Using one example of a completed EIT-Health funded implementation project, JIGSAW-E (Joint Implementation of Guidelines for oSteoArthritis in Western Europe), this presentation will highlight some of the challenges of implementation such as: understanding the context; competing priorities; lack of time and funding; stability of the workforce; and differing health care systems. It will describe the use of Knowledge Mobilization and Communities of Practice as methods for overcoming these challenges and optimizing holistic treatments.

The presentation will offer some of the key factors for implementation such as 'leading from the middle' and brokering across silos; working with patients and the public '*Patients are the most under-used resource in any health care system*'; using theories, models and frameworks to plan, understand and evaluate implementation; using pilot sites to build momentum with dedicated Communities of Practice; and agreeing what success should look like.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8464

SP0123 NEW TREATMENTS: WHY SHOULD WE WAIT?

Daniel Morales. *University of Dundee, Population Health and Genomics, Dundee, United Kingdom*

Background: Improving access to new and established medicines for rheumatological disease is of public health importance. However, drug development processes, medicines regulation and health technology requirements may significantly impact on when a new medicine become available to be used by health care professionals.

Objectives: The objectives of this session are to present some of the challenges and opportunities for accessing new and established medicines for rheumatological disease.

Methods: Drug development processes, medicines regulation and health technology requirements may significantly impact on when a new medicine become available to be used by health care professionals. Although these requirements may be perceived as barriers, many of these requirements are in place to ensure a medicines benefit risk profile is favorable and is cost effective in terms of quality of life. This session will briefly discuss issues around the process of making medicines newly available from drug development to gaining new market approvals with an emphasis on rheumatological disease, including the post-authorization safety requirements that are in place to safe guard public health.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8542

FRIDAY, 14 JUNE 2019

13:30:00 – 15:00:00

New assessments in clinical practice

SP0124 WHICH MEASURES TO USE TO ASSESS REMISSION IN RHEUMATOID ARTHRITIS

Annamaria Iagnocco. *Academic Rheumatology Unit Università degli Studi di Torino, Academic Rheumatology Centre, Turin, Italy*

Remission is the ideal target of treatment in rheumatoid arthritis (RA) patients. However, the definition and characterization of remission is still a theme of discussion and its assessment can be a challenging issue in RA clinical practice. Indeed, nonetheless the new treatments and therapeutic strategies for RA make remission possible, sub-clinical inflammation can still be present both at the joint site and at the patient level, leading to damage progression and to occurrence of flares.

Clinically, remission entails persistent absence of any sign of joint and systemic inflammation. However, the presence of some residual joint inflammatory activity can be accepted by current clinical indexes such as DAS28, SDAI, CDAI and Boolean remission, although the latter is clearly based on more stringent parameters (1,2). Based on those criteria, and particularly with the use of SDAI and Boolean cut-offs, complete and persistent remission is then quite uncommon in late RA, while it seems to be more easily possible in early disease (3). Another interesting issue to consider in clinical practice is the presence of sustained remission which seems to occur less frequently than remission at different point times and with only a minority of cases reaching a complete disease recovery (4).

Depending on the modality that is used, the assessment of remission by imaging encompasses the evaluation of a wide spectrum of lesions. While ultrasound is able to show intra- and peri-articular signs of inflammation and to differentiate active from inactive synovitis with the use of Doppler modes, MR shows also bone marrow inflammatory-related abnormalities. Moreover, ultrasound detects inflammation at multi-site level and allows the measurement of stable remission over

time on longitudinal evaluation. Interestingly, also tenosynovial Doppler inflammation has been demonstrated to be a frequent finding in patients in clinical remission and, compared to joint synovitis, it is more associated with self-perceived unstable remission (5). In addition, tenosynovial and joint Doppler positivity has been demonstrated to be an independent risk factor of flare in RA patients in remission (6). Residual joint inflammation in patients in remission can be demonstrated also by other imaging techniques, such as PET which shows enhanced tracer uptake at different joint sites (3). Basically, the capability of imaging to demonstrate sub-clinical disease activity even in patients in clinical remission, by allowing the detection of residual inflammation at different joint sites and at different disease stages gives it an added value compared to clinical assessment alone.

In conclusions, clinical evaluation of remission alone appears frequently inadequate to capture a real persistent lack of inflammation at different joint sites. Imaging can complement the assessment of patients in clinical remission, offering additional data that may still reveal a certain amount of sub-clinical disease activity. With new therapeutic strategies RA management has become increasingly complex over the last years (7). The relevance of this information is then substantial, being structural damage the result of both previous and current phases of disease activity.

REFERENCES:

- [1] Felson, et al. *Ann Rheum Dis* 2011;70: 404–13.
- [2] Chandrashekar, et al. *International Journal of Rheumatic Diseases* 2013; 16: 291–6.
- [3] Bugatti, et al. *Front Med (Lausanne)* 2018; 15: 140-8.
- [4] Pope, et al. *Athrits Care Res (Hoboken)* 2019 Mar 1. doi: 10.1002/acr.23862.
- [5] Bellis, et al. *Rheumatology* 2016; 55: 1826-36.
- [6] Filippou, et al. *Ann Rheum Dis* 2018; 77: 1283-9.
- [7] Smolen, et al. *Ann Rheum Dis* 2017; 76: 960-77.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8504

SP0125 HOW TO ASSESS PATIENT WITH SUSPECTED VASCULITIS

Raashid Luqmani. *University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom*

Background: Systemic vasculitides are multi-organ, multi-system conditions which can mimic many other diseases. They are rare but very significant because they can rapidly lead to end organ damage or death if left untreated. The difficulty faced by clinicians in diagnosing a patient with vasculitis is further compounded by the presentation of limited forms of vasculitis, which can be difficult to recognise as due to vasculitis, the effects of co-existing co-morbidity and the use of drugs either for medicinal or recreational purposes. Giant cell arteritis is one of the most common serious forms of vasculitis in adults, leading to blindness if untreated. In view of this risk, many clinicians will initiate treatment of any patients with suspected giant cell arteritis before definitive investigations have been performed. Unfortunately this can result in inadequate outcomes from diagnostic tests such as ultrasound or biopsy of the temporal artery. There are no diagnostic criteria for most forms of vasculitis apart from Behcet's syndrome. Some tests can be very useful in ruling out other causes as well as helping to confirm a diagnosis of vasculitis. We will review some of the strategies for diagnosing vasculitis, complementing a thorough history and examination with selected investigations to improve diagnostic certainty.

Objectives: To consider the strategies used to assist the diagnosis of systemic vasculitis; to assess the frequency of multi-system involvement in systemic vasculitis; to critically evaluate the role of diagnostic testing in systemic vasculitis.

Methods: A review of current literature on the approach to diagnosis and classification of vasculitis.

Results: Table 1 summarises the clinical manifestations of some forms of primary systemic vasculitis, comparing the different frequencies of the common presenting features. Patients with large vessel vasculitis are usually more distinct as a clinical group from other forms of vasculitis but increasingly we see an overlap between GCA and older patients (especially males) with Takayasu arteritis. There is considerable overlap of clinical features amongst the small vessel vasculitides, despite different immuno-pathogenetic pathways. Amongst the anti-neutrophil cytoplasm antibody (ANCA) associated vasculitides (AAV), the presence of active nephritis characterises most patients with MPA; it is less common in GPA and least common in EGPA. Lung involvement is prevalent in all three forms of AAV, but has different characteristics: bronchial wall inflammation with ulceration plus nodules and infiltrates in GPA; transient infiltrates and bronchospasm in EGPA; lung haemorrhage at presentation in MPA, with subsequent risk of developing lung fibrosis. The different patterns of disease activity help in differentiating

Abstract SP0125 – Table 1. Clinical features of some forms of systemic vasculitis

Type of vasculitis	Systemic	Eye	Skin	ENT	Lung	Heart	Gut	Renal	PNS	CNS
Takayasu arteritis	<65%	30%	3-28%	-	50-86%	5-55%	7-9%	0-50%	-	33%
Giant cell arteritis	40%	20-50%	<5%	<50%	<10%	10%	-	-	14%	0-90%
Polyarteritis nodosa	<66%	10-20%	8-27%	-	-	10-40%	40-60%	30-50%	50-75%	1%
Granulomatosis with polyangiitis	30-97%	28-58%	10-50%	75-98%	52-94%	0-12%	5-11%	40-100%	15-41%	6-13%
Microscopic polyangiitis	73-92%	28-30%	35-60%	20-30%	25-55%	9-18%	30-56%	up to 100%	14-58%	0-40%
Eosinophilic granulomatosis with polyangiitis	69-100%	10%	51-69%	0-80%	100%	28-49%	8-59%	16-27%	65-76%	9-11%

individual forms of vasculitis, but it is important to remember that many features associated with medication and co-morbidity may make this patient group more homogeneous, especially if the original disease manifestations are now quiescent.

We will explore the potential use of classification criteria as substitutes for diagnostic criteria in different forms of vasculitis and evaluate the role of specific tests to assist in the diagnosis, with a focus on ANCA testing in small vessel vasculitis and on imaging in large vessel vasculitis.

Conclusion: A rational approach to diagnosis in vasculitis is required, based on a combination of clinical features together with relevant investigations. Diagnostic certainty can vary in the absence of definitive evidence from investigations, especially if patients have already been partly treated prior to completing all relevant investigations. Diagnostic testing is improving and with the development of new criteria for classification, this forms a stronger basis to develop a more sound approach to diagnosis. However, we should always be prepared to apply a provisional diagnosis and reconsider any emerging evidence to suggest an alternative condition.

REFERENCES:

- [1] Monti S, Águeda AF, Luqmani R. The use of ultrasound in the management of large-vessel vasculitis: an evolving concept. *Clin Exp Rheumatol*. 2018 Sep-Oct;36 Suppl 114(5):96-102
- [2] Ponte C, Águeda AF, Luqmani RA. Clinical features and structured clinical evaluation of vasculitis. *Best Pract Res Clin Rheumatol*. 2018 Feb;32(1):31-51.
- [3] Seeliger B, Sznajd J, Robson JC, Judge A, Craven A, Grayson PC, Supiah RS, Watts RA, Merkel PA, Luqmani RA. Are the 1990 American College of Rheumatology vasculitis classification criteria still valid? *Rheumatology (Oxford)*. 2017 Jul 1;56(7):1154-1161
- [4] Slart RHJA; Writing group; Reviewer group; Members of EANM Cardiovascular; Members of EANM Infection & Inflammation; Members of Committees, SNMMI Cardiovascular; Members of Council, PET Interest Group; Members of ASNC; EANM Committee Coordinator. FDG-PET/CT(A) imaging in large vessel vasculitis and polymyalgia rheumatica: joint procedural recommendation of the EANM, SNMMI, and the PET Interest Group (PIG), and endorsed by the ASNC. *Eur J Nucl Med Mol Imaging*. 2018 Jul;45(7):1250-1269.

Disclosure of Interests: Raashid Luqmani Grant/research support from: Roche, Vifor and GSK

DOI: 10.1136/annrheumdis-2019-eular.8528

SP0126 CLINICAL IMPORTANCE OF ANA ANTI-DSF70 ANTIBODIES

Johan Rönnelid. Uppsala University, Department of Immunology, Genetics and Pathology, Uppsala, Sweden

Background: Analysis of anti-nuclear antibodies (ANA) is a hallmark in the classification criteria for many systemic rheumatic diseases, including systemic lupus erythematosus (SLE). ANA investigations performed with indirect immune fluorescence (IF) on HEP-2 cells detect autoantibodies against a large number of nuclear autoantigens, and is often followed by, or done in parallel to, investigations which determine the autoantibody specificities causing the IF ANA staining. Two IF ANA-associated SLE-specific autoantibodies, anti-double stranded DNA and anti-Sm, are included both in previous as well as emerging SLE classification criteria. But IF ANA itself is also included in all of these classification criteria (1-3). This is because a positive IF-ANA is regarded as an independent risk factor for SLE, irrespective of what autoantibody specificity determines the nuclear staining. Antibodies against lens epithelium-derived growth factor 70/75 kD autoantigen creates a specific dense fine speckled IF-ANA pattern, and the autoantibodies are generally called anti-DFS70. The rather recently described anti-DFS70 pattern is unique and has obtained the AC-2 pattern in the recent universally accepted International Consensus on ANA Patterns (ICAP) classification system (www.anapatterns.com), but was not previously recognised and might be misinterpreted. In

contrary to other IF-ANA patterns/specificities, isolated anti-DFS70 is not associated with systemic rheumatic diseases, and might even be more common among healthy individuals than among diseased populations (4). However, when anti-DFS70 occur together with other ANA specificities, different IF-ANA patterns may predominate.

Objectives: The European Consensus Finding Study Group on autoantibodies (ECFSG), a.k.a. the EULAR autoantibody study group, regularly investigate autoantibody content in new autoantibody reference standards produced to obtain consistent results between clinical laboratories.

Methods: In the 2018 ECFSG serum investigation, a newly produced pooled anti-DFS70 reference standard was investigated blindly concerning IF ANA patterns and autoantibody specificities by 38 participating laboratories.

Results: Most laboratories correctly described the IF-ANA pattern correctly as the dense fine speckled AC-2 pattern; however 5/38 laboratories reported the pattern as homogenous (AC-1). Concerning autoantibody specificities, the standard was determined to be monospecific for anti-DFS70. This new reference standard has recently been described (5), and will be available via www.autoab.org.

Conclusion: In my talk I will give a background on the emergence of anti-DFS70 antibodies, and report on the outcome of the ECFSG investigation of the anti-DFS70 reference standard. Moreover, I will present an algorithm for how to incorporate investigations for anti-DFS70 in ANA investigations in a cost efficient way.

REFERENCES:

- [1] E. M. Tan, et al. *Arthritis Rheum*. 25, 1271 (1982).
- [2] M. Petri, et al. *Arthritis Rheum* 64, 2677 (2012).
- [3] S. K. Tedeschi, et al. *Ann Rheum Dis* (2019).
- [4] M. Mahler, et al. *J Rheumatol* 39, 2104 (2012).
- [5] A. Dellavance, et al. *Clin Chem Lab Med* in press (2019).

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8575

FRIDAY, 14 JUNE 2019

13:30:00 – 15:00:00

The benefits of involving patients in health technology assessment

SP0127 PATIENT ENGAGEMENT WITHIN THE EUROPEAN MEDICINES AGENCY

Nathalie Bere. European Medicines Agency (EMA), Public engagement Department, London, United Kingdom

The European Medicines Agency (EMA) is the European regulatory body whose role is to evaluate and supervise medicines across the European Union.

EMA has been engaging with patients and consumers for many years and today, patient involvement is an integral part of the work at EMA, with a diverse range of opportunities in place to include the patient's voice at various stages along the medicines regulatory life-cycle. Key to successful engagement has been the need for flexibility, a range of well-tested methodologies and a robust system of support and training.

Patients and caregivers' real-life perspectives and unique insights complement the scientific data within EMA reviews; they provide input on proposed protocol designs and participate in expert meetings and written consultations on medicines evaluation. They are voting members of EMA committees and they review medical information written for the public. Evidence has shown their contributions make a difference and ultimately help ensure that the Agency's outcomes are as meaningful and relevant as possible for all concerned.

Some of the key challenges and conclusions of our journey will be highlighted to serve as a guide to those considering a similar, rewarding path.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8427