

<b>Title: Shared Care Guidelines for Disease Modifying Anti-Rheumatic Drugs (DMARDS) in Rheumatology</b>		 NHS Foundation Trust <hr/> University Teaching Trust  	
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<b>To be read in conjunction with the following documents:</b>  <b>BSR guidelines for DMARD therapy (Rheumatology 2008; 47: 924-5)</b> <b>British National Formulary <a href="http://BNF.org">BNF.org</a></b> <b>Electronic Medicines Compendium <a href="http://www.medicines.org">www.medicines.org</a></b>			
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**Required NHSLA Evidence****N**

If this policy is required for NHSLA evidence, then this document must have been checked against the current standards for compliance. If this is not known by the author, confirmation should be sought from the Risk and Health and Safety Department.

## Policy Statement

These guidelines are to support the safe prescribing and monitoring of disease modifying anti-rheumatic drugs (DMARDs) in patients with rheumatoid arthritis and other rheumatological conditions. The guidelines are intended for use by the rheumatology team at Salford Royal NHS Foundation Trust, and any GP who has responsibility for the care of such patients.

### 1. Roles and Responsibilities

The rheumatology team and relevant Primary Care staff are responsible for ensuring that prescribing of DMARDs for patients under their care is in accordance with these guidelines

The rheumatology team is responsible for implementing and monitoring the effectiveness of this policy, and for reviewing the guidelines on a regular basis

### 2. Protocol

#### Scope of the guidelines

Shared care may be appropriate in the following situation:

- Patients with rheumatological conditions who have been referred to secondary care for assessment and recommendation of a treatment regimen.
- Patients receiving *conventional* DMARDs, as per the attached information sheets.

**N.B. Where “consultant” is referred to throughout this document, a designated deputy may undertake the role depending on the systems in place.**

Early introduction of disease-modifying anti-rheumatic drugs (DMARDs) is now recognised as being vital in order to minimise the risk of irreversible joint damage in Rheumatoid Arthritis (RA), the most common form of inflammatory arthritis. DMARDs are also used in the treatment of various other rheumatological conditions, including other types of inflammatory arthritis and connective tissue disease.

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General practitioners are becoming more involved in active management of these conditions with the recognition that patients should be referred early for specialist advice and initiation of DMARDs.

Patients who are taking specialist drugs with potential unpredictable side effects should continue to have secondary care input. However, there is a place for the monitoring of patients on widely used and accepted drugs within a general practice setting. Patients on these more commonly used drugs require intermittent follow up in secondary care to assess for disease activity, altering of medications and general assessment. The more frequent requirement for blood monitoring for potential side effects may be more appropriately carried out in primary care.

These guidelines look at the shared care management of patients treated with DMARDs.

## **2.1 DMARD information and treatment regimen to be used**

See the attached information sheets for each drug (Appendix 2)

## **2.2 Regimen Management**

The NHS Management Executive issued guidance in 1991 (Responsibility for prescribing between hospitals and GPs EL(91)127) and 1994 (Purchasing and prescribing EL(94)72) which reinforced the basic premise that:

- The doctor who has clinical responsibility for a patient should undertake prescribing
- If care is to be shared there should be proper hand-over procedures from hospital specialists to GPs

Aligning clinical and prescribing responsibility enhances patient safety. The prescriber will also be responsible for ensuring that the required monitoring is undertaken and will have access to the necessary results.

When a shared care agreement for an individual patient is in place, the general practitioner will be responsible for ensuring the continued monitoring and the prescribing of recommended drugs. The rheumatology department will provide all patients with a shared care booklet for recording of blood results, allowing access by both Consultant and GP.

Shared care must be agreed before the patient is directed to primary care. Patients must not be put in a position of uncertainty where to obtain supplies of their medication.

### **a) Aspects of care for which the consultant is responsible**

The consultant will confirm the patient's diagnosis and carry out any baseline tests as necessary.

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- The consultant will ensure that the patient is educated, provided with written information about their treatment and the importance of attending monitoring appointments.

The consultant will initiate and continue to prescribe the DMARD until the patient's drug dose and monitoring interval are stable. Dose changes in previously stable patients should be initiated in secondary care whilst prescribing and monitoring may continue in primary care with any changes in dosage and monitoring clearly communicated in writing to the GP and patient.

If a second DMARD is added in alongside an existing DMARD, the prescribing and monitoring of the new DMARD should also be prescribed and monitored in secondary care until the patient's drug dose and monitoring interval are stable.

- Transfer of prescription and monitoring to primary care would typically take place at 3 months after the patient has been on a *stable dose* of DMARD. Exceptions to this are for Hydroxychloroquine (transfer after 3 months) and Leflunomide (transfer after 6 months).
- The consultant will then determine whether shared care is appropriate for the patient's condition and will contact the GP via letter (see Appendix 1).
- The consultant will issue the patient with a patient-held shared care booklet and a letter informing them of the shared care process (see Appendix 1). Mechanisms must be in place to ensure that the shared care booklet is updated.
- The consultant will provide the patient's general practitioner with the following information:
  - Diagnosis of the patient's condition with the relevant clinical details.
  - Details of any treatment to date and treatments to be provided by the GP.
  - A copy of the Rheumatology Shared Care Guidelines
  - DMARD information / monitoring sheet for the relevant drug (Appendix 2)
- When a patient is reviewed in secondary care, a written summary will be sent within 14 days to the GP. Urgent information, e.g. dose changes, will be given to the patient to take to the practice.
- The consultant or his representative will be available to provide information or advice to the GP.
- The consultant will ensure that the patient is given appropriate appointments for secondary care follow-up. Defaulters from follow-up will be contacted to arrange alternative appointments.

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## **b) Aspects of care for which the GP is responsible**

- Ensuring that he/she has sufficient information and knowledge to understand the therapeutic issues relating to the patient's clinical condition.
- Agreeing to the principles & responsibilities of this shared care agreement. Agreeing that in his/her opinion a particular patient should receive shared care for the diagnosed condition, unless good reasons exist for the management to remain within secondary care.
- Producing all prescriptions in an accurate, legible form according to the guidance in the current BNF. It is important to stress that the individual signing a prescription carries the legal liability for the consequences of prescribing the drug.
- Following initiation and stabilisation of DMARD treatment by the consultant, prescribing continuing treatment on the recommendation of the supervising consultant.
- The GP will ensure that the patient is monitored according to the British Society of Rheumatology guidelines and will take the advice of the supervising consultant if there are any amendments to the suggested monitoring schedule.
- For patients on 2 or more DMARDS in combination, the most frequent monitoring schedule should be followed
- Keeping the patient held shared care booklet up to date with the results of investigations, changes in dose and alterations in management.
- Reporting any adverse effects in the treatment of the patient to the consultant.
- It is the GP's responsibility, after discussion with the consultant, to decide whether to continue treatment in a patient who does not attend appointments required for follow up and monitoring, but in general, the prescription should not be issued if blood monitoring is not being done. A system should be in place to ensure detection of non-attenders.

## **c) Aspects of care for which the patient or carer is responsible**

- Taking medicines as prescribed or informing doctors if they have not been taken.
- Making appointments for monitoring at the advised intervals.
- Attending for monitoring and follow-up as required and rearranging appointments if unable to attend for whatever reason.
- Making their shared-care booklet available to be updated.

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- Reporting of any side effects to their GP.
- Informing their GP and consultant of any other medication they may be taking including products purchased “over the counter” and herbal medicines.
- Ensuring they have a clear understanding of their treatment.

### **2.3 Support, education and information**

Advice will be available from the rheumatology team (consultant, junior medical staff, nurse practitioners, rheumatology pharmacist).

Advice and education will also be available from the DMARD monitoring service and rheumatology drug education clinic.

### **2.4 Summary of cautions, contra indications, side-effects**

- See the attached shared care information sheets for each drug (Appendix 2)
- DMARD Monitoring- Quick Reference Guide (Appendix 3)
- See the Summary of Product Characteristics (SPC) for each drug at the Electronic Medicines Compendium [www.medicines.org.uk](http://www.medicines.org.uk)

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## 2.5 Back-up care available to GP from Hospital, including emergency contact procedures and help line numbers

### Contact details

#### Consultant rheumatologists:

Dr Roger Bucknall	01612065990 / 01612061097
Professor Robert Cooper	01612065990 / 01612061097
Dr Hector Chinoy	0161 2065161
Professor Ariane Herrick	0161 2064264
Professor Anthony Jones	0161 2064264
Professor Terence O'Neill	0161 2064627

#### Nurse practitioners:

Pat Lambe	0161 2065196
Jayde Lane	0161 2065196

#### Rheumatology helpline:

(Answerphone – calls normally answered within 24 hours Mon- Fri)

0161 2064191

#### Rheumatology Pharmacist:

Sarah Wills	0161 2061151
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#### Other useful contacts:

Arthritis Care	<a href="http://www.arthritiscare.org.uk">www.arthritiscare.org.uk</a>
Arthritis Research UK	<a href="http://www.arthritisresearchuk.org">www.arthritisresearchuk.org</a>
British Rheumatology Society	<a href="http://www.rheumatology.org.uk">www.rheumatology.org.uk</a>

## 2.6 Statement of agreement

Shared care is an agreement between the GP and the Consultant. This policy is a request by the consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care and initiating the suggested medication, please make this known to the consultant within 14 days, ideally stating the nature of your concern.

## 3. Policy Implementation Plan

The rheumatology team have overall responsibility for implementing and reviewing this policy.

There will be close liaison with primary care to ensure the smooth launch of the finalised guidelines.

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The rheumatology team will be informed of the initiation of the guidelines at clinical governance and directorate meetings.  
The guidelines will be posted on the Trust intranet, rheumatology website, and Salford PCT website

#### **4. Monitoring and Review**

These guidelines will be reviewed every 2 years or earlier if new evidence is published that means an update or revision is required.

The guidelines will be audited after 6 months by SRFT and Salford PCT

#### **5. References**

- BSR guidelines for DMARD therapy (Rheumatology 2008; 47: 924-5) - also available on the BSR website ([www.rheumatology.org.uk](http://www.rheumatology.org.uk) - under Guidelines)
- British National Formulary No. 63 March 2012
- NHS Management Executive, Responsibility for prescribing between hospitals and GPs (EL(91) 127)
- NHS Executive, Purchasing and prescribing (EL(94)72)
- GMMMG Shared Care Guidelines for DMARDS April 2009

## Appendix

### APPENDIX 1

#### Written information provided to the GP & patient

- Draft letter for GPs re Shared Care process

#### Re: Shared Care Process for patients on DMARDs

Dear

Your patient was started on .....(drug) on .....(month/year) . He/she is now on a stable dose of .....(dose) and blood monitoring has been satisfactory. As such, he/she is now suitable for transfer to the Shared Care process in which prescribing and monitoring can be undertaken in primary care

As part of the process, the GP is responsible for prescribing and monitoring the drug after initial stabilisation in secondary care. Your patient has been issued with a shared care booklet in which you can record the blood test results. The patient is responsible for ensuring that the results are kept up-to-date and for presenting the booklet at all hospital and GP visits.

If you have any questions about the Shared Care process or about DMARD monitoring / toxicity, please contact either myself or the rheumatology nurse specialists.

Kind Regards

Dr.....

- Draft letter to patients about to transfer to shared care monitoring of DMARDs

**Re: Shared Care process for patients on DMARDs**

Dear .....

You have recently been started on treatment with .....which is a disease-modifying anti-rheumatic drug (DMARD). You are now on a stable dose and your blood monitoring has been satisfactory. As such you can be transferred to the Shared Care process for DMARD monitoring. This means that your GP will now be responsible for prescribing and monitoring the drug.

You should now make arrangements with your GP practice to have regular blood tests. Your GP has been provided with the relevant monitoring protocol. You should have been issued with a shared care booklet (from the hospital Rheumatology department) in which your blood test results will be recorded. Please ensure that you attend for the blood tests as requested. If you are unable to attend any appointments, or if you stop your medication, then please advise your GP accordingly. You will also need to make sure that the results are kept up to date in your booklet and that you bring the booklet to all your appointments at the hospital or with your GP.

You should already have received education and an information sheet about your medication from the Rheumatology department at the hospital. If you have any concerns about the monitoring process or possible side effects of the drug, you can either discuss that with your GP or contact the Rheumatology Helpline (ansaphone – most calls returned within 24 hrs Mon-Fri) on 0161 2064191. Alternatively, please contact one of the Rheumatology team on the telephone number at the top of this letter.

Yours sincerely

Dr.....

## APPENDIX 2

### DMARD Information and Monitoring Sheets

- Azathioprine
- Ciclosporin
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Mycophenolate mofetil
- Sodium aurothiomalate
- Sulfasalazine

**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**AZATHIOPRINE**

**Azathioprine:** Is converted to mercaptopurine, an anti-metabolite interfering with nucleic acid synthesis, and so acts as an immunosuppressant.

**Pre-treatment assessment:** FBC, U&Es, creatinine, LFTs and **TPMT assay**.

**Administration:** Oral, swallowed with plenty of water, or just after food to minimise nausea.

**Typical dose regimen:** 1 mg/kg/day increasing after 4-6 weeks to 2-3 mg/kg/day.

**Precautions:** Use lower doses if there is significant renal or hepatic impairment. If allopurinol is co-prescribed, the dose of azathioprine must be cut to 25% of the original dose. Live vaccines should be avoided in patients taking azathioprine. Pneumovax and annual "flu vaccine" should be given. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.

**Time to therapeutic response:** Approximately 2-3 months

**Monitoring requirements:** FBC weekly for 6 weeks, then fortnightly for one month after each dose increase and thereafter monthly. LFTs monthly until dose stable. In patients heterozygote for TPMT, LFT monitoring should continue at **monthly** intervals. U&E's – 6 monthly.

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC < 3.5 x 10 <sup>9</sup> / l	Withhold until discussed with rheumatology
Neutrophils <2.0 x 10 <sup>9</sup> / l	Withhold until discussed with rheumatology
Platelets <150 x 10 <sup>9</sup> / l	Withhold until discussed with rheumatology
>2-fold rise in AST, ALT or Alk Phos (from upper limit of reference range)	Withhold until discussed with rheumatology
Rash or oral ulceration	Withhold until discussed with rheumatology
MCV>105fl	Investigate. If B12 or folate low, start appropriate supplementation
Abnormal bruising or sore throat	Withhold until FBC results available
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance</b>	

**Side-effects:**

*Haematological:* Leucopenia, anaemia, neutropenia, thrombocytopenia, macrocytosis, erythroid hypoplasia.

*Hepatic:* Liver dysfunction (tends to be dose-related).

*Gastrointestinal:* Nausea, loss of appetite and diarrhoea.

*Mucocutaneous:* Urticaria, erythematous pruritus, oral ulceration and alopecia.

*Other:* Myalgia, arthralgia, drug fevers, pancreatitis and opportunistic infections.

**Significant drug interactions: (refer to BNF)**

Allopurinol - If co-prescribed the dose of azathioprine must be cut to 25% of the original dose.

Co-trimoxazole & trimethoprim can cause life threatening haematotoxicity

Aminosalicylates (sufasalazine, mesalazine, olsalazine, balsalazide) can cause bone marrow toxicity

Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking azathioprine.

Caution with rifampacin and warfarin.

Sunscreens should be encouraged to reduce sunlight exposure

**Pregnancy and breastfeeding: Discuss with rheumatologist.**

**For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373).**

**Routine: Contact Sisters Pat Lambe or Jayde Lane on 0161 2064191.**

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**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**CICLOSPORIN (Neoral)**

**Ciclosporin:** Is an immunosuppressive agent, originally used to prevent organ graft rejection, which exerts its immunosuppressant action directly through effects on T-lymphocytes.

**Pre-treatment assessment:** FBC, U&Es (x2), creatinine (x2), LFTs, fasting lipids. Blood pressure should be normal on two separate occasions prior to treatment commencement.

**Administration:** Oral. Patients should avoid taking grapefruit juice or eating grapefruit for one hour before and after ciclosporin ingestion. Capsules should be taken 12 hours apart, with plenty of water.

**Typical dose regimen:** 2.5mg/kg/day in two divided doses increasing after 4 weeks by 25mg increments to a maximum of 4mg/kg/day.

**Precautions:** Ciclosporin is contraindicated in patients with abnormal renal function or uncontrolled hypertension. There are numerous drug interactions involving ciclosporin and it is recommended that the data sheet is consulted at the time of first prescription and if any other drugs are introduced. In addition to potentially serious toxicity there appears to be a large number of troublesome non-serious side-effects too numerous to mention. If in doubt please consult the data sheet. Pneumovax and annual 'flu vaccine should be given. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.

**Monitoring requirements:** FBC and LFTs monthly until dose has been stable for 3 months, then 3 monthly. Serum lipids 6 monthly. Serum creatinine and BP fortnightly until the dose has been stable for 3 months, thereafter monthly. Blood pressure monitoring each attendance. BP > 140/90 on 2 consecutive readings 2/52 apart – treat hypertension before stopping ciclosporin (note possible drug interactions). If BP cannot be controlled, stop ciclosporin and obtain BP control before restarting ciclosporin.

<b>Action to be taken if monitoring shows abnormalities</b>	
Creatinine rise by 30% of baseline	Withhold until discussed with rheumatology
Plasma potassium rises above normal range	Withhold until discussed with rheumatology
BP rises to abnormal range	Discuss with rheumatology
Significant rise in lipids	Withhold until discussed with rheumatology
Platelets < 150 X 10 <sup>9</sup> / l	Withhold until discussed with rheumatology
>2-fold rise in AST, ALT or Alk Phos (from upper limit of reference range)	Withhold until discussed with rheumatology
Abnormal bruising	Withhold until FBC results available

**Side-effects:**

*Renal:* Renal impairment is a frequent and potentially serious dose-dependent complication. Evident as reversible serum creatinine increases, and necessitates reduction or discontinuation of therapy. Irreversible renal damage may follow long-term treatment at toxic doses.

*Cardiovascular:* Hypertension; which may require anti-hypertensive therapy or dose reduction

*Mucocutaneous:* Hypertrichosis, gingival hypertrophy, rashes

*Haematological:* Anaemia,

*Gastrointestinal:* Nausea, vomiting, abdominal pain, and colitis.

*Hepatic:* Hepatic dysfunction, pancreatitis.

*Nervous system:* Headaches, tremor, neuropathy, confusion, parasthesia, convulsions, fatigue.

*Other:* Weight gain, dysmenorrhea or amenorrhoea, gynaecomastia (particularly when co-administered with spironolactone), hyperkalaemia, hyperuricaemia, hypomagnesaemia, hypercholesterolaemia. A rare syndrome of thrombocytopenia in combination with microangiopathic haemolytic anaemia and renal failure.

**Significant Interactions:-**

There are numerous drug interactions involving ciclosporin and it is recommended that the manufacturer's summary of product characteristics is consulted at the time of first prescription and if any other drugs are introduced. In particular, note the following:

- Diclofenac – the dose of diclofenac should be halved if ciclosporin is co-prescribed.
- Colchicine and nifedipine should be avoided.
- Maximum dose of simvastatin is 10mg
- Potassium sparing diuretics & other drugs that can cause hyperkalaemia (e.g. ACE inhibitors & angiotensin II antagonists should be used with caution).
- Grapefruit juice should be avoided for 1 hour before & after taking ciclosporin
- Live vaccines (oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking ciclosporin.

**Pregnancy and breastfeeding:** - Discuss with rheumatologist.

**For Telephone Enquiries Regarding Monitoring:**

**Urgent:** Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)

**Routine:** Contact Sisters Pat Lambe or Jayde Lane on 0161 2064191.

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**HYDROXYCHLOROQUINE**

**Hydroxychloroquine:** An anti-malarial drug, which is also effective in rheumatoid arthritis and systemic lupus erythematosus. Mode of action may be related to inhibition of cellular enzyme release and interference with intracellular function.

**Pre-treatment assessment:** Visual acuity assessment, FBC, U & Es, LFTs.

**Administration:** Oral; should be taken after food with plenty of water. Some patients find orange juice useful to mask the bitter after taste.

**Typical dose regimen:** 200-400 mg daily, aiming for a maintenance dose of 3-5 mg/kg/day, depending on response.

**Time to response:** Approximately 3-6 months.

**Precautions:** Hydroxychloroquine is contraindicated in patients with hepatic or renal impairment, and in those with eye conditions. An eye test should be carried out if there is visual disturbance, and for those over 60 years.

**Relative contraindications:**

- Psoriasis.
- Pre-existing maculopathy of the eye.
- Epilepsy

**Monitoring requirements:** Annual review either by an optometrist or enquiring about visual symptoms, rechecking visual acuity and assessing for blurred vision using the reading chart provided by The Royal College of Ophthalmologists. Discuss with ophthalmologist if on treatment for >5 years

**Side-effects:**

*Mucocutaneous:* Pruritic erythematous macular rash occurring soon after treatment commenced, blue-black pigmentation of skin.

*Gastrointestinal:* Nausea, diarrhoea, abdominal cramps.

*Renal:* Haematuria, proteinuria which may rarely progress to nephrotic syndrome.

*Ocular:* Cycloplegia, i.e paralysis of the ciliary muscles (would manifest with focusing difficulty and pupillary dilatation, usually of minimal severity), keratopathy (reversible even on continuation of treatment), photophobia (patients should be advised to wear sunglasses in bright light), irreversible retinopathy (maculopathy), but no cases of retinopathy found when treatment for < 10 years or when dose < 6.5/kg/day (*Rheum Dis Clin N America. 1994, 20: 243-263*).

*Other:* Other rare side-effects include headache, bleaching of skin and hair, proximal myopathy, peripheral neuropathy, thrombocytopenia and agranulocytosis (very rare).

**Pregnancy and breastfeeding:**

Hydroxychloroquine has been used relatively safely in pregnancy but need to discuss with rheumatologist. Women should not breastfeed whilst on hydroxychloroquine

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**Drug interactions:**

- Antacids decrease absorption
- Anti-convulsants (antagonises)
- Digoxin (enhances levels)
- Amiodarone
- Moxifloxacin
- Ciclosporin

**For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)**

**Routine: Contact Sisters Pat Lambe or Jayde Lane on 0161 2064191**

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**Salford Royal NHS Foundation Trust  
Department of Rheumatology**

**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**LEFLUNOMIDE**

**Leflunomide:** Suppresses the activated lymphocytes involved in inflammatory arthritis. Active metabolites have half-lives of up to 4 weeks, thus an initial loading dose may be given to rapidly reach therapeutic levels.

**Pre-treatment assessment:** FBC, LFTs, U&Es and blood pressure. If BP >140/90 treat before starting leflunomide.

**Administration:** Oral, the tablets being swallowed whole with plenty of water. Absorption not affected by food.

**Typical dose regimen:** 10-20 mg daily.

**Precautions:** Leflunomide may inhibit the metabolism of **warfarin, rifampicin, phenytoin and tolbutamide**. It has an extremely long half-life, so interactions with these and other drugs may occur long after leflunomide discontinued. Male/female patients should not procreate within two years of discontinuing leflunomide. If procreation is being considered within 2 years of drug discontinuation, blood levels should be measured. If a severe side-effect occurs, or for any other reason rapid removal of its active metabolites is required, a washout procedure with cholestyramine 8gm three times a day or activated charcoal 50gm five times a day, each for 11 days, is available. Leflunomide increases susceptibility to infections, which should thus be treated promptly. Leflunomide is contraindicated in patients with liver impairment or moderate to severe renal failure, serious infections, severe immunodeficiency states including AIDS, and severe hypoproteinaemia, including that due to nephrotic syndrome.

**Time to response:** Begins after 4-6 weeks, but improvements may continue for 4-6 months.

**Monitoring requirements:** FBC and LFTs monthly for the first 6 months, then two-monthly. Check blood pressure at each blood monitoring visit.

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC < 3.5 X 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Neutrophils < 2 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Platelets < 150 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
>2-fold rise in ALT, AST or Alk Phos ( from upper limit of reference range)	Withhold until discussed with rheumatology
Rash, itch or mouth ulcers	Withhold until discussed with rheumatology
Severe sore throat or abnormal bruising	Withhold until FBC results available
BP > 140/90	Treat hypertension
>10% weight loss	Reduce dosage or stop
Breathlessness	Withhold until discussed with rheumatology
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or</b>	

**Side-effects:**

*Mucocutaneous:* Eczema, dry skin, itching, urticaria, oral ulceration and alopecia (diffuse hair loss may occur in ~ 10% of patients, usually reversible). NB In case of ulcerative stomatitis, stop treatment. If Stevens Johnson's syndrome or toxic epidermal necrolysis occur, treatment should be stopped. A complete washout *is essential* in such cases.

*Haematological:* Leucopenia, anaemia, mild thrombocytopenia, eosinophilia, and rarely agranulocytosis.

*Gastrointestinal:* Nausea, vomiting, anorexia, abdominal pain, taste disturbance and diarrhoea (usually self-limiting).

*Hepatic:* Severe liver dysfunction rare, but small liver function test (LFT) elevations more common. Patients should be advised that alcohol consumption should be avoided, or kept to a minimum.

*Nervous system:* Headaches, dizziness, asthenia, paraesthesia and anxiety.

*Musculoskeletal system:* Tenosynovitis, tendon rupture.

*Cardiovascular:* Hypertension may occur in ~ 10% of the patients. Pre-existing hypertension predisposes.

*Allergic reactions:* Mild allergic reactions may occur (rash, pruritus, urticaria). Anaphylaxis rare.

**Infection:** Severe infection may necessitate stopping drug and administering a washout. Patients with previous tuberculosis need careful monitoring as there is increased risk of reactivation.

**Vaccinations:** Pneumovax and annual 'flu vaccine should be given. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.

Vaccination with **live vaccine is not recommended**. The very prolonged half-life of leflunomide should be considered when contemplating live vaccine after stopping the drug.

**Pregnancy and breastfeeding:-**

It is important that women of childbearing potential do not start leflunomide until pregnancy has been excluded and both men and women must use reliable contraception. If, during treatment, there is a delay in onset of menstruation or other reason to suspect pregnancy then the patient must notify their GP and consultant as soon as possible.

It is possible that rapidly lowering the blood level of the active metabolite through the drug washout procedure the risk to the foetus may be reduced. Male and female patients should not plan a pregnancy within two years of discontinuing leflunomide. Blood concentrations of its active metabolite should be measured two years after discontinuation (should be < 20µg/L on two occasions, 14 days apart) before pregnancy occurs (this waiting time may be reduced by using the drug washout procedure).

Women must not breastfeed while they are taking leflunomide.

**For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)**

**Routine: Contact Sisters Pat Lambe or Jayde Lane on 0161 2064191.**

**Salford Royal NHS Foundation Trust  
Department of Rheumatology**

**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**METHOTREXATE**

**Methotrexate (MTX):** A folic acid antagonist and its major site of action is the enzyme dihydrofolate reductase. Its main therapeutic effect is inhibition of DNA synthesis but it also impairs RNA and protein synthesis. It is thus an antimetabolite cytotoxic agent.

**Pre-treatment assessment:** FBC, U&Es, creatinine, LFTs and chest x-ray. Pulmonary function tests with transfer factor in selected patients

**Typical dose regimen:** 10 mg weekly, given orally, increasing by 2.5mg every 6 weeks as necessary, up to a maximum of 25mg. Patients who do not respond to the maximum oral dose of methotrexate or who experience GI side effects could be changed to s/c methotrexate. The prescribing and monitoring of s/c methotrexate should be carried out in secondary care

**Precautions:** Lower doses should be used in the frail elderly or if there is significant renal impairment. Regular folic acid supplements are thought to reduce toxicity and a dose of 5mg once a week should be prescribed (taken at any time except on day of MTX). Annual flu vaccine should be given. MTX is contraindicated in patients with severe anaemia, leucopenia and thrombocytopenia.

**Monitoring requirements:** FBC, LFTs and U &E's fortnightly until 6 weeks after last dose increase, then monthly for 1 year. Then based on clinical judgement.

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC <3.5 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Neutrophils < 2 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Platelets <150 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
>2-fold rise in ALT, AST or Alk Phos ( from upper limit of reference range)	Withhold until discussed with rheumatology
Unexplained fall in albumin	Withhold until discussed with rheumatology
Rash or oral ulceration	Withhold until discussed with rheumatology
New or increasing dyspnoea or cough	Withhold until discussed with rheumatology
MCV >105fl	Investigate. If B12 low, start appropriate supplementation
Significant deterioration in renal function	Reduce dose
Abnormal bruising or sore throat	Withhold until FBC result available
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance</b>	

### **Side Effects:**

*Haematological:* Neutropenia, thrombocytopenia, macrocytosis and rarely aplastic anaemia.

*Hepatic:* Cirrhosis and fibrosis, risk factors are alcohol abuse, obesity and previous liver disease. Alcoholism is an absolute contraindication, but one or two glasses of wine or two pints of beer a week are permitted.

*Gastro-intestinal:* Nausea, vomiting, abdominal pain and diarrhoea.

*Pulmonary:* Pneumonitis is a rare early complication, manifesting as a troublesome dry cough. If drug not discontinued, pneumonitis may be followed by interstitial fibrosis. The latter may occur without preceding pneumonitis, and can be progressive and thus lethal.

*Mucocutaneous:* Rashes, urticaria, erythematous pruritus, oral ulceration, skin pain and alopecia

*Renal:* Acute tubular necrosis is a rare complication. Renal impairment is a relative contraindication, but therapy may still be used if serum creatinine is monitored and dosage adjusted accordingly.

*Other:* Headaches, depression, irritability and enteritis. Opportunistic infections may occur. Suppression of ovarian and testicular function may occur.

### **Interactions:**

- Co-trimoxazole or trimethoprim must be avoided in patients taking methotrexate (increased antifolate effect).
- Phenytoin: antifolate effect is increased
- NSAIDs reduce tubular excretion of methotrexate and thereby enhance toxicity but clinically significant interaction is rare.
- Tolbutamide: Serum concentration of methotrexate may be increased.
- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided
- Excess alcohol should be avoided (or limit to max. 6 units per week)
- Probenecid can severely inhibit renal excretion of MTX, and so is contraindicated.

### **Pregnancy and breastfeeding**

Methotrexate is teratogenic, so effective contraception is required in women of child-bearing age, or men whose partner is of child-bearing age, and for 6 months afterwards. MTX may result in a reversible decrease in fertility.

Women must not breastfeed while they are taking methotrexate

### **For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)**

**Routine: Contact Pat Lambe or Jayde Lane on 0161 2064191.**

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**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**MYCOPHENOLATE MOFETIL**

**Mycophenolate mofetil** (MMF) is a pro-drug of the active metabolite of mycophenolic acid. It is a suppressor of T and B cell proliferation and adhesion and inhibits inosine monophosphate dehydrogenase that eventually blocks the progression to DNA synthesis and proliferation

**Pre-treatment assessment:-** FBC, U&Es, LFTs and CXR.

**Typical dosage regimen:** 500mg/d for 1 week then increase by 500mg per week until optimal dose reached (usually 1-2g/d) up to a maximum of 3g/day. Mycophenolate should always be prescribed by a rheumatologist in secondary care.

**Precautions:**

Avoid if previous Hep B/C, if recurrent herpes/shingles and caution if marked renal failure (eGFR below 25ml/min). Pneumovax and annual 'flu vaccine' should be given. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.

**Time to response:** 6 weeks to 3 months

**Monitoring:** FBC weekly until dose stable for 4 weeks, then every 2 weeks for 2 months & thereafter, monthly

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC < 3.5 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Neutrophils < 2.0 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Platelets < 150 X 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Abnormal bruising or sore throat	Withhold until FBC results available
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance</b>	

**Side effects**

**Common:** Mouth ulcers, nausea, pruritus and metallic taste, diarrhoea, nausea, vomiting, abdominal cramps and dyspepsia

**Less Common:**

Uro-genital: Sterile haematuria, urinary tract infection, renal tubular necrosis.

Haematological: Abnormal bruising with or without sore throat may indicate bone marrow failure.

Severe rash, leucopaenia (WBC < 3.5 and neutrophils < 2.0 ), thrombocytopenia (platelets < 120), proteinuria (> 300 mg/L)

**Potential drug interactions:** (see BNF for all)

-Azathioprine

-Antacids (decrease levels)

-Aciclovir: Causes increase in the concentration of both MMF and aciclovir

- in renal failure)
- Cholestyramine (decrease levels)
  - Probenecid
  - Rifampicin
- Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking MMF

**Pregnancy and breastfeeding:**

MMF is contra-indicated during pregnancy & breastfeeding. Contraception should be used for 6 weeks after stopping the drug.

**For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)**

**Routine: Contact Sisters Pat Lambe or Jayde Lane on 0161 2064191.**

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**SHARED CARE GUIDELINES**

**DMARD PRESCRIBING AND MONITORING INFORMATION**

**SODIUM AUROTHIOMALATE (MYOCRISIN)**

**Pre-treatment assessment:** FBC, urinalysis, U&Es, serum creatinine, LFTs.

**A typical dose regimen may be:** 10mg test dose by deep intramuscular injection (which should be given in the *clinic* followed by 30 minutes observation) followed by weekly injections of 50mg until significant response. Thereafter, either 50mg monthly **or** 50mg fortnightly for three months, 50mg three weekly for three months, and then 50mg monthly. If after a total dose of 1gram has been administered no response has occurred treatment should be stopped.

**Time to response:** Benefit should not to be expected until a cumulative dose of at least 500 mg has been given. If there is no response after a cumulative dose of 1000mg has been given, consider alternative DMARD therapy

**Monitoring:-** FBC and urinalysis at the time of each injection. The results of the FBC need not be available before the injection is given but must be available before the next injection i.e. it is permissible to work one FBC in arrears. Patient should be asked about the presence of rash or oral ulceration before each injection.

**Precautions:** Caution in elderly

- Avoid if significant renal or hepatic impairment
- Caution if known blood dyscrasia
- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking myocrisin.
- Systemic lupus erythematosus
- Significant pulmonary fibrosis

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC < 3.5 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Eosinophils > 0.5	Withhold until discussed with rheumatology
Neutrophils < 2.0 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Platelets < 150 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
>1+ proteinuria on > 1 occasion	Check MSU. If sterile, withhold until discussed with rheumatology
Rash or oral ulceration	Withhold until discussed with rheumatology
Abnormal bruising or sore throat	Withhold until FBC results available
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance</b>	

**Side effects**

**Common:** Mouth ulcers, nausea, pruritus and metallic taste.

**Less Common:** Severe rash, leucopaenia (WBC <3.5 and neutrophils <2.0 ), thrombocytopaenia (platelets <120), proteinuria (>300 mg/L)

**Pregnancy and breastfeeding:**

Avoid in pregnancy and breastfeeding – discuss with rheumatologist.

**For Telephone Enquiries Regarding Monitoring:**

**Urgent:** Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373) **Routine:** Contact Pat Lambe or Jayde Lane on 0161 2064191

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**Salford Royal NHS Foundation Trust  
Department of Rheumatology**

**SHARED CARE GUIDELINES**

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**SULFASALAZINE**

**Sulfasalazine:** Modifies the inflammation of rheumatoid arthritis, but its mechanism(s) of action are unknown.

**Pre-treatment assessment:** FBC, U&E's and LFTs.

**Administration:** The tablets should be taken with or after food, but not taken two hours before or after antacids or iron tablets, as they interfere with DMARD absorption.

**Typical dose regimen:** 500mg/day increasing by 500mg/day/week, to a maximum of 2.0-3.0g/day depending on efficacy and tolerability.

**Precautions:** Sulfasalazine is contraindicated in patients with known hypersensitivity to sulphonamides or salicylates. Do not use in children.

**Drug interactions:** Digoxin (reduced absorption), Azathioprine (increased bone marrow toxicity)

**Monitoring requirements:** FBC and LFTs monthly for the first 3 months, reducing to three-monthly thereafter if dose and bloods stable. Patients should be asked about the presence of rash or oral ulceration at each visit.

<b>Action to be taken if monitoring shows abnormalities</b>	
WBC < 3.5 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Neutrophils < 2.0 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
Platelets < 150 x 10 <sup>9</sup> /l	Withhold until discussed with rheumatology
>2-fold rise in ALT, AST or Alk Phos ( from upper limit of reference range)	Withhold until discussed with rheumatology
Rash or oral ulceration	Withhold until discussed with rheumatology
MCV > 105fl	Investigate. If B12 low, start appropriate supplementation
Nausea/ dizziness/ headache	Try to continue as will usually settle. May have to reduce dose or stop if symptoms severe
Abnormal bruising or sore throat	Withhold until FBC results available
<b>Please note that, in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance</b>	

**Side-effects:**

*Haematological:* Neutropenia, thrombocytopenia and rarely haemolytic or aplastic anaemias.

*Hepatic:* Allergic hepatitis usually causes liver dysfunction early on, i.e when dosage being increased.

*Gastrointestinal:* Mild nausea common early, but severe nausea and vomiting may preclude drug's use.

*Other:* Mild headaches with nausea early on, usually settle within a few days. Persistent severe headaches or nausea may preclude use. Peripheral neuropathy and reversible oligospermia may occur.

Patients need to be warned about characteristic orange-yellow discolouration of urine, which may stain undergarments and permanently stain extended-wear (i.e soft) contact lenses (daily-wear soft contact lenses and gas-permeable lenses respond to standard cleansing).

*Mucocutaneous:* Photosensitisation, erythematous pruritus, especially early in treatment; desensitisation kits are available from the manufacturer. Rarely exfoliative dermatitis and Stevens-Johnson syndrome can occur

### **Pregnancy and breastfeeding**

Sulfasalazine should be used with caution in pregnancy and not in doses > 2g/day. Folic acid supplements should be given before conception & during pregnancy. Small amounts of the drug may be excreted in breast milk, although these are not thought to be a risk to a healthy infant. Need to discuss with rheumatologist.

### **For Telephone Enquiries Regarding Monitoring:**

**Urgent: Contact on-call Rheumatology SpR, via Salford Royal Hospital switchboard (Tel 0161 789 7373)**

**Routine: Contact Sisters Pat Lambe or Jayde Lane on 0161 20641**

### APPENDIX 3

**Department of Rheumatology : DMARD Monitoring- Quick Reference Guide (to be used in conjunction with Shared Care Guidelines for Disease Modifying Anti-Rheumatic Drugs (DMARDS) in Rheumatology 2012)**

DMARD	FBC	U/E's/Serum creatinine	LFT's	Serum Lipids	BP	Other
<b>Azathioprine</b>	<b>Weekly for 6 weeks, then every 2 weeks, until dose stable then monthly</b>	6 monthly	<b>Weekly for 6 weeks, then every 2 weeks, until dose stable then monthly</b>			TPMT pre treatment
<b>Ciclosporin</b>	<b>Monthly until dose and results stable for 3 months. Thereafter 3 monthly</b>	<b>2 weekly til dose or bloods stable for 3 months, then monthly</b>	<b>Monthly til dose and results stable for 3 months. Thereafter 3 monthly</b>	6 monthly	At each attendance. If BP > 140/90 on 2 consecutive readings 2/52 apart- treat hypertension	
<b>Hydroxychloroquine</b>	Only pre treatment	Only pre treatment	Only pre treatment			Annual review by Optometrist
<b>Leflunomide</b>	<b>Monthly for 6 months, if stable, 2 monthly thereafter</b>	<b>Monthly for 6 months, if stable, 2 monthly thereafter</b>	<b>Monthly for 6 months, if stable, 2 monthly thereafter</b>		At each attendance. If BP > 140/90 treat in line with NICE guidance. If BP remains elevated stop Leflunomide. Consider washout	Weigh at each visit, if >10% loss reduce dose or stop. Consider washout
<b>Methotrexate</b> (oral and parental) <b>+ Folic Acid</b>	<b>Every 2 weeks until dose and monitoring stable for 6 weeks. Thereafter monthly for</b>	<b>Every 2 weeks until dose and monitoring stable for 6 weeks. Thereafter monthly for 1 year.</b>	<b>Every 2 weeks until dose and monitoring stable for 6 weeks. Thereafter monthly</b>			Avoid prescribing trimethoprim and cotrimoxazole

	<b>1 year.</b> Then based on <b>clinical judgment.</b>	Then based on <b>clinical judgment.</b>	<b>for 1 year.</b> Then based on <b>clinical judgment</b>			
<b>Mycophenolate mofetil</b>	<b>Weekly</b> until dose stable <b>for 4 weeks</b> , then <b>fortnightly for 2 months. Then monthly</b>	Only pre treatment	Only pre treatment			
<b>Sodium Aurothiomalate (Myocrisin)</b>	<b>Before each injection</b> (including differential WBC and platelets) (FBC need not be available, it is permissible to be one in arrears)					<b>Urine pre each injection</b>  Ask about skin rash or oral ulceration
<b>Sulfasalazine</b>	<b>Monthly for 3 months.</b> If bloods and dose stable, <b>then 3 monthly</b>		<b>Monthly for 3 months.</b> If bloods and dose stable, <b>then 3 monthly</b>			Ask about skin rash or oral ulceration



Record of Changes to Document - Issue number: 1 so no changes				
Changes approved in this document by - Corporate Governance and Risk Management				Date: September 2012
Section Number	Amendment ( <i>shown in bold italics</i> )	Deletion	Addition	Reason

## Screening Equality Analysis Outcomes (Policies/Procedures)

The Trust is required to ensure that all our policies/procedures meet the requirements of its service users, that it is accessible to all relevant groups and **further the aims of the Equality Duty for all protected groups by age, religion/belief, race, disability, sex, sexual orientation, marital status/civil partnership, pregnancy/maternity, gender re-assignment. Due consideration may also be given to carers & socio/economic.**

<p><b>Have you been trained to carry out this assessment? YES</b>  <b>If 'no' contact Equality Team 62598 for details.</b></p>	
<p><b>Name of policy or document : Shared Care Guidelines for Disease Modifying Anti-Rheumatic Drugs (DMARDS) in Rheumatology</b></p> <p><b>Key aims/objectives of policy/document (impact on both staff &amp; service users):</b> To support the safe prescribing and monitoring of disease modifying anti-rheumatic drugs ( DMARDS) in patients with rheumatoid arthritis and other rheumatological conditions. The guidelines are intended for use by the rheumatology team at Salford Royal NHS Foundation Trust, and any GP who has responsibility for the care of such patients.</p>	
1) a) Whom is this document or policy aimed at?	1a) The Rheumatology Team at SRFT and Primary Care
2) a) Is there any evidence to suggest that your 'end users' have different <u>needs</u> in relation to this policy or document; (e.g.health/employment inequality outcomes) <b>(NB If you do not have any evidence you should put in section 8 how you will start to review this data)</b>	2a) No
3) a) Does the document require any decision to be made which could result in some individuals receiving different treatment, care, outcomes to other groups/individuals?	3a) No
b) If yes, on what basis would this decision be made? <b>(It must be objectively justified)</b>	3b)
4) a) Have you included where you may need to make reasonable adjustments for disabled users or staff to ensure they receive the same outcomes to other groups ?	4a) Yes

5) a) Have you undertaken any consultation/involvement with service users or other groups in relation to this document?	5a) Full discussion with NHS Salford
b) If yes, what format did this take? face/face or questionnaire? (please provide details of this)	5b) Face to face meeting
c) Has any amendments been made as a result?	5c) Yes
6) a) Are you aware of any complaints from service users in relation to this policy?	6a) No
b) If yes, how was the issue resolved? Has this policy been amended as a result?	6b) n/a

7) a) To summarise; is there any evidence to indicate that any groups listed below receive different outcomes in relation to this document?

	Yes		No	unsure
	Positive	Negative*		
Age			No	
Disability			No	
Sex			No	
Race			No	
Religion & Belief			No	
Sexual orientation			No	
Pregnancy & Maternity			No	
Marital status/civil partnership			No	
Gender Reassignment			No	
Carers *1			No	
Socio/economic**2			No	

1: That these two categories are not classed as protected groups under the Equality Act.

2: Care must be taken when giving due consideration to socio/economic group that we do not inadvertently discriminate against groups with protected characteristics

### **Negative Impacts**

\*If any negative impacts have been identified you must either a) state below how you have eliminated these within the policy or b) conduct a full impact assessment:

8) How will the future outcomes of this policy be monitored? Regular review and audit by secondary and primary care as detailed in the policy
<p>9) <b>If any negative impact has been highlighted by this assessment, you will need to undertake a full equality impact assessment:</b></p> <p>Will this policy require a full impact assessment? No (delete)  (if yes please contact Equality Team, 62598/67204, for further guidance)</p> <p>High/Medium/Low signed Sarah Wills  date: 30/07/12</p>