Institution: University of Leeds

Unit of Assessment: UOA3 (Allied Health Professions, Dentistry, Nursing & Pharmacy)

Title of case study: Case study 1. Leeds Foot and Ankle Studies - introducing evidence-based podiatry for musculoskeletal services

1. Summary of the impact

Since 1998 the University of Leeds has developed the Leeds Foot and Ankle STudies in Rheumatology (FASTER) programme – to drive improvements in UK musculoskeletal foot care services. Results from FASTER clinical trials and a national survey of podiatry services directly informed NICE guidelines on foot care in arthritis. FASTER's research also provided key evidence for a national consensus on standards of care and aided a shift in the treatment paradigm for foot care in arthritis patients. These standards and NICE recommendations are included in the latest Royal College of GPs curriculum. They have also informed government policies on commissioning for podiatry services throughout England. Since the inception of the FASTER programme independent reports suggest that access to foot health services for people with rheumatoid arthritis has increased from less than 50% immediately prior to FASTER, to nearly 80% of patients today.

2. Underpinning research

Early work*:* Initial work (1998-2003) conducted at the University of Leeds by **James Woodburn** (Medical Research Council Fellow, 1994-2003) and other colleagues from Leeds, and Bradford Hospitals NHS Trust identified a role for mechanical foot therapy (i.e. adding contoured inserts into footwear) in the treatment of rheumatoid arthritis (RA). These studies were the first to show that this form of therapy could reduce pain in the short-term and slow the progression of foot deformity over the long-term [1]. In 2002, **Anthony Redmond** was appointed as Arthritis Research Campaign Lecturer (later Senior Lecturer) to formalise the implementation of an evidence-based approach in this field under the banner of the Leeds FASTER programme, and extend work in RA into related musculoskeletal (MSK) conditions.

Establishing the landscape – MSK podiatry service in the UK: Around half of patients aged over 55 years and as many as 90% of patients with RA suffer from foot-related problems, ranging from stiffness and pain to severe immobility. With more than 500,000 RA patients in the UK, between 2002 and 2005 **Redmond** spearheaded a programme systematically to describe and evaluate MSK foot health services across more than 200 centres in the UK. The study found that only 6% of these specialist centres had referral guidelines for foot services for RA patients [2], revealing the need for greater service access, training and dissemination of findings from the Woodburn study [1] and further clinical research on foot therapies.

New methods to evaluate MSK podiatry interventions: To enable the FASTER team to acquire data for the systematic evaluation of different foot therapies, **Redmond** has created a series of measures for clinical outcomes. In particular, his foot posture index (FPI) was the first-ever criterion-referenced quantitative system for evaluating foot posture in relation to pathologies [3]. The FPI provides a quantitative, objective measure of pathology and the effect of therapy, paving the way for trials of new therapeutic interventions. An international population normative dataset was produced during the census period. Collaborators from the Universities of Sydney, LaTrobe and Cardiff worked on data processing, programming and patient recruitment. Alongside this, between 2002 and 2005 Philip **Helliwell** (Senior Lecturer, 1993-present) led the development of the Leeds Foot Impact Scale. This assessment tool quantifies the impact of RA on foot problems.

Novel therapies and insights into mechanisms of action: Between 2002 and 2013 **Heidi Siddle** (nee Davys) (NIHR Research Fellow, 2008-present) built on earlier work by **Woodburn** and combined Doppler power imaging and biomechanical studies to reveal relationships between disease processes and structural changes in the forefoot. In particular, she showed that failure of the plantar plate was a key component of catastrophic damage to forefoot joints in RA [4].

Over a period of seven years, with funding from Arthritis Research UK, **Redmond** led research with collaborators from the Universities of Perth and Leeds to explore the pathology and treatment of osteoarthritis affecting the first metatarsophalangeal joint. This was the first research to describe the effect of bone remodelling, function and inflammation which occurs in the joints [5]. A linked, large-scale community study led by **Anne-Maree Keenan** (Senior Lecturer, 2001-present) studied the prevalence of joint problems in >14,000 people. It was the first to establish the importance of the cumulative effect of multiple joint involvement and the impact on quality of life [6].

Clinical trials: The FASTER team has led a number of clinical trials, using instruments such as the FPI and the Leeds Foot Impact Scale to assess clinical outcomes from interventions. Follow-up studies to **Woodburn's** early research (2002-2013) have shown that functional orthoses – inserts which actively change the function of a patient's foot when they walk – have a role to play in managing symptoms in other diseases such as connective tissue disease and osteoarthritis. **Redmond** also compared the relative costs of treatment approaches, finding that off-the-shelf devices have comparable mechanical properties to customised inserts. In another series of clinical trials, latterly funded by NIHR, **Siddle** established that the removal or reduction of calluses is of no benefit in the foot care of people with RA [7].

3. References to the research

1. **Woodburn J**, Barker S & **Helliwell PS** (2002). A randomized controlled trial of foot orthoses in rheumatoid arthritis. *Journal of Rheumatology*, **29:**1377-83.

*This peer-reviewed paper reports on an MRC-funded trial. It is referenced in NICE guidance (see Section 4) and in two systematic reviews. The paper has **75 citations**.*

2. **Redmond AC, Waxman R & Helliwell PS** (2006). Provision of foot health services in rheumatology in the UK. *Rheumatology*, **45:**571-6. DOI:10.1093/rheumatology/kei205.

*This peer-reviewed paper on the ARUK funded assessment of podiatry provision UK rheumatology departments provides a benchmark on foot health service delivery in MSK diseases. **16 citations** including the ARMA/PRCA National Standards of Care for people with musculoskeletal foot health problems and the RCGP curriculum statement.*

3. **Redmond AC**, Crosbie J & Ouvrier RA (2006). Development and validation of a novel rating system for scoring standing foot posture: the Foot Posture Index. *Clinical Biomechanics,* **21:**89-98. DOI: 10.1016/j.clinbiomech.2005.08.002.

*This peer-reviewed paper was the **No.1 most cited paper** in the journal Clinical Biomechanics in the period Dec 2006-Dec 2011 (source: Elsevier journal citation report [Accessed 5 Jan 2012] : **136 citations.** http://www.elsevier.com/wps/find/journaldescription.cws_home/30397/description).*

4. **Siddle HJ, Hodgson RJ, O'Connor PJ, Grainger AJ, Redmond AC, Wakefield RJ, Helliwell PS** (2012). Magnetic Resonance Arthrography of Lesser Metatarsophalangeal Joints in Patients with Rheumatoid Arthritis: Relationship to Clinical, Biomechanical, and Radiographic Variables. *Journal of Rheumatology*, **39:**1786-1791. DOI: 10.3899/jrheum.120392.

*This Arthritis Research UK funded study is one of a series of reports by **Siddle** on the pathology and impact of failure of the plantar plate in the forefoot of people with RA. It has fundamentally changed our understanding of the forefoot in RA. This work has been recognised by the award of an Arthritis Research UK Silver medal for best research and 'Jewel in the Crown' status at the College of Podiatry annual congress.*

5. **Keen HI, Redmond A, Wakefield RJ, Freeston J, Grainger AJ, Hensor EM, Emery P, Conaghan PG** (2011). An ultrasonographic study of metatarsophalangeal joint pain: synovitis, structural pathology and their relationship to symptoms and function. *Annals of the Rheumatic Diseases*, **70:**2140-3. DOI: 10.1136/annrheumdis-2011-200349.

This study, the fourth in series of linked projects, was published in the world's top ranked rheumatology journal and highlighted the relationship between patient reported outcomes and state of the art imaging.

6. **Keenan AM, Tennant A, Fear J, Emery P & Conaghan PG** (2006). Impact of multiple joint problems on daily living tasks in people in the community over age fifty-five. *Arthritis Care and Research*, **55:**757-764. DOI: 10.1002/art.22239.

This paper is part of a body of work by Keenan defining foot problems in the broader context of multiple joint involvement and comorbidity. The quality of the work in this paper has been recognized through the award of the Arthritis Research UK Silver medal for best research. **42 citations**.

7. **Davys [now Siddle] HJ, Turner DE , Helliwell PS, Conaghan PG, Emery P, Woodburn J** (2005). Debridement of plantar callosities in rheumatoid arthritis: a randomized controlled trial. Rheumatology, **44**:207-210. DOI: 10.1093/rheumatology/keh435

This clinical trial is the second in what is now a series of three trials that has investigated the short and longer term efficacy of callus reduction in people with RA. This work was cited directly in NICE guidance CG 79. **18 citations.**

Note: All Leeds researchers in **bold**. All citation data from SCOPUS [Accessed 23/10/13]. All journals are peer-reviewed with international editorial boards. Copies of all publications are

available from the HEI on request.

Key research grants

a. **Backhouse, Buch, Redmond,** Arden. Prefabricated and custom orthoses in early RA (PREACHER) NIHR Postdoctoral Fellowship. 2013-2017. £429,484.
b. **Conaghan, Fisher, Redmond, Kingsbury, Keenan**. Experimental Osteoarthritis Treatment Centre establishment and infrastructure funding. Arthritis Research UK. 2012-2015. £150,000.
c. **Redmond, Gray, Halstead, Helliwell, Keenan, Roddy, Grainger**. Functional foot orthoses in the treatment of symptomatic midfoot OA using clinical and biomechanical outcomes: a feasibility study. Arthritis Research UK OA Clinical Studies Group Pilot Award. 2012-2013. £29,989.
d. Torgerson, Adamson, Watson, Cockayne, Hewitt, Chang, Menz, **Keenan**, Vernon, McIntosh, Lamb, **Redmond**, Hull. Randomised trial of a multifaceted podiatry intervention for falls prevention. REFORM trial. NIHR Health Technologies Assessment Programme (HTA). 2011-2014. £1.1 million.
e. **Burnett, Hodgson, Redmond.** Improving safety and patient experience in the magnetic resonance imaging of arthritis. NIHR Clinical Doctoral Fellowship. 2011-2015. £389,897
f. **Alcacer-Pitarch, Redmond, Buch, Emery.** Multifactorial pathways contributing to the development and impact of foot problems in scleroderma. NIHR Clinical Doctoral Fellowship. 2009-2013. £281,771.
g. **Redmond, Denton, Herrick, Buch, Pavitt, Siddle, Helliwell, Worthy, Emery.** Pressure and pain In Scleroderma, an Evaluation of a Simple intervention (PISCES). Arthritis Research Campaign CTDs Clinical Studies Group Clinical Trial Award (18826). 2009-2012. £199,119.
h. **Wakefield, O'Connor, Davys, Redmond, Emery**. Equipment grant (18620). Arthritis Research Campaign. 2008-2011. £45,030.
i. **Redmond, Keenan, Conaghan, McGonagle.** Pathological processes and candidate interventions in mechanically induced foot pain. Arthritis Research Campaign PhD Studentship (18256). 2008-2011. £78,000.
j. **Redmond**. Mechanical and biological interactions in RA and OA of the foot. Department of Health/ NIHR: Personal Awards Scheme, PAS3 PDA (03/07/047). 2007-2010. £298,390.
k. **Davys, Redmond, Helliwell, Wakefield**. Factors leading to plantar plate (ligament) damage in rheumatoid arthritis. Arthritis Research Campaign. 2007-2012. £177,000.
l. **Helliwell, Redmond, Davys, Dagg.** NIHR, Research for Patient Benefit Scheme (10143): Callus Reduction in RA (CARROT) randomised controlled trial. 2007-2010. £87,000.
m. **Redmond, Helliwell**. (17866): Predictors of outcome of forefoot surgery in RA. Arthritis Research Campaign PhD Studentship. 2007-2011. £75,760.
n. **Redmond, Helliwell**. Standards of Care for Musculoskeletal Foot Health Services. Arthritis Research Campaign. 2007-2009. £28,699.

4. Details of the impact

Access to specialist RA foot care services: There are approximately 580,000 people with RA in the UK; the prevalence of foot problems in this group is consistently reported to be over 90%. The publication of the FASTER national evaluation of podiatry services in rheumatology departments provided the NHS with key benchmark data on foot care services to these patients. Combined with the findings of a 2004 report by Williams (University of Salford), which suggested that in northwest England only 21% of these patients had any access to NHS foot care, the FASTER study stimulated significant changes in the provision and delivery of foot care to RA patients across the country (detailed in the sub-sections below).

A subsequent national review by Otter and colleagues (University of Brighton) provided strong evidence that the care guidelines and NHS policies, based in part on Leeds evidence, have transformed practice: by 2011 some 70-78% of patients with RA had access to foot care.

Changing practice - clinical guidelines: The Woodburn and Siddle clinical trials were instrumental in shaping recommendations on foot wear and callus reduction in NICE clinical guidelines for osteoarthritis [A] and two specific, numbered recommendations on foot care in patients with RA [B]. This latter document makes four references to the Leeds research.

Changing practice – new standards of care and GP curriculum: The FASTER evaluation of podiatry services and the growing volume of evidence-based recommendations on foot care interventions led to Arthritis Research UK funding in 2008, a national project led and chaired by **Redmond** and supported by the UK umbrella body ARMA and the Podiatry Rheumatic Care

Association, to set out formal, universally agreed standards of care for the management of foot related problems in MSK diseases [C]. A total of six citations to Leeds' research are noted in the standards which have been distributed to about 5000 specialist practitioners since 2008.
The contribution of the FASTER group's extensive impact on practice across the field is reflected in **Redmond**'s listing in the Times newspaper's list of the top 100 doctors in the UK in 2010 [D].
The adoption of the approach has also been supported by the publication in 2011 of a commissioned ARUK Topical Review on the subject, co-authored by **Helliwell**, **Redmond** and **Siddle** [E]. The review forms part of a long-standing series published by Arthritis Research UK which is distributed to all practitioners in the UK and overseas on the ARUK database, a total of approximately 4000 primary and secondary care professionals from medical, surgical, nursing and allied healthcare backgrounds.
The evidence from the FASTER research and the new standards of care have been included for the first time in 2012 in the new musculoskeletal syllabus handbook for the Royal College of GPs. This will ensure that all training GPs (~3000 per year) will learn about foot care for arthritis patients based on the Leeds research [F].
Redmond, **Helliwell** and **Siddle** coordinate the British Society for Rheumatology annual foot and ankle course which in the last twelve years has been attended by more than 300 consultants, registrars, GPs and AHPs. **Redmond** also co-convenes the Society's foot special interest group which ensures that the Leeds research directly informs medical training and, in turn, practice.
Changing government policies: The specific recommendations of the NICE guidance and standards documentation were incorporated during 2011-2012 into the Department of Health implementation guidelines for Any Qualified Provider (AQP) commissioning for podiatry services throughout England [G]. These guidelines highlight how a disease staged approach, based on the FASTER body of work, can target types of intervention to patients with rheumatoid arthritis at the correct time in the disease.
Redmond has also made contributions to the All Party Parliamentary Advisory Group on inflammatory arthritis and given an invited formal address in parliament. In particular, he provided background materials and evidence to inform a debate on the provision of MSK services [H].
Improving foot care research, screening and rehabilitation for musculoskeletal conditions: Redmond's development and subsequent validation of the Foot Posture Index has had impact on foot care research worldwide [I]. The index is now commonly used to measure clinical outcomes in foot care studies. Since 2008 it has been used as an assessment tool in more than 150 clinical studies including government-led population studies, military screening studies and for measuring the outcomes of rehabilitation approaches.

5. Sources to corroborate the impact

A. NICE Clinical Guideline CG59: Osteoarthritis. National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guideline for care and management in adults. London: Royal College of Physicians, 2008.
B. NICE Clinical Guideline CG79: Rheumatoid Arthritis. National Collaborating Centre for Chronic Conditions. Rheumatoid arthritis: national clinical guideline for care and management in adults. London: Royal College of Physicians, 2009.
C. Arthritis and Musculoskeletal Alliance/Podiatry Rheumatic Care Associated Standards of Care for People with Musculoskeletal Foot Health Problems. London 2008.
D. Times top Doctors list 13th Nov 2010. Published as a supplement to the print edition of the newspaper and available online at : www.thetimes.co.uk/tto/public/article2800905.ece (accessed Nov 2010)
E. Arthritis Research UK (2011). Topical Review Series 6 Number 8. *The foot and ankle in rheumatoid arthritis.*
F. Warburton, L. (ed); Musculoskeletal Disorders in Primary Care (curriculum statement 15.9). Royal College of General Practitioners, London. 2012. ISBN 9780850843330
G. Department of Health (2012). Any Qualified Provider Implementation Guidelines for Podiatry. http://www.supply2health.nhs.uk/AQPResourceCentre/Documents/AQP%20Podiatry%20Pack%2012012012.pdf (Accessed 29th March 2012)
H. Hansard 19/1/2010 Column 1WH. Adjournment motion 'Musculoskeletal Conditions'.
I. Letter: Director of Research Rehabilitation Institute, Auckland University of Technology, NZ