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Mr. Jeremy Powell
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9th August, 2009

Dear Jeremy,

**NRAS Response to MTA appraisal of Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor**

We are pleased to have the opportunity to respond to the above appraisal and I would first of all like to confirm that NRAS supports and endorses the joint submission by ARMA/BSR as well as that submitted by the RCN and I do not propose to repeat all the points made in those submissions here other than to reinforce any particular points made from the patient perspective in regard to the best overall strategy for treatment of people with RA.

It is important to place on record that NICE have given us very little time to prepare this submission bearing in mind that the scoping meeting was on the 9th July and the revised protocol for this MTA was only sent out on 31st July with a deadline of 10th August. This is a holiday period and both the clinical experts who have been supporting NRAS throughout the work on switching are away on annual leave. As this Appraisal is not scheduled until February 2010 we feel that NICE have not appreciated the difficulty that patient organisations face with such short timescales, particularly at this time of year.

It seems logical to address the questions raised in NICE protocol dated 17th July.

**4.1 Decisions to be made**

***Problem 1***

***Whether there are significant differences in clinical and cost effectiveness between Adalimumab, Etanercept, Infliximab, Rituximab and abatacept.***

This is a difficult question for a patient organisation to address, however we have noted one paper which is relevant citing sequenced Anti-TNF therapy initiated with Adalimumab + MTX as being most cost effective.[1]

In regard to Rituximab we would observe that if given at 6 monthly intervals, the cost, bearing in mind the cost of providing hospital resources and facilities to administer all the infusions at baseline, 6 months and then at 12 months, would be higher than providing sub-cutaneous Anti-TNF therapy over a 12-13 month period. Has this scenario been modelled?

We would reinforce the point made in the BSR submission that there are now 3 large cohorts of patients who have shown maximum benefit from abatacept after the first 12 months of treatment and health economic analysis of abatacept should take into account the increase in efficacy which takes place after the first year of treatment.

***Problem 2***
***Whether the interventions are clinically effective and cost effective compared to conventional DMARDs.***

It is clear from many studies that returning people to failed and/or palliative DMARDs, is of no benefit, and in regard to use of steroids, is in fact detrimental. In fact patients who have experienced using steroids at some time will tell you that the drug that is most likely to relieve symptoms of pain and stiffness when taken in sufficient dosage is steroid, but most patients are aware that there are major side effects precluding the long term use of steroids, and in fact in February 2009 NICE published the guidelines for Rheumatoid Arthritis in adults.

Questions the Guideline Development Group asked were:
_ Should recent-onset RA patients be treated with some form of steroids (oral or intramuscular)?
_ Do the benefits of steroids out-weigh the disadvantages?
_ Do steroids have a lasting impact on symptoms, function of joints and quality of life?
_ Should steroids be classified as disease modifying drugs?

**From evidence to recommendations**

**Recent-onset RA**

The GDG noted that there was a considerable mismatch between the available data and what actually happens in clinical practice. For example, both in the initial presentation of disease and during flare-ups, steroids (oral, intra-muscular and intra-articular) are often used to obtain symptomatic benefit and to achieve disease control whilst waiting for the more slowly-acting DMARDS to take effect, despite the lack of evidence to support this. The clinical efficacy of this approach is so well established that it is doubtful that any future randomised controlled clinical trials would ever be conducted, and the GDG felt that there should therefore be a recommendation endorsing this use of steroids, both for those patients with newly diagnosed rheumatoid arthritis who are not already receiving steroids as part of DMARD combination therapy (see recommendation R22), and for the management of flare-ups in those with recent onset or established disease.

**Established RA**

The GDG noted that the evidence for the use of steroids in established disease was sparse, of limited quality, and that in two trials the much older drugs penicillamine and gold had been used as comparators. There was a need to establish the merits of combining steroids with drugs such as methotrexate in established disease, where there was much less evidence for disease modification by steroids than in recent-onset disease.

Although a consistent theme for both recent-onset and established disease is that the symptomatic benefit produced by steroids is usually only short lasting, the GDG noted that, in routine clinical practice, there are nevertheless some patients who appear to be reliant on long term low dose steroids since withdrawing them results in flare-up of disease activity. This use of steroids in this particular group of patients may have to be accepted, even though the situation is not ideal, although attempts should always be made to replace the steroids with other disease modifying drugs and to keep the

steroids to the lowest dose that controls symptoms. It was also felt important to emphasise the specific potential serious complications associated with long-term steroid therapy.

**RECOMMENDATIONS**

**R22** Consider offering short-term treatment with glucocorticoids (oral, intramuscular or intra-articular) to rapidly improve symptoms in people with newly diagnosed RA if they are not already receiving glucocorticoids as part of DMARD combination therapy.
**R23** Offer short-term treatment with glucocorticoids for managing flares in people with recent onset or established disease, to rapidly decrease inflammation.
**R24** In people with established RA, only continue long-term treatment with glucocorticoids when:
_ the long-term complications of glucocorticoid therapy have been fully discussed, and
_ all other treatment options (including biological drugs) have been offered.

In regard to clinical effectiveness of switching to a second TNF, data from the BSR Biologics Register (Hyrich et al. Outcomes after switching from one Anti-TNF to a second … 2007) states "in conclusion, these data from a large unselected population of RA patients suggest that, based on treatment continuation rates, there is a strong case for switching patients to a second Anti-TNF agent when failure to respond to the first agent occurs. In fact, our findings showed that more than 70% of patients continued on a second agent for at least 6 months. This was the case for patients stopping either because of inefficacy or because of certain AEs. … Further studies will be needed to determine whether there is a role for yet a third Anti TNF agent in these patients or whether it is better to move onto a different class of biologic agent".[2]

**Problem 3**
**Whether the interventions are clinically effective and cost-effective compared to other biologic agents (including tocilizumab, golimumab and certolizumab).**

My understanding from data from the Biologics Register is that the three TNFs in current use are similarly clinically effective. The other three drugs are not yet in use in the NHS and I don't believe there are any head to head studies comparing TNF against other biologic agents.

We have said in previous submissions to NICE that whilst there have been recent advances in understanding the genetic and molecular basis of rheumatoid arthritis, its individual pattern of expression and reasons for responding to one treatment over another require ongoing and future development of better diagnostic and prognostic biomarkers which we hope will lead ultimately to being able to identify an optimum treatment regimen without having to cycle through often expensive therapies. We have not reached this point but it is clear that there are patients who are more likely to respond to an IL6, or a particular TNF or a B-cell modifier, we just don't have the ability yet to match patient to optimum drug. It is equally clear that patients will need access to all these different biologic therapies and unless we are able to use them to gain the clinical experience we need to further this research agenda, we are not going to reach a point where biologics can be used and sequenced much more effectively and economically.

**Problem 4**

**Whether the interventions are clinically effective and cost effective compared to supportive care.**

We have partially addressed this issue under Problem 2 above, however, added to what we have said above in regard to use of failed DMARD therapy and long term use of steroids, must be the arguments over increased use of healthcare resources by this group of patients. Patients who are inadequately controlled and receiving 'supportive' care will:

- Visit their GP much more frequently
- May be hospitalised from time to time due to inability to cope with severity of disease, symptoms and disability
- Will become increasingly disabled as their bones erode
- Will require more frequent surgery
- Will risk job loss and will lose their job more than controlled patients
- Will be more likely to claim benefits
- Will be a greater burden to social care costs
- Will have greater impact on their family who are more likely to also suffer job loss to become 'carers'
- Incur worse health economic outcomes
- Be less able to self manage adequately
- Have a significantly worse quality of life
- Have higher morbidity and mortality

We think that there is general lack of awareness that about 50% of people with RA die of cardiovascular disease and that there is significantly increased morbidity and mortality due to upper-gastrointestinal disease as a result of treatment for RA.[3]

There is also a lack of awareness that associated co-morbidities in these patients reinforce each other, impacting on disability, and that the number of co-morbidities in each patient is in itself an independent risk factor for premature death.[4]

There is a suggestion by NICE that there should be a clear distinction made between putting patients back on DMARDS (having failed one TNF and/or one TNF and RTX) on which they have already failed and those DMARDs which patients have either not tried at all or have an inadequate response. Data suggests that patients who fail on Methotrexate are unlikely to respond to other DMARDS.[5] From a patient perspective, either situation would be considered a retro-grade step and a course of action which would cause substantial alarm by comparison to being allowed to try a second TNF or indeed other biologic such as abatacept, or in due course, tocilizumab, certolizumab or golimumab.

There is evidence to show that x-ray progression is greater in patients who are on DMARDS than on those on Anti-TNF. X-ray progression leads to joint deformity, disability and ultimately surgery.

**Problem 5**
**Whether the clinical and cost-effectiveness of the interventions differ significantly between certain sub-groups of patients.**
We would like to support the submission of the BSR in regard to our concerns over use of Rituximab in sero-negative patients, methotrexate intolerant patients and patients with co-morbidities such as heart failure for whom some treatments may be contra-indicated.

## Additional areas of interest and concern to NRAS

***Costs associated with joint replacement and hospital admissions***

This is an area where we believe costs are inadequately represented in the economic model and we very much reinforce the suggestions for further research put forward in the RCN submission on this subject.

***HAQ – QoL***

An on-going source of debate which is of great importance to us is the relationship between HAQ score and Quality of Life.

Patients with rheumatoid arthritis face considerable physical, social and emotional disabilities. In this chronic disease, improving patients' health-related quality of life is of the utmost concern to us, particularly as the use of long-term biologic therapy increases. Early HRQoL outcome measures in RA focused on physical functioning, but the social and emotional aspects of the disease are now increasingly important. **No one tool covers all areas of HRQoL that affect the patient with RA.**

We all understand that the reason the HAQ improvement is lower in the BSRBR observational cohort than other studies of Anti-TNF is due to the long disease duration of these patients who had failed on at least 4 DMARDS before going onto their first, never mind their second Anti-TNF. The difficulty is therefore in measuring the clinical benefits for economic modelling in a way which adequately reflects quality of life in a meaningful way to all patients with RA.

There are two recent papers which are of interest here. The first, published on 21st June, 2009 is entitled 'Perceived functional disabilities among rheumatoid arthritis patients'[6] and points out (which is extremely relevant from a patient perspective), that in HAQ, to determine the functional disability, the functions themselves have been chosen by rheumatologists, and the selection of the functions solicited from patients is based on the views and opinions of the clinicians. Therefore all such measures reflect functional disabilities in those functions which the clincians ***assume*** to be relevant for the patients. In this study there were a total of 354 mentions of functional difficulty (telephone interviews carried out with 143 patients with RA) and problems in physical tasks were reported by almost 9 out of 10 patients. The most commonly

mentioned disabilities were walking and opening jars, however, **the most commonly mentioned disabilities were not those with the highest perceived disabilities by patients**.

In the second paper, published on 11th July 2009, 'Measure of function in rheumatoid arthritis: individualised or classical scales?'[7], data were obtained from a 6 month, prospective, open-label study involving 378 RA outpatients treated with Leflunomide. In this study patients had to rate the importance to them of each HAQ question and then had to prioritise the 5 activities they considered the most important in their lives. **For each item, severity and importance scores were weakly or not significantly correlated** and concluded that even if individualisation is probably not needed for group assessment in all RCTs, the use of individualised questionnaires could be clinically relevant in decision making for individual patients.

**Recent Important Publications of relevance to this appraisal:**

Kings Fund Report[8]

National Audit Report[9]

Fit for Work – The Work Foundation[10]

NICE RA Guidelines[11]

Sir Ian Kennedy Report into Innovation [12]

Health Select Committee Report into NICE[13]

NICE submission to the Kennedy Report[14]

**Summary of key points from the NAO Report of relevance**

The NAO estimate that rheumatoid arthritis costs the NHS around £560 million a year in healthcare costs, with the majority of this in the acute sector, and that the additional cost to the economy of sick leave and work-related disability is £1.8 billion a year. In the NICE submission to Sir Ian Kennedy's report[14] into innovation, the following key paragraph from NICE's own processes, states:

2.22 The 2008 NICE Guide to the methods of technology appraisal states that "Technologies for which a substantial proportion of the costs (or cost savings) are expected to be incurred outside of the NHS and PSS, or which are associated with significant non-resource effects other than health, should be identified during the scoping stage of an appraisal. In these exceptional circumstances, information on costs to other government bodies, when these are not reflected in HRQL measures, may be reported separately from the reference-case analysis. The intention to include such data will normally be agreed with the Department of Health before finalisation of the remit." This was undertaken for the appraisal for conduct disorder in children (TA102). In public health the perspective taken is "in connection with … the effective use of resources in the health service and other available public funds".

At no time that I am aware of during the scoping meeting which took place was this mentioned by any of the NICE personnel present and at that time the NICE response to Sir Ian's report had not been published.

That NICE take into account some of the wider societal costs associated with RA in the economic modeling is a hugely significant issue to all the stakeholders of this appraisal and one which we have raised on every possible occasion. We would like to register a request under your own processes, that we have exceptional circumstances as identified by the NAO report which demand referral to the DH in respect of this appraisal.

The following paragraphs all serve to reinforce our above request.

The report also identified that currently only 10 per cent of people with the disease are treated within three months of symptom onset. The NAO economic modelling suggests increasing this to 20 per cent could initially increase costs to the NHS by £11 million over 5 years due to higher expenditure on drugs and associated costs of monitoring people with the disease (after around nine years, earlier treatment could become cost neutral to the NHS). This increase in treatment could, however, result in productivity gains of £31 million for the economy due to reduced sick leave and unemployment. On average, this could also increase quality of life by four per cent over the first five years, as measured by quality adjusted life years (QALY) gained. This information must be taken into account by the Appraisal Committee.

**The Department's approach to rheumatoid arthritis**

The NHS Improvement Plan also set out the Department's plans to improve care for people with long-term conditions by moving away from reactive care based in acute hospitals, towards a systematic patient-centred approach rooted in primary care. The Department's plans were further developed in its January 2005 policy document, 'Supporting people with long-term

conditions', which promoted earlier detection; more effective medicines management; and improving quality of life by empowering people to manage their own condition.

The NAO have estimated that around 26,000 new cases of rheumatoid arthritis are diagnosed each year. Around three quarters of people are working age when diagnosed. The DWP estimates that in 2007-08, expenditure on incapacity benefits for people with rheumatoid arthritis was £122 million. Estimates of the total cost of rheumatoid arthritis to the economy, including NHS costs as wells as carer costs, the costs of nursing homes, private expenditure, sick leave and work-related disability are as high as £3.8 to £4.8 billion a year.

**Surgery for people with rheumatoid arthritis**
Earlier and more aggressive treatment has been shown to reduce surgery rates.[15]

**Understanding of rheumatoid arthritis by employers and support provided on employment**
According to the report, an employed person with rheumatoid arthritis has on average 40 days sick leave per year, and reduced productivity at work. Comparisons of productivity loss for people with rheumatoid arthritis in employment indicate that, on average, those who respond to treatment have up to 24 fewer sick days per year than those who do not.[16]

Given the timescale of next February, we would request that other data which is not yet in the public domain but intended to be presented at this year's ACR in late autumn 2009 be able to be taken into account.

Given the complexity of the issues which NICE must take into account in this Appraisal, NRAS believe it would be appropriate and very helpful if greater collaboration between industry, all stakeholders and NICE were possible such that an element of risk-sharing between industry and the NHS could be considered whereby patients who fail a first TNF are able to trial a second providing that very strict cessation criteria is established, minimising prolonged use of therapy where there is an inadequate response.

Yours sincerely,

[redacted]

**References**


1 Cost Effectiveness of Sequential Therapy with Tumor Necrosis Factor Antagonists in early RA. *Andrew Davies et al. J Rheumatology January 2009 36(1): 16-26; doi.10.3899/jrheum.080257*

2 Outcomes After Switching from one Anti-Tumor Necrosis Factor Agent to a Second Anti-Tumor Necrosis Factor Agent in Patients with Rheumatoid Arthritis. Results from a Large UK National Cohort Study. *Hyrich et al. Arthritis & Rheumatism Vol. 56, No. 1, January, 2007*

3 Accelerated atherosclerosis: an extraarticular feature of Rheumatoid Arthritis. *Van Doornum et al. I.P. (2002) Arthritis & Rheumatism 46(4), 862-873*

4 Co-morbidity in Rheumatoid Arthritis. *Mikuls et al. Rheumatic Diseases Clinics of North America 27(2), 283-303.*

5 Limited efficacy of conventional DMARDs after initial MTX failure inpatients with recent onset RA. *Van der Kooij SM, et al. Ann. Rheumatic Disease 2007; 66:1356-62*

6 Perceived functional disabilities among rheumatoid arthritis patients. Risto Tuominen et al. Rheumatology Int. DOI 10.1007/s00296-009-1043-z.

7 'Measure of function in rheumatoid arthritis: individualised or classical scales?'. *Raphaele Seror et al. Ann. Rheum Dis. DOI: 10. 1136/ard.2008.102137*

8 'Perceptions of patients and professionals on rheumatoid arthritis care'. *A consultancy report by the King's Fund for the Rheumatology Futures Group, January, 2009.*

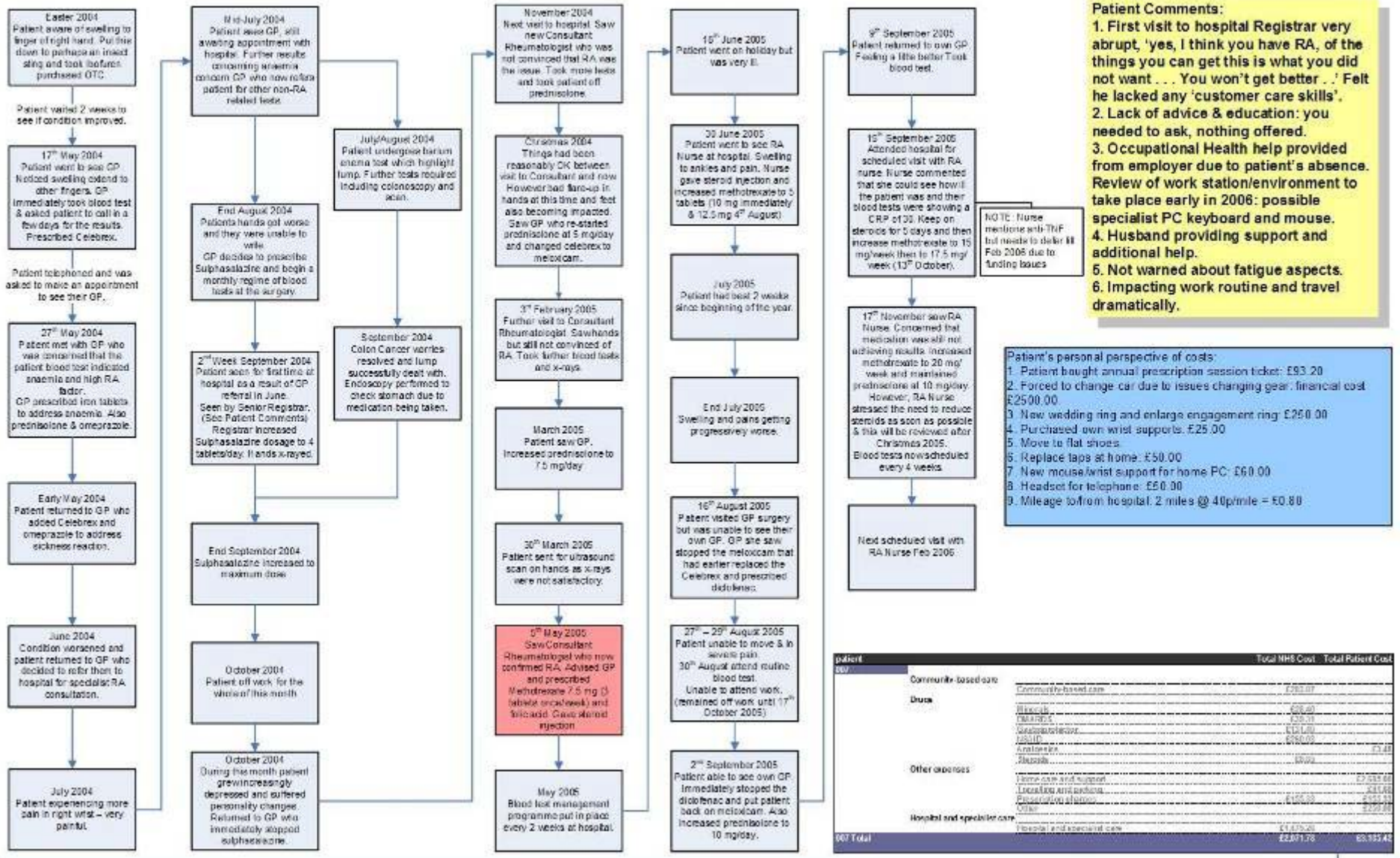
9 Services for People with Rheumatoid Arthritis. Report by the Comptroller and Auditor General. *National Audit Office - HC 823 Session 2008-2009 | 15 July 2009*

10 Fit for work? Musculoskeletal Disorders and Labour Market Participation. *A report by The Work Foundation, September 2007.*

11 Rheumatoid arthritis: The management of rheumatoid arthritis in adults. *NICE Clinical Guideline 79, February 2009.*
12 Appraising the value of innovation and other benefits. *A short study for NICE by Professor Ian Kennedy, July 2009.*
13 National Institute for Health and Clinical Excellence, First Report of Session 2007 – 08. *House of Commons Health Committee, January 2008.*
14 NICE submission to the Kennedy Report 'Appraising the value of innovation and other benefits'*, June 2009.*
15 Decrease of RA-related orthopaedic surgery of the upper limbs between 1998 and 2004*: R.J. Weiss et al (2008): data from 54 579 Swedish RA inpatients. Rheumatology 47 (4): 491-4*
16 Systematic review of studies of productivity loss due to rheumatoid arthritis. *W. Burton et al (2006). Occupational medicine 56: 18-27.*
Fatigue reduction and physical function improvements associated with increased productivity at work and at home in rheumatoid arthritis patients. *J.M.W. Hazes et al (2008). Annals of Rheumatic Diseases 67 (Suppl II): 79.*

# NRAS Client 007 – Female: age 46

Tuesday, October 24, 2006



# NRAS Client 010 – Female: DoB 23.05.75

Wednesday, April 19, 2006

Patient Background
1999 Patient experienced problems with neck and headaches (GP discussed possible dysphasia); sleepiness (narcolepsy also considered) & depression.

14th February 2002
Patient woke but unable to move. GP made home visit but not regular GP (locum). Unable to make immediate diagnosis. Suggested issue was due to depression.

New locum GP thought symptom might indicate Rheumatoid Arthritis. . Prescribed anti-inflammatory drug and pain-killers. Referred to Consultant Rheumatologist. Told there would be an 18 month wait. Patient decided to pay for private consultation as she was getting married in May 2002.

April 2002
Patient saw Consultant Rheumatologist who was also unable to confirm RA. Referred back to GP.

May 2002
Went back to GP feeling depressed and concerned that this was 'all in the mind'. GP suggests it may still be a form of arthritis and prescribed steroids. Symptoms improved for a short while.

May 2002
Patient got married and went on honeymoon. However, on her return 'things began to fall apart' and she felt terribly unwell again.

June 2002
Returned to GP who referred patient to National Rheumatology Hospital in Bath.

August 2002
Patient visited Bath on Thursday and admitted the following Tuesday (probably 6th August 2002) for 3 weeks to undergo tests. She was taken off all medication; subjected to intensive physiotherapy and eventually diagnosed with RA.
Patient describes this as a great relief to at least know what was wrong & referred to the years of uncertainty and depression that included the prescription of drugs such as prozac & seroxat. She calls one occasion when she fell and was in plaster for 12 weeks because of concerns over possible torn ligaments and wonders whether an earlier investigation might have prevented this.

September 2002
Patient is prescribed Sulphasalazine and a programme that required 2-monthly visits to Bath supported by monthly blood tests by her GP.
Also prescribed amitriptyline.

December 2002
Patient taken off sulphasalazine as no improvement made and prescribed Methotrexate which is to be increased every 2 months till the effective dose is established. Patient recalls spending Christmas 2002 being sick and nauseous.

Patient followed this regime but became progressively worse, eventually becoming bed-bound.

May 2003
Patient emergency admission to local hospital with a blood clot. Given steroid injection, tests taken placed on steroid drip. Found to be intolerant to methotrexate.

May 2003
Transferred from Bath to Rheumatologist in her region. Referred to physiotherapist and OT via RA Unit.

Tried a short period of methotrexate injections

July 2003
Patient taken off methotrexate and prescribed laflunomide, 100 mg initial dose then 20 mg regular dosage. Patient reports that this did help for for a few months. Fortnightly blood tests at GP's.

December 2003
Patient feeling very poorly again. Given steroid injection and advised by hospital that she would need to continue with this drug regime until permission approved to try Humira (adalimumab).

Frequent steroid injections given to ease condition

July 2004
Patient prescribed Humira: 40 mg injections fortnightly. Within days patient feeling much better and able to go on holiday.

July – December 2004
Patient continues with Humira and steroid injects as needed. Continues to have occasional flare-ups and blood test readings not satisfactory: high ESR – low CRP.

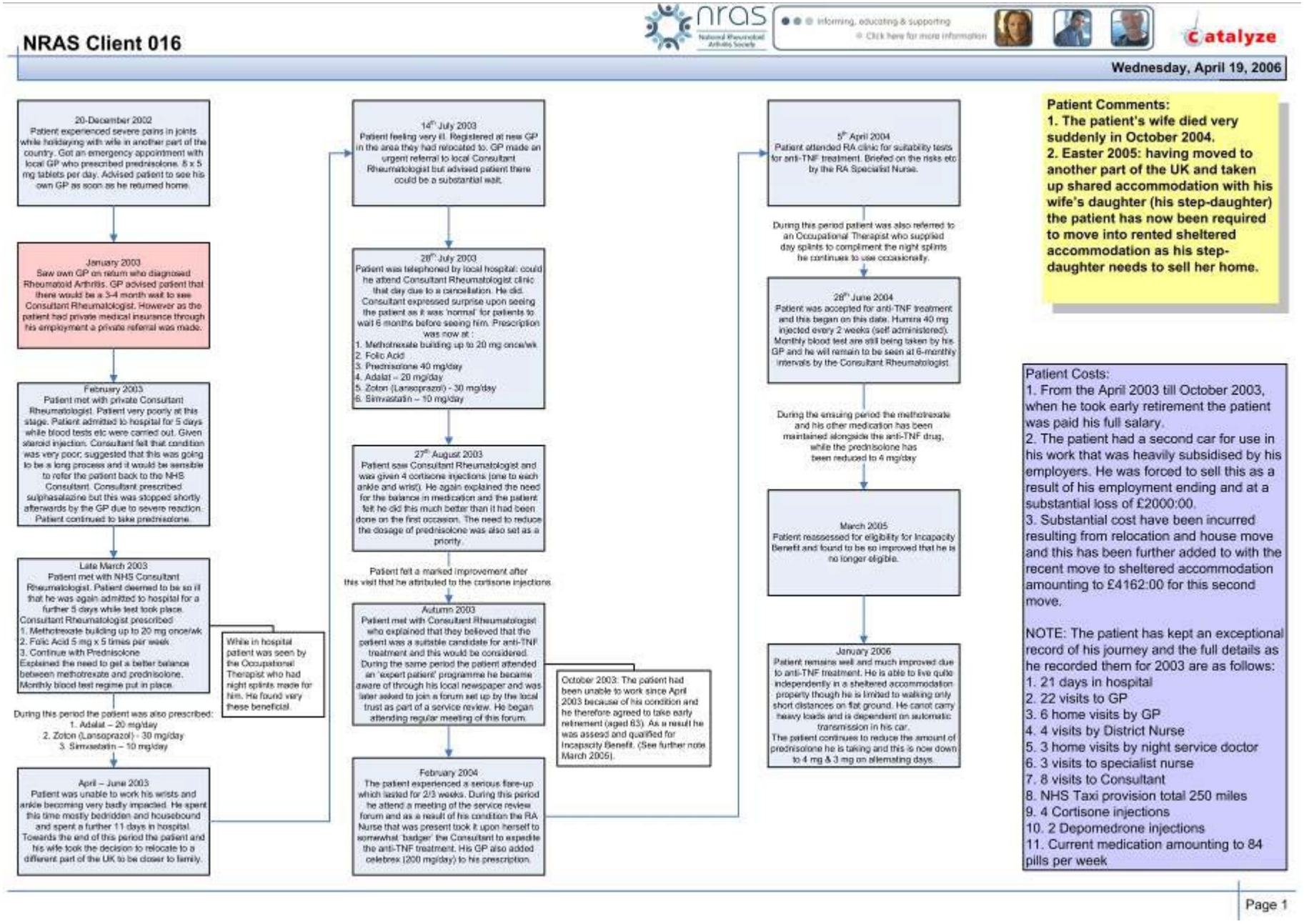
December 2004
Laflunomide 20 mg prescription added to the Humira injections. Patient is still taking daily prescription of amitriptyline. She also takes diazepam as needed when spasms in neck really bad.

December 2005
Patient's current drugs regime:
1. Humira (adalimumab) 20 mg/fortnight
2. laflunomide 20 mg/day
3. paracetamol up to 8/day as needed for pain
4. tramadol up to 8/day for arthritic pain (taken with paracetamol)
5. ibrufen (ibuprofen) up to 4/day (unable to take stronger anti-inflammatory due to stomach cramps caused by length of time on these drugs.
6. amitriptyline 50 mg/day taken each night
7. Kapake up to 8/day (for migraine)
8. Zimovane 1/night (sleeping tablet)
9. cod liver oil tablets (suggested y doctor)
10. stemitel 3 x 5 mg/day (for vertigo as required)

**Patient Comments:**
**1. Patient forced to give up employment as an In-house Social Worker a job she had held for 6-years and an income of between £1000 - £2000 per month. She now claims Incapacity Benefit, Disability Allowance, Mobility and Care Allowance.**
**2. During the period the patient's marriage ended and she was forced to sell the family home as her income could not fund mortgage. It is worth noting that she had moved with her husband in December 2003 from their two-storey home into a bungalow with adaptations to support her condition. This was sold in October 2005 and she now lives with her mother and step-father who help care for her. (see costs below)**
**3. Occupational Therapist has provided help with special aids such as raised toilet seat, wheelchair, furniture with raising seat, handles, shower chair, soft and hard wrist splints, cutlery, long handled sponge, etc.**
**4. Prior to the patient's marriage ending her husband took substantial amounts of time off work resulting in lost earnings. Cost were also incurred through frequent trips/stays in Bath. (see below)**

Patient Costs:
1. April 2002 private consultation £80:00.
2. March 2003 patient bought electric motor scooter to aid mobility: £1000.00. and needed to change her car to accommodate her electric scooter and change to automatic control: cost £3000.00 allowing for part exchange of previous car.
3. Substantial costs involved in sale of house, agents, solicitor, redemption costs total more than £1000.00.
4. Other aids:
   - shower cubicle £900.00, taps (bathroom & kitchen) £150.00
   - raised oven unit £500.00, kitchen sundries (kettle, knife, etc.) £50.00
   - orthopaedic bed £1000.00
   - gas fire with remote control £350.00
   - various personal aids, e.g. electric toothbrush, heat pad, various supports, etc. £
5. Extra costs for life insurance/mortgage protection, travel insurance, house insurance.
6. Prescription costs: since the patient sold her home she is now required to pay prescription charges because of capital. Currently costing at least £34.00 per month. Intending to buy annual prescription.
7. Food, such as ready meals the patient can prepare herself when left alone: £1000.00 p.a.
8. B&B costs were incurred for patient's husband when staying in Bath at £35.00 per night for approximately 7 nights, totalling £245.00.
9. Travel: journeys to Bath were 300 miles (return) which at IR rates of 40p/mile amount to £120.00 per trip x 6 visits = £720.00. Visits to Haverfordwest calculated on the same basis amount to £11.20 per trip.

# National Rheumatoid Arthritis Society Mapping Files



# National Rheumatoid Arthritis Society Mapping Files

## NRAS Client 019 – Female: DoB 12.02.1970

Thursday, May 04, 2006

**2000 - 2003**
Almost 5 years ago the patient began feeling tired and this worsened over a 2/3 year period. Prior to this she had led an active lifestyle including swimming (2-3 times/week), walking, yoga, etc. During this period she also developed a dryness in her mouth and later pains in her hip.

**February 2004**
Patient saw GP regarding a pain in the hip and was referred for X-ray. All seemed fine and she was refereed for physiotherapy.

**April 2004**
Patient saw physiotherapist 4 times. The physiotherapist confirmed a weakness in the hip and gave the patient and exercise regime to follow, supplying her with 'rubber band' exercise apparatus.

**May/July 2004**
Patient continues to have problems with pain in hips and dryness in mouth. Referred to colorectal clinic: manual examination given and appeared OK but further appointment to be made for colonoscopy. Antibiotics prescribed. Muscular pains worsen, spread to legs.

**August 2004**
Dryness in mouth worsening and pains now present in the wrists as well as hips and legs. GP prescribes Meloxicam. Towards the end of August patient experiencing severe diarrhoea and exhaustion, and fingers now swollen. She asks GP to refer her for RF tests based on her own research.

**September 2004**
Patient advised by alternate GP that there was no abnormality in oral flora but offers 'saliva pastilles' to relieve dry mouth & refers to Maxillofacial department. Patient received letter from Rheumatology saying appointment will be within 13 weeks. GP prescribed new painkiller:
Diclomax SR 75 mg twice/day.
Second X-ray appointment this time at Orthopaedic dept. Consultant advises that joints look normal but decides to ask for blood tests base on other symptoms.

**October 2004**
Patient maintaining drugs regime as detailed below but still getting muscle twitches in arms and legs as well as pains in wrists, fingers, soles of feet, ankles and some toe joints. Still experiencing stomach cramps even when empty and with no bowel movement. Patient still having diarrhoea.

**November 2004**
Patient has first rheumatology appointment with Registrar who took a detailed history and further blood tests and x-rays.
GP arranged for a visit from an Occupational Therapist. Diarrhoea reducing in frequency but still severe.

**December 2004**
Patient received letter from meeting with Rheumatologist confirming RF +ve, raised ESR and weak +ve for cardiolipin antibody. Letter confirms that patient will be seen by Consultant Rheumatologist in January 2005. Diarrhoea continues to subside to about once every two weeks. Patient links this to starting pain-killers.

**January 2005**
Patient seen by Consultant Rheumatologist who took blood tests and x-rays. The patient was given an immediate 125 mgs intra-muscular depo-medrone injection.
Consultant prescribed:
1. sulphasalazine building up to 4 tablets/day
Patient was also referred to a physiotherapist and weekly sessions commenced during the month.
A regime of 2-weekly blood tests was initiated by the Consultant. (See Note)
Neurophysiology tests indicated no problem with nerve conduction.
Maxillofacial appointment suggest patient needs a biopsy to confirm Sjogren's syndrome.
OT visits patient and arranges for banister to be fitted to stairs and grab rail in the bathroom. Also supplies knife, fork, spoon etc. OT also suggest the fitting of a bath lift but the patient declined as she felt mentally not ready to accept.

**February 2005**
Patient reports that muscles in legs continued to weaken and now she has very little energy. She has started using walking stick in an attempt to decrease the pain in the left leg.
Maxillofacial appointment confirmed Sjogren's upon biopsy and it is suggested that she use a saliva spray.
Patient unable to go to work after 22nd. GP provided a 2-week sick-note. 2nd IM depo-medrone injection administered at the hospital. Patient saw physiotherapist at the hospital but only managed 10 minutes of exercise before being completely exhausted and required a wheelchair to take her to her parent's car. The physiotherapist was concerned that the disease was not being managed and suggested that she should be admitted to hospital to resolve this. The patient was very distressed by this and could not accept that she was so very ill. She went home.
Patient now recognised that she needed more help and accepted the bath lift offered by the OT.

**March 2005**
Mother took patient to GP who stressed the need for the patient to be urgently admitted to hospital. With some reluctance the patient agreed and her mother drove her to the hospital where she was admitted. (March 2nd)
Patient advises that she was given Amitriptyline (25 mg/night) because of irregular sleep patterns that had developed. This was in addition to the drugs already referenced. The diclofenac was changed from slow release to a 3/day dose. Hospital organised hydrotherapy and lung function test. Also referred patient to podiatrist for collapsed arches in feet.

Patient remained in hospital for 3 weeks

**April - July 2005**
April: Patient changed GP after issues over blood tests (see note).
May: Lung function test indicate no problems.
June: Podiatrist supplies arch supports.
July: Patient attends rheumatology education sessions.
Patient still experiencing pains but reducing severity.

**August 2005**
Patient prescribed:
1. hydroxychloroquine 200 mg/day
To see if this will improve energy levels

**September 2005**
Patient was able to take up her teaching duties again. Patient now worked part-time (3 hours/afternoon 3 days/week). Diarrhoea decreased significantly. Appointment with sigmoidoscopy confirmed – patient has minor diverticuli.

**October 2005 to date**
Patient has accepted her condition. However her energy levels are still low but she is adjusted to this and plans accordingly monitoring her routine.
Her current medication is now:
1. Sulphasalazine 1 tablet 4 times/day
2. Hydroxychloroquine 1 tablet/day
3. Diclofenac 1 tablet 3 times/day (occasionally the patient will omit one tablet in a day if pain is low).
Additionally the patient has tramadol, and paracetamol to take as needed. If her pain is worse she may add codeine phosphate but overall she has reduced her need for pain-killers.

One evening she was driving home and the pain became very intense. When home she called NHS Direct who advised her to contact her GP. She did this and was advised to take paracetamol. She did not have any pain-killers at home and lives alone. When she advised her GP of this he told her she would need to call an ambulance. Later the pain become so severe the patient decided to call NHS Direct a second time and related her situation and the conversation with the GP. NHS called for an ambulance. When this arrived the patient was so badly immobilised the ambulance crew needed to dress her.
On admission to A&E she was seen by a doctor who examined her and diagnosed myositosis and prescribed:
1. tramadol – 8 tablets/day
2. Kapake 8 tablets/day
3. Paracetamol 8 tablets/day
While continuing to take Diclofenac.

**Patient Comments:**

**1. She found it very hard to come to terms with the RA diagnosis and in her own words was "in strong denial" asking why this was happening to her. This continued even when admitted to hospital where the patient found it hard to accept her inability to walk. Counselling was offered while in hospital but the patient felt she was not ready for this. Patient felt very angry about her condition.**
**2. The patient lives in a major city but had moved from her parents home (approximately 5 miles) some time before the diagnosis while retaining her family GP. An issue arose with the need for a fortnightly visit by the phlebotomist. This was initially agreed by one of the practice GP's but later rescinded. The issue was eventually resolved but required intervention by the Patient Advice & Liaison Service (PALS) and the Practice Manager. The patient later moved GP and blood testing was undertaken by the hospital.**
**3. New GP had no experience of RA medication believing that this is too specialist for a GP practice. This has remained with the hospital unit.**
**4. Patient has educated herself on her condition rather than rely on others.**
**5. Various items of equipment have been provided via the Occupational Therapist on NHS loan; this has included a bath lift, bath grab rails, bath step, commode, fitting a banister, cutlery, mesh cooking baskets, ergonomic knife, jar opener, perch stool, foot stool, trolley, walking sticks and a walking frame.**

Patient Costs:
1. Loss of patient income due to sick leave and reduced working hours. Allowing for statutory sick pay this still amounted to £4000.00 lost income.
3. Travel Costs: Hospital journey was 6 miles each way = 12 miles @ 40p/mile = £4.80. Visits to GP were 2 miles e/w = £1.60.
4. Prescription costs: Patient initially paid prescriptions as issued but since February 2005 she has purchased an annual pre-paid certificate at a cost of £93.20.
5. Patients mother has supported her with daily visits that required loss of work and travel costs. This has been estimated at £2000.00 in loss of mother's earnings and travel costs (based on a return journey of 10 miles daily for almost 7 months) of £784.00
6. Employer Costs: The patient's employer had to provide cover during her absence and they have estimated this at £5500.00.