SUMMER 2014 ISSUE

Editor's Letter

Welcome to our Summer 2014 edition of AS News. We hope that this edition finds you all safe, healthy & active and continuing to get out and about in, hopefully, some fine weather.

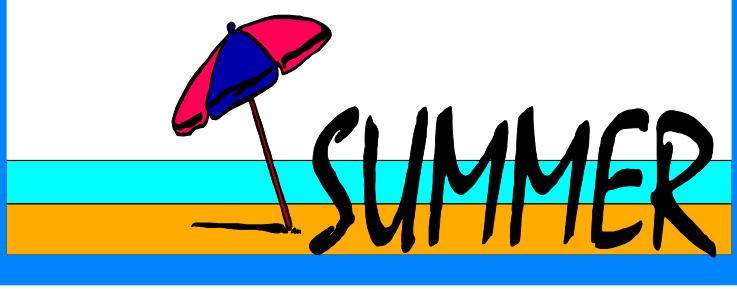
I was fortunate enough to attend the Eular 2014 Annual European Congress of Rheumatology in early June and was very pleased to see the amount of research that is currently underway that is related to AS – more on this topic inside.

The great response we have had (and not just in Ireland by the way) to our *SUAS* app and supporting book means we have now taken it onto the android platform too, see details on the right.

We have repeated the details of WWA – Working with Arthritis: Strategies and Solutions. This is a free occupational therapy programme developed in Limerick University and operating out of Galway – Check it out on page 2.

We have also included details of a study taking place at Trinity College Dublin, see page 8, on ***Patient perspectives on physical activity in AS***. I would strongly encourage you to participate.

Seserie



SUAS Available on Android.

Great news, the app is now available on android devices.

This has largely come about due to the popularity of the app on iOS systems (iPhone and iPad) and the popularity of the accompanying book.

So now we will be able to reach a wider group of people living with AS on iPhone, iPad, android smartphones and tablets.

The *SUAS* app continues to be supported by the Rheumatology unit in Waterford Regional Hospital, Arthritis Ireland, the Irish Society of Chartered Physiotherapists and Pfizer. The development work was once again undertaken by the team from Publicis D Healthcare. Our website has also been updated to take account of the fact that the app is now on both iOS & android.

asai Ankylosing Spondylitis Association of Ireland
Waterford Regional Hospital Rheumatology Unit
Pfizer
Supported by an unrestricted educational grant from Pfizer Healthcare Ireland.
PUBLICIS D HEALTHCARE

In This Issue

Working with Arthritis
strategies and solutions

The University of Limerick have commenced a new occupational therapy programme `***Working with Arthritis (WWA): Strategies and Solutions***'. This program aims to promote work/ education participation for those with arthritis who are in receipt of disability/illness payment.

Funding has been granted by the Disability Activation Project, which is linked with the European Social Fund (ESF) and the Department of Social Protection (DSP). Officially announcing the funding on 25th October 2012, Minister for Social Protection Joan Burton TD, stated:

"These projects will provide vital learning to my Department on how best to ensure that people with disabilities are enabled to avail of progression, education and development opportunities".

People with Arthritis are at very high risk of unemployment and work disability. Arthritis and musculoskeletal disorders are the main cause of work disability and work-loss in the general work-force. Work disability carries far-reaching negative effects; from human, societal and economic perspectives. On a human level, the negative effects of unemployment include poorer physical, financial and emotional well-being and feelings of social exclusion.

On the flip side, re-engaging with suitable work/ education has shown to result in improvements in psychological and physical well-being, plus general quality of life. Society and the economy also benefits as there is a reduced demand on health-care and social protection systems, plus an increase in productivity and general work performance.

Individuals may be entitled to this free program if they are

- **Aged between 18 and 65**
- **Have a diagnosis of arthritis**
- **From the Border, Midlands and Western region**
- **Are in receipt of a disability or illness payment**

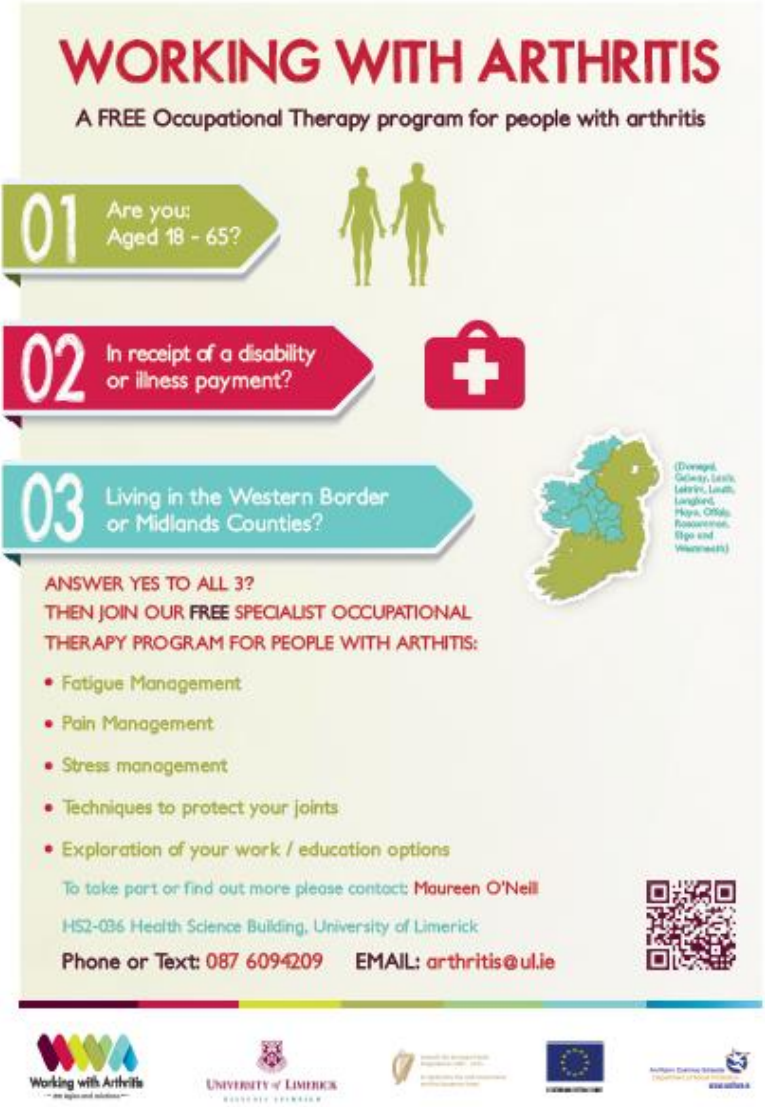
The 'Working with Arthritis: Strategies and Solutions' program will be delivered by two skilled Occupational Therapists (Eimear Lyons and Miriam Noonan) and will take place in the Working with Arthritis clinic in Galway city or in the individual's community or home environment.

Occupational Therapists explore physical, environmental, psychological and social disruptions which can be created due to conditions such as arthritis. The aim of Occupational Therapy is to facilitate a successful adaptation to these lifestyle disruptions and to improve a person's ability to perform valued life roles at work, home, recreation and social environments.

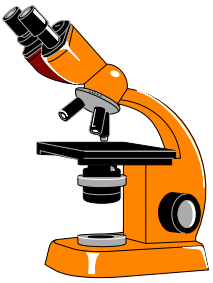
The WWA programme is based on best available international evidence for reducing work disability among people with arthritis. The programme was developed by Dr. Katie Robinson and colleagues at the University of Limerick. The program will improve a person's work ability via the improvement of participants' skills in relevant areas including pain, stress and fatigue management; joint protection; job seeking and preparation and lifestyle balance. Other interventions undertaken on behalf of the participant will include employer liaison and work site assessments.

To take part or to find out more information, please contact:

Maureen O' Neill,
HS2-036 Health Science Building,
University of Limerick
T: 087 6094209
E: arthritis@ul.ie



Posture
Exercise
Activity
Regularly



Research News

Research studies in the area of AS

I was very fortunate to be able to attend the Eular 2014 Annual European Congress of Rheumatology in Paris in early June. This congress happens every year around this time and this year I attended in my role as president of the Ankylosing Spondylitis International Federation (ASIF).
I was particularly pleased to see the amount of research that is currently underway that is related to AS.
Basically a selection of research studies into rheumatic diseases are given an opportunity to display an information "poster". There are lots of reviews, presentations and discussions about some of them and in there there were lots related to AS and aspects of its management.

Although I didn't get around to see the all the posters, one of our old friends from ASIF (Prof Ernst Feldkeller) did, I can tell you that the number of research studies in AS related areas are now significant. For example;

Spondyloarthritis – Clinical aspects (other than treatment):
There are 97 studies in this area ranging from "***Course and Outcome of Uevitis in Patients with Ankylosing Spondylitis***" to "***Clinical Characteristics of Non-Radiographic Axial Spondyloarthritis in Korea: In Comparison with Ankylosing Spondylitis***" and everything in between.

A Walk in the treatment forest of SpA:
There are 7 studies in this area covering a wide range of topics for example "***Anti-TNF therapy may influence structural progression in the Sacroiliac joints of patients with Axial Spondyloarthritis***" or "***Effects of Methrotrexate on the Immunogenicity of TNF Inhibitors in Sppondyloarthritis patients***".

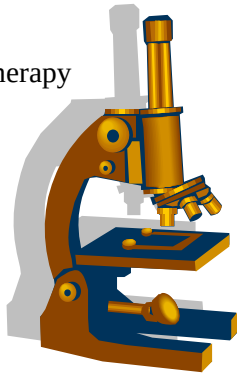
Spondyloarthritis – etiology, pathogenesis and animal models:
There are 10 studies in this area with everything from a study on "***Progression of early Axial Spondyloarthritis to Ankylosing Spondylitis after 6-Year follow-up***" to another on "***The molecular convergence of non-HLA Ankylosing Spondylitis risk genes with autoimmune diseases***".

Spondyloarthritis – treatment:
There are 45 studies in this area covering some of the ones from the 7 mentioned earlier plus others, for example "***The influence of Golimumab levels on clinical response in Spondyloarthritis patients at 52 weeks of follow-up***" or "***Do patients with Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis respond similarly well to NSAID's***".

I know that some of the names of these studies, or the studies themselves, may not appear mean a whole lot to us as people living with AS but rest assured that this in effect means a lot of work is on-going into our condition and its management.

We have to be pleased with that and we have to take hope for the future understanding and knowledge about the condition and its management.

It should not be assumed that these are the only studies that are underway into AS and its management, take for instance those we mentioned in our previous newsletters*, but it is an excellent indication of an increasingly large body of work on AS, its impact and its management. I would encourage all of you to take part in any studies that present opportunities to participate. ☺



**** AS and Fatigue***
Clodagh Fitzpatrick is an Occupational Therapy post-graduate student currently doing research into Ankylsoing Spondylitis (AS) and fatigue. This study is being carried out by the staff of the Rheumatology Department, St James's Hospital and the Discipline of Occupational Therapy, Trinity College Dublin.

How do you take part?
If you wish to take part in the study, or require more information please contact:
Clodagh Fitzpatrick by phone or email on:
Telephone: 01 896 3222 or 085 1448617
Email: fitzpacl@tcd.ie
I have exchanged emails with Clodagh and she is currently working through the analysis of the data. We would hope to have some more information on the study later in the year.

**** Patient Perspectives On Physical Activity In Ankylosing Spondylitis: Benefits, Barriers & Compliance***

Tom O'Dwyer, a Physiotherapy PhD candidate from Trinity College Dublin is conducting this study. This study aims to explore the views of adults with AS on physical activity and exercise. See page 8 for more details.
If you wish to take part in the study, or require more information please contact:
Tom O'Dwyer by phone or email on:
Telephone: 01 8963613 Email: odwyertk@tcd.ie

What's new in AS

This is from an article by Dr. Karl Gaffney in the Spring edition of AS News – the magazine of the National Ankylosing Spondylitis Society (NASS)in the UK, to whom we are grateful for on-going access to the information they have.

Five years ago the National Institute for Health and Clinical Excellence (NICE) approved the use of anti TNF therapies adalimumab (Humira) and etanercept (Enbrel) for use in severe ankylosing Spondylitis. In 2011 golimumab (Simponi) was also approved.

Infliximab (Remicade) is alos licenced for use in severe AS but NICE have not approved it for use in the UK on cost grounds. Certolizumab (Cimzia) has recently been licenced for AS and non-radiographic axial spondyloarthritis but has not yet been reviewed by NICE.

Anti TNF therapy has transformed the lives of many of those people who were not managing their symptoms with non steroidal anti inflammatories (NSAIDs) and exercise. From the NASS survey of 1630 members undertaken in Summer 2013, we know that a third (33%) are now receiving anti TNF therapy. It is estimated that 10,000 AS patients in the UK are benefiting from this treatment.

Data from clinical practice indicates 7 in 10 AS patients respond to anti-TNF; especially when used alongside a daily stretching and exercise routine. The NASS survey also shows that patients rate their satisfaction with anti-TNF as 4.25 out of a possible 5.

In 2014 NICE is undertaking a review of the current anti TNF guidance for AS. We hope they will be looking into:

1. **The use of anti TNF therapy in people whio have inflammation on MRI but not on x-ray (non-radiographic axial spondyloarthritis).** Both Humira and Cimzia are licenced for use in non-radiographic axial spondyloarthritis and available in Scotland and wales.
2. **Switching to a second anti-TNF after failure of the first agent due to loss of effectiveness (benefit).** Under current NICE guidance, AS patients can only try one anti-TNF. If this does not prove effective, or if the effectiveness decreases over timew, there is noi flexability in Existing guidance to allow for a change in therapy. This is despite mounting evidence that changing to a second or even third anti-TNF can be beneficial in up to 50% of patients.

NASS has submitted a statement on this subject to NICE.

Many people with AS do not need anto TNF therapy because they are managing well on medications such as NSAIDs along with physiotherapy. If you have been through a range of different therapies, are in pain and your AS is really having a negative impact on your life then do ask your rheumatologist whether you are eligible and suitable for anti TNF therapy.

Remember that only a consultant rheumatologist can prescribe anti TNF therapy. Your GP cannot offer it to you. So if you are not under the care of a rheumatologist do ask your GP to refer you to see a specialist.

What's new on the horizon

From the NASS survey in Summer 2013 we found that almost 5% of you are currently participating in a clinical trial.

Secukinumab

Secukinumab is an anti-linterleukin-17A monoclonal antibody. Interleukin-17 (IL-17) is known to be important in the development of AS.

A clinical paper was published on secukinumab in The Lancet (Volume 382, Issue 9906) on November 23rd 2013. Professor Paul Wordsworth (a NASS trustee) is one of the co-authors. This preliminary study found that secukinumab rapidly reduced clinical or biological signs of active AS and was well tolerated. The authors state that:

It is the first targeted therapy that we know of that is an alternative to anti-TNF to reach its primary end point in a phase 2 trial.

There are larger ongoing, randomised, multicentre clinical trials of secukinumab in AS and more results will be available during 2015.

Ustekinumab

Ustekinumab (Stelara) is a human monoclonal ntibody which is directed against interleukin 12 and interleukin 23. These are natuarally occurring proteins that regulate the immune system. It is currently used to treat severe plaque psoriasis in cases where other medicines have not worked or have caused negative side-effects.

In a preliminary clinical trial ustekinumab was administered at week one, week four and week 16 to 20 patients with active AS. The aim of the study was to establish the effectiveness and safety of ustekinumab in this small group.

Results e-published on January 3rd 2014, in the "Annals of the Rheumatic Diseases", reveal that 65% of patients were able to reach the ASAS 20 Disease Activity Score which signifies clinically important or major improvement. In addition patients were able to reduce their reliance on NSAIDs.

NASS looks forward to seeing the results of larger ustekinumab tials in the future.

There are exciting new drugs in development for patients with AS and hopefully a range of new treatments will become available in the near future.

Dr. Karl Gaffney is a consultant rheumatologist with Norfolk & Norwich University Hospitals NHS Foundation Trust. Some of you may also remember he presented at a meeting in Waterford regarding AS in 2013.

Managing the fatigue that comes with AS

This is from an article by Dr. Jane Martindale in the Spring edition of AS News – the magazine of the National Ankylosing Spondylitis Society (NASS)in the UK, to whom we continue to be grateful for on-going access to the information they have.

Understanding that fatigue can be an integral part of living with AS has for many people been a revelation and something they had not been aware of.

As healthcare professionals we recognize that sadly we do not have all the answers to help you live with the consequences of fatigue. Currently, we do not fully understand what AS fatigue is or how to manage it effectively. This article aims to share some things that may help and highlight that this is a shared experience among people with AS.

So what do we think fatigue is?

Fatigue may mean different things to different people. It can be described as extreme tiredness, 'feels like flu', feeling drained, no energy, your whole body is tired, feeling tired after rest, complete 'wipe-out' or weariness.

Fatigue may also affect people differently. It might mean reduced energy to complete tasks such as daily activities, hobbies or shopping, difficulty concentrating, difficulty thinking and speaking, becoming agitated or tearful or affecting your ability at work.

We have some idea of what happens in Rheumatoid Arthritis (RA) but unfortunately very little is known about what happens in AS. We know that in RA physical factors have been identified that may contribute to fatigue. Examples include pain, working postures leading to strain on joints, inability to exercise, anaemia and poor/disturbed sleep. Emotional factors may also play a part including the emotional strain of dealing with a chronic illness, stress/worry, anxiety, depression or feeling low and hiding your illness from others.

Dr. Jane Martindale is a clinical specialist physiotherapist with Wrightington Wigan and Leigh NHS Foundation Trust

Ideas for how to manage your fatigue

Pacing Activities:

- Plan short rests during the day
- Plan rests before beginning an activity
- Balance heavy (vacuuming, laundry, ironing) and lighter (dusting, short walk) jobs through the day and week.

Prioritising:

- Does the task have to be all done today or could it be broken up into smaller tasks?
- Do you have enough energy to complete the task today?
- How important is the task to you?
- If you know you have a busy day cut out unnecessary activities.

Balancing rest with exercise:

- Regular exercise will improve your general fitness and keep your muscles strong to support your joints
- We recommend you exercise 5 times a week for 30 minutes at a time.
- Choose an exercise method which best suits you
- Initially start slowly with regular breaks and set a time limit on the activity.

Achieve good sleep:

- Eliminate noise
- Avoid caffeine / alcohol a few hours before bed
- Do not use your bedroom for watching TV
- Avoid reading anything that could overstimulate your mind.
- Try a warm bath before bed
- If you cannot sleep get up and walk around

Relaxation:

- Can help with feelings of anxiety or stress
- It can help prepare you for sleeping

European Summit on Chronic Diseases (April 2014)

This is from an article by Luisa Avedano, the CEO of the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA), in the May edition of their magazine, to whom we are grateful for on-going access to the information they have.

The "European Summit on Chronic Disease" was a two day conference that Commissioner Borg strongly supported in the last semester of his mandate in the General Directorate on Health and Consumers' Protection (DG SANCO).

The focus was to address the medical, social and economic burden of chronic disease in the European Union bringing together key policy makers, stakeholders and interest groups, including pharmaceutical companies and other health related industries, to explore ways to tackle chronic diseases effectively and to develop recommendations.

It has to be said that the majority of interventions were focused on the so-called major non communicable diseases: cancer, cardio-vascular & respiratory diseases and diabetes, being the first cause of death in Europe. Nevertheless some space was also left for other diseases, in particular those related to mental health and the vast galaxy of "minor" ones whose impact, in terms of people suffering from them, is still considered less urgent and visible.

However, many messages and interventions from speakers and from the floor can be considered an excellent starting point for tuning lobbying activities for better placing our disease group in the European Commission agenda in the current programming period, 2014 – 2020.

All speakers agreed that chronic diseases have a significant economic impact, however Ricardo Baptista Leite, member of the Portuguese Parliament highlighted that it was essential to shift away from the vision of health as being about spending and instead to think about health in terms of an investment.

The necessity of involving and empowering patients in the healthcare process was highlighted many times, emphasizing that patients should not be seen as part of the problem but part of the solution as well. For proper patients' empowerment, however, proper resources should be made available by the means of patients' based policies that should be established and implemented in all Member States.

The discussion revolved then around the need to share best practices across Member States, but also across sectors. In particular European policies would make an impact for citizens supporting joint actions, such as "Health in All Policies" (HIAP) considered an important approach that integrates this vision and cooperation between the Member States as well as international and national strategies to control the burden of chronic diseases.

In conclusion Health Commissioner Tonio Borg summarized in his final remarks that a strong political leadership was necessary to prevent increasing rates of chronic diseases in the European Union and he re-affirmed that a removing of the burden of chronic disease is a Commission priority.

Two intense days of debates that led to a set of policy recommendations under the heading of "Inaction is not an option". Among them:

A. Strengthen political leadership to address chronic diseases – including consistent and coordinated approaches and integration of the health in all policies approach, broad involvement of civil society, prevention by strengthening effective action on the key major risk factors such as tobacco, alcohol, nutrition and physical activity.

B. Target key societal challenges – ageing societies, addressing the health, social and equity dimension of chronic diseases.

C. More efficient use of available resources – prevention, behaviour and lifestyle change, effective funding, integration of health objectives into other policies and fully exploit e-health, m-health and other IT solutions.

D. Strengthen the role, the involvement and empowerment of citizens, patients and the health and social sector in policy development and implementation, help and support patients, promote the participation of patients, the role of health and social professions, taking into account equity issues, as well as the social and gender dimension

E. Strengthen evidence and information as well as efforts into research and development

The full text of the recommendations is available at: http://ec.europa.eu/health/major_chronic_diseases/docs/ev_20140403_mi_en.pdf

Intervention of Luisa Avedano, CEO EFCCA, during the European Summit on Chronic Diseases, Brussels, April 5th 2014:

"I'd like to point out that there is a big set of chronic diseases whose causes / cures are unknown and where prevention is not possible by definition ….have a huge impact in terms of quality of life, of discrimination against in the labour market and education and I urge the European Union to take also these chronic diseases into consideration, including them in its strategy and in the research programmes recently launched under Horizon 2020.

A Focus on Biosimilar Medicines*

This is from an article the May edition of the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA), magazine. The biologic drugs for AS are the same as those for Crohn's & Ulcerative Colitis, Rheumatoid Arthritis, psoriatic arthritis etc.

Biotechnology has enabled the discovery of treatments for a variety of serious diseases. Worldwide, over 350 million patients have benefited from approved medicines manufactured through biotechnology. Currently, over 650 new biological medicines and vaccines are being developed to treat more than 100 diseases. As the exclusive rights for these biological medicines expire, similar biological medicines, or "biosimilars", are being developed, with some already available on the European market.

Biological medicines are comprised of proteins and other substances that are often naturally produced in the human body. In healthcare, biotechnology is being used in three primary areas: therapeutic medicines, vaccines and diagnostics. When compared to chemical medicines, biological medicines are generally more complex and usually much larger in size than chemical medicines.

The complexity is predominantly due to the manufacturing process for biological medicines, as they are developed in living systems the exact characteristics and properties are highly dependent on the manufacturing process. Chemical medicines can be approved either by national medicines authorities or by the "centralised procedure" carried out by the European Medicines Agency (EMA). However, all biological medicines must follow the "centralised procedure" for approval.

Due to the composition and large molecule size of biological medicines, they have the inherent potential to induce (unwanted0 immune reactions. Therefore, in order to identify unwanted immune reactions, and for post regulatory approval commitments, treating physicians should state the brand name and batch number, as opposed to the International Non-Proprietary Name (INN) when prescribing. Furthermore, due to the unique nature of biosimilars, there should not be automatic substitution of the reference product, this decision should be left with the treating physician.

**This information is from the EuropaBio literature "Guide to Biological Medicines". EuropaBio is the voice of the European biotech industry and represents the interests of the industry towards European institutions so that legislation encourages and enables biotechnology companies in Europe to innovate and provide for society's unmet needs.*

Generics and biosimilars have an important role to play in fostering competition in the market place, and thereby contributing to the sustainability of healthcare budgets. However, as the research and development costs of biosimilars are much higher than generics, suitable pricing and reimbursement environments are needed to foster the development of new products. Furthermore, adequate intellectual property protection is vital to ensure that companies are able to fund research and development of biological medicines, and therefore develop and produce more potential treatments. Upon expiry of such protection, biosimilar products (unlike chemical generics these are not exact copies, as they are made in living systems the exact characteristics are dependent on the manufacturing process) can enter the market to compete with the original "reference product".

So far the European Union has approved 7 biosimilars, across 3 product classes. In the United States, the biologics Price Competition and Innovation Act, signed into law in March 2010, created a statutory framework for the approval of biosimilars by the Food and Drug Administration (FDA). Over the last two years, the biosimilar market shares have steadily increased in most countries. In several European countries, biosimilars now have a higher volume market share than the reference product, and this trend appears to be accelerating.

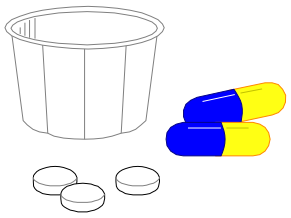
For Patients

Patients need and deserve to be fully informed about any medical treatment that they are receiving. If a physician chooses to prescribe a medicine to a patient, the patient should be involved in that decision, meaning that the patient understands why the choice has been made as well as what it will mean for his or her treatment.

Patients may not be completely aware of the complexities of biological, including biosimilars, and the implications of using them. This includes the potential of different products to provoke different immunogenic reactions in the patient. It is important that the patients are not obliged to "switch" their treatment from one biological to another purely on cost grounds, the specific therapeutic needs of the patient must always be taken into account.

According to a survey by the International Alliance of Patients' Organisations (IAPO), the key interests of patients with regards to biological treatments are:

- Cost and the potential to increase access to biological treatments
- Safety and efficacy
- Patient information and decision-making



- Regulatory process, and
- Interchangeability

Therefore, it is very important that the label and other product information relating to the biosimilar reflect the specific characteristics (such as reference product, potential side effects etc.).

For Healthcare Professionals

Healthcare professionals need to understand the EMA approval process for biosimilars and be aware of the scientific data underlying their approval (in particular the abridged clinical data requirements, which can allow the extrapolation of indications). For physicians too, it is very important that the label and other product information relating to the biosimilar reflect the specific characteristics (such as reference product, potential side effects etc.). The summary of product information on biosimilars should also list the available data in order to show which applications were substantiated by studies and which were derived from the biological medicine of the original manufacturer without separate data extrapolation.

Healthcare professionals must be aware that the interchangability between the biosimilar and its reference product has not been evaluated by the regulatory authority. Physicians should not be obliged to prescribe a certain medication purely on the grounds of cost, but should be allowed to exercise appropriate clinical judgement.

With regards toi patients, it is very important for healthcare professionals that the label and other product information of the biosimilar reflect its specific characteristics (clinical data, reference product, etc.).

Patient perspectives on physical activity in AS: benefits, barriers & compliance

The study aims to explore the views of adults with AS on physical activity. Exercise and an active lifestyle are important components in the management of AS. It is hoped that this study will help us understand more about the benefits, barriers and motivations to exercising - this will in turn help in designing more effective treatment programmes in the future. The study involves participants meeting a member of the research team to complete a short questionnaire and take part in a short interview.

Who is doing the research?

Tom O'Dwyer is a Physiotherapy PhD candidate from Trinity College Dublin. The study will be supervised by Dr. Fiona Wilson, Physiotherapist and Lecturer at Trinity College Dublin.

Who can take part in the study?

To be involved in this study, you must be over 18 years of age with a diagnosis of Ankylosing Spondylitis, and be able to read and understand English.

What does this study involve?

This study involves meeting with a member of the research team for approximately one hour, on one occasion. You will be required to fill in a questionnaire which will ask you about your condition, quality of life and your physical function. You will then be interviewed about your views on exercise in managing your condition. During this interview your voice will be recorded. A copy of your interview transcript will be made available to you. There is no special preparation required for this study.

Where does this study take place?

You can meet a researcher in the Trinity Centre for Health Sciences in St. James's hospital, or at a location of your choosing in the Dublin area. Outside of Dublin you should contact the research team to discuss possible options.

What benefits are there to taking part in this study?

A benefit of this study will be to help physiotherapists and doctors understand the benefits and barriers to exercising from the perspective of someone with ankylosing pondylitis. This will help in designing more effective treatment programmes.

Are there any risks involved in taking part in this study?

As this study is a combination of a paper questionnaire and an interview, no risks are anticipated.

Confidentiality

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research team.

Data Storage and Disposal

All information will be held on a password protected computer and kept in a secure office.

Permission

This research has been approved by the Research Ethics Committee of St. James's Hospital / AMNCH.

Further information

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Tom O'Dwyer who can be telephoned at (01) 8963613 or emailed at odwyertk@tcd.ie .

If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.