gender, age group (20-34; 35-44; 45-54; 55+) or site of primary diagnosis. Current self-reported work-ability correlated with the physical (r = .423; p < 0.001) and mental (r = .274; p = 0.001) components of the SF-12, indicating that poorer work-ability was associated with a reduced HRQoL.

Conclusion: Whilst many individuals with MSDs are able to continue to work effectively, some may experience difficulties at work with a concurrent reduction in their quality of life.

Understanding the factors that enhance work ability may assist in the development of targeted interventions to help people stay at work without compromising their overall well-being.

Abstract 14

Poster Presentation 12

Acceptance and Commitment Therapy: A retrospective study of outcomes from a Hospital-based, Outpatient, Group Pain Rehabilitation Programme for patients attending Rheumatology Services in the SE of Ireland.

Author(s): Noirin Nealon Lennox, Siobhan O'Neill & Ailish Hannigan

Department(s)/Institution(s): University Ulster & University Limerick & University Hospital Waterford

Aim/Introduction: Acceptance and Commitment Therapy (ACT) is a form of cognitive behavioural therapy which focuses on psychological flexibility and behavior change. ACT has been advocated for the treatment of Persistent Pain. A recent systematic review concluded that ACT is efficacious for enhancing general physical functioning and for decreasing distress amongst adults with chronic pain attending Pain Rehabilitation Programmes (Hann & McCracken 2014). The aim of this study was to assess the effects of an eight-week ACT group-based programme for people with persistent pain on pain acceptance, activity engagement, psychological distress and self-efficacy.

Method: Patients were referred to the programme by one of three Consultant Rheumatologists in University Hospital Waterford over a five-year period. Over one hundred patients' outcome measures were available for this retrospective study from a convenience sample. Consent had been sought routinely from patients who attended the ACT programme and ethical approval was granted from the Hospital Research Ethics Committee (REC) and Ulster University REC. Participants had attended at least six out of eight days of the programme including a six month review. The interprofessional pain rehabilitation team comprised a Clinical Nurse Specialist, a Psychologist, a Physiotherapist and an Occupational Therapist. Baseline measures were taken at assessment, on the final day of the programme and at the follow up six-month review.

Results: Data will be analysed with One Way Repeated Measures ANOVA using SPSSv20. Effect sizes will be calculated using Partial Eta Squared and interpreted using the guidelines proposed by Cohen (1998).

Conclusion: Results will be available for IRHPS September meeting.

ISR SPRING MEETING 2017
Limerick
Friday, 31 March 2017



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INDICATION

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.¹




Otezla[®]
(apremilast) 30mg tablets

Prescribing Information: OTEZLA[®] (apremilast) 10mg, 20mg and 30mg film coated-tablets.

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

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 cyclosporine, 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 according to the following schedule: Day 1: 10mg in morning; Day 2: 10mg in morning and 10mg in evening; Day 3: 10mg in morning and 20mg in evening; Day 4: 20mg in morning and 20mg in evening; Day 5: 20mg in morning and 30mg in 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. Clinical experience beyond 52 weeks is not available in psoriasis. **Special populations:** Paediatric population: The safety and efficacy of apremilast in children aged 0 to 17 years have not been established. No data are available. 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 apremilast 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[®] be titrated using only the morning doses and the evening doses be skipped. Patients with hepatic impairment: No dose adjustment is necessary for patients with hepatic impairment. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the following excipients: Microcrystalline cellulose, Lactose monohydrate, Croscarmellose sodium, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide red (E172). The 20mg tablets also contain iron oxide yellow (E172). The 30mg tablets also contain iron oxide yellow (E172) and iron oxide black (E172). OTEZLA[®] is contraindicated in pregnancy and 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. OTEZLA[®] should be dose reduced to 30mg once daily in patients with severe renal impairment. Apremilast

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. Apremilast 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 apremilast, which may result in a loss of efficacy of apremilast. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with apremilast is not recommended. In clinical studies, apremilast 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 apremilast. Apremilast can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between apremilast and methotrexate in psoriatic arthritis patients. Apremilast can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between apremilast and oral contraceptives containing ethinyl estradiol and norgestrel. Apremilast 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. Prescribers should consult the summary of product characteristics in relation to other side-effects. **NHS list price:** £265.18 per 14 day titration pack; £550 per pack of 56 tablets (30mg). **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, United Kingdom. **Date of preparation:** January 2015. **Approval code:** UK-18140098.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk Adverse events should also be reported to Celgene Drug Safety Tel: 0808 238 9908; Fax: 0844 801 0468

References:
1. OTEZLA Summary of Product Characteristics available at www.medicines.org.uk 2. Mease PJ, et al. Poster 310 presented at the Annual Meeting of ACR/ARHP, San Diego, California, October 26-30, 2013. **Date of Preparation:** February 2015 UK-18140071b

ISR Spring 2016



Eoin Quigley (left) and Richard Gardiner (right) Grunenthal



Conor Lowney, Hayley Collins and Claire Madigan - Pfizer



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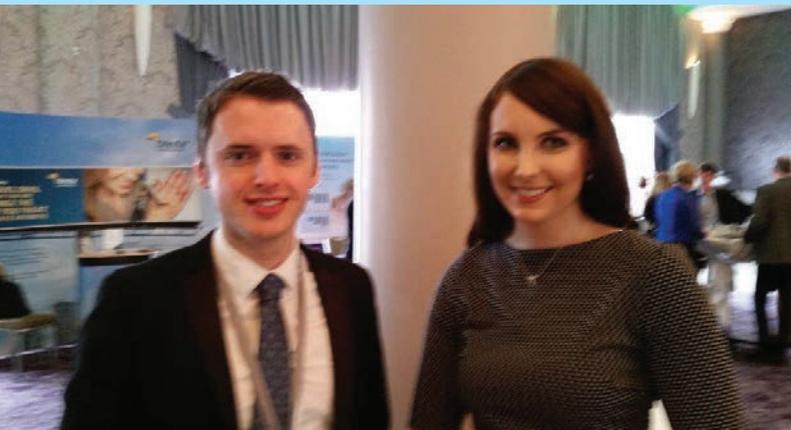
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CLINICAL PARTICULARS 1) Rheumatoid arthritis: Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in adult patients with active disease when the response to 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 fistulating, 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.

Pharmacology 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 does not respond 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 infusions 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) **Fistulating, 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 26 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

ISR Spring 2016



Dr Shakeel Alraki, Ollie Kinlough, Dr Barry O'Shea, Hugh Sheehan, Marie Kennedy



Dr Clare Sheehy, Dr Rhona Mullan and Gerard Walsh



Ronan Sheridan and Tommy O'Donoghue - MSD.



Patrick Tehan - Fannin



Dr Carmel Silke, Prof Gaye Cunnane, Dr Grainne Kearns, Dr Frances Stafford



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Conor Doyle, Maire O'Connell, Brian Whately - Novartis



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More than 5700 publications¹⁹

1 Over million patients treated¹⁰

of partnership and experience¹
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Uses: Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. 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). Polyarthritides (rheumatoid factor positive or negative) and extended oligoarthritides 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: Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients 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 life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. Paediatrics: Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. 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 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. European Marketing Authorisation Numbers: Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. Legal Category: S1A. European Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. API Reference Number: EN 8_0. Pfleat number: 2013-0003980. Date of Prescribing Information: July 2014.

therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. Pregnancy & Lactation: Enbrel is not recommended in pregnant or breast-feeding women. Undesirable Effects: Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. Paediatrics: Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. 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 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. European Marketing Authorisation Numbers: Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. Legal Category: S1A. European Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. API Reference Number: EN 8_0. Pfleat number: 2013-0003980. Date of Prescribing Information: July 2014.

† Across all indications.

References: 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. November 2015. 3. Humira Summary of Product Characteristics. November 2015. 4. Remicade Summary of Product Characteristics. September 2015. 5. Cimzia Summary of Product Characteristics. December 2015. 6. Simponi Summary of Product Characteristics. November 2015. 7. Remicade EMA report. 8. http://clinicaltrials.gov. Accessed 12 Nov 2014. 9. www.pubmed.org. Accessed 12 Nov 2014. 10. Data on File. January 2015. 11. Data on File. March 2014.

Date of preparation: March 2016. PP-ENB-IRL-0004

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THINK RoACTEMRA¹

IN DMARD-IR AND TNF-IR RA PATIENTS,
WHEN COMBINATION WITH MTX IS NOT AN OPTION

ABRIDGED PRESCRIBING INFORMATION (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC). **Indications:** RoActemra SC: 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 adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. 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/SC 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, 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 if they experience symptoms of an allergic reaction before administering the next dose. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. **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 >100 kg, doses >800 mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥ 2 years, 8mg/kg diluted to final volume of 100ml for patients <30 kg or 12mg/kg diluted to final volume of 50ml for patients ≥ 30 kg 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 <30 kg 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. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or 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 $2 \times 10^9/l$. **Special Populations:** No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with moderate to 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. **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, associated with 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. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. 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. 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 infection 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 $> 5 \times$ ULN; caution in patients with ALT or AST $> 1.5 \times$ 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 $< 0.5 \times 10^9/l$ or platelet count $< 50 \times 10^9/l$. Do not initiate RoActemra treatment where ANC is below $2 \times 10^9/l$. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, 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 should be clearly recorded in patient file to improve traceability of biological medicines. **Drug 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-fetal 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:** ADRs occurring in RoActemra trials: Very Common ($\geq 1/10$): upper respiratory tract infections, hypercholesterolaemia. Common ($\geq 1/100 - <1/10$): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **sJIA:** 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 ($\geq 1/10$): upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. Common ($\geq 1/100 - <1/10$): 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 ($\geq 1/10$): upper respiratory tract infections, nasopharyngitis, headache. Common ($\geq 1/100 - <1/10$): nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. **RoActemra SC:** 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. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including site 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). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** August 2016. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19. **Date of items:** September 2016. IE/RACTE/0916/0020



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