Rheumatology Shared Care Guidelines
for Disease Modifying Drugs (DMARDs)
also for use in
Dermatology & Gastroenterology

SEPTEMBER 2012

Jointly developed by:

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- Helen Osinski, Inflammatory Bowel Disease Specialist Nurse
- Rachel Hodkinson, WAHT Pharmacy
- Louise Beal, WAHT Pharmacy
- Emma Blanden, Practice Pharmacist, Arden Commissioning Support Unit

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Review date: September 2015
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Introduction

Disease Modifying Anti-Rheumatic drugs (DMARDs) are added at increasingly early stages in the treatment of rheumatoid arthritis (RA) to suppress the processes responsible for the chronic inflammation of RA, they may be used either as mono-therapy or in combination. DMARDs are also used for the treatment of other rheumatology conditions (e.g. connective tissue disorders and vasculitis) and in other specialities, including dermatology, respiratory medicine and gastroenterology.

A number of these drugs are recommended for prescribing in unlicensed indications. All recommendations are based on the practice of a responsible body of peers of similar professional standing (e.g. British Society of Rheumatologists; see References for full details). Prescribers are advised to discuss with the patient if the medicine is used out of license and document this agreement in the patient’s medical record.

These shared care guidelines outline suggested ways in which the responsibilities for managing the prescribing of DMARDs can be shared between the specialist and general practitioner in primary care. DMARDs should be initiated by hospital specialists only and should not be initiated in the Primary Care setting. GPs are invited to prescribe DMARDs and participate in shared care in accordance to the written instructions given by the Acute Trust Specialists once the patient has reached a stable dose. If the GP is not confident to undertake these roles, then the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe drugs for this treatment, the GP should reply to this request as soon as practicable. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Please consult the manufacturer’s Summary of Product Characteristics (SPC) (www.medicines.org.uk) and the current BNF for full prescribing information on contra-indications, side-effects and interactions.

If the patient is pregnant or is thinking of becoming pregnant (in relation to both maternal and paternal patients) then advice should be sought from the originating prescriber. Further information can also be obtained from Medicines Information at Worcester Royal Hospital (email: drug.info@worcsacute.nhs.uk or telephone: 01905 760611/ Ext 30235)
Availability of back-up advice and support

**Rheumatology**
Rheumatology Advice Line Worcestershire Royal Hospital 01905 760461

Kirsty Edwards, Rheumatology CNS ................................. 01905 760086
Worcestershire Royal Hospital Ext 33592

Claire Rochelle, Community Specialist Nurse, Kidderminster Hospital ........... 01562 823424
(Wyre Forest and Tenbury Wells Localities)

Julie Cahill, Rheumatology CNS ........................................... 01527 47914
Alexandra Hospital Ext 47914

Teresa Ford, Rheumatology CNS ........................................... 01905 760461
Worcestershire Hospital Ext 33466

Dr I Rowe, Consultant Rheumatologist ................................ 01905 760460
Worcestershire Royal Hospital

Dr A Rai, Consultant Rheumatologist
Worcestershire Royal Hospital ........................................... 01905 760460
Kidderminster General Hospital ........................................... 01562 513093

Prof A Prabu, Consultant Rheumatologist
Alexandra Hospital Redditch .............................................. 01527 44133

**Dermatology**
Dr B. Cave, Consultant Dermatologist .................................. 01905 760157
Worcestershire Royal Hospital

**Gastroenterology**
Inflammatory bowel disease helpline (answer phone) /
Helen Osinski, Inflammatory Bowel Disease Specialist Nurse .................. 01905 760732
email, ............................................................................................................. helen.osinski@worcsacute.nhs.uk

Dr N Hudson, Consultant Gastroenterologist ............................... 01905 760623

Dr S Hellier, Consultant Gastroenterologist ............................... 01905 733118

Dr I Gee, Consultant Gastroenterologist ............................... 01905 760585

Dr A Elagib, Consultant Gastroenterologist ............................... 01905 760337

Medicines Information at Worcester Royal Hospital .................. 01905 760611/ Ext 30235
drug.info@worcsacute.nhs.uk

**OUT OF HOURS EMERGENCY CONTACT** (5pm until 9am Mon to Sat and all weekend)
Contact the Acute Medical Unit (AMU) at either Worcester Royal Hospital or the Alexandra Hospital
OUT OF HOURS in the event of SEVERE NEUTROPENIA
AMU Worcester Royal Hospital .............................................. 01905 760545
AMU Alexandra Hospital ....................................................... 01527 512091

Worcestershire DMARD Shared Care Guidelines September 2012
Responsibilities of Speciality Team, GP Team, Pharmacy Team & Patient

**Specialist responsibilities**

1. Provide patient with information on disease and drug treatment options and explain where drugs are used outside of license.
2. Discuss the benefits and side effects of treatment with the patient and the intention to share care.
3. Carry out pre-treatment assessment, including necessary blood tests.
4. Confirm that the GP is willing to participate in shared care.
5. Review pre-treatment assessment, including blood test results.
6. Initiate treatment with DMARD & give the patient a monitoring booklet/ patient info leaflet as appropriate.
7. Send GP details of baseline assessments and results, prescribed dose of DMARD, monitoring requirements and a summary of the information that has been given to the patient.
8. At first review appointment check initial monitoring results and assess response to treatment.
9. Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, and when any changes in monitoring are required.
10. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
11. Ensure that clear backup arrangements exist for GPs to obtain advice and support.

**General Practitioner responsibilities**

1. Reply to the request for shared care as soon as practicable.
2. Prescribe the DMARD at the dose recommended.
3. Carry out monitoring according to the guideline recommendations.
4. Ensure the patient is aware of any treatment change and that where held, the monitoring booklet is up to date.
5. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
6. Refer patient to specialist if his or her condition deteriorates.
7. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
8. Report adverse events to the specialist team.

**Pharmacist responsibilities**

1. Ensure appropriate dose prescribed with clear directions not 'as directed'.
2. Provide advice on adverse effects and any drug interactions with prescription and/or OTC medicines.
3. Issue patient information leaflets where appropriate.
4. Monitor frequency of prescription requests and contact GP if quantities in excess of the prescribed dose are ordered.

**Patient responsibilities**

1. Report to the specialist or GP if he or she does not have a clear understanding or has any concerns in relation to treatment.
2. Ensure safe storage and handling of medicine.
3. Request repeat prescriptions from GP.
4. Ensure the GP and specialist are aware of any over-the-counter medicines they may be taking.
5. Where patient-held monitoring booklets have been given ensure these are brought to each appointment with their GP or specialist.
6. Report any adverse effects to the GP or specialist.
Prescribing Information & Monitoring Requirements  
(see page 11 for advice on actions to be taken)

In addition to absolute values for haematological indices a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance.

U/E and creatinine, CRP and/ or ESR should be checked every 6 months – this will enable monitoring of renal disease and disease activity.

<table>
<thead>
<tr>
<th>DRUG</th>
<th>Indication &amp; dose</th>
<th>Pre-treatment assessment</th>
<th>FBC</th>
<th>U&amp;E, Creatinine</th>
<th>LFT</th>
<th>URINE DipStick Protein</th>
<th>Additional information</th>
</tr>
</thead>
</table>
| Azathioprine      | RA: 1mg/kg  per day increase at 4-6 weekly intervals to max 3mg/kg per day       | FBC, U&E, LFT, Creatinine, TPMT assay-gives additional information on risks of treatment but does not replace routine monitoring. Homozygous deficiency -serious and fatal toxicity- can occur within 6 weeks of starting. Heterozygous deficiency - linked to serious adverse events, symptoms may not be evident until 6 months after starting treatment | Weekly for 6 weeks and then every 2 weeks until dose stable for 6 weeks; then monthly.  
After dose increase repeat after 2 weeks and then monthly  
If dose and test results stable for 6 months consider reducing to 3 monthly.  
In patients heterozygote for TPMT, monitoring should continue at monthly intervals | 6 monthly | Weekly for 6 weeks and then every 2 weeks until dose stable for 6 weeks; then monthly.  
After dose increase repeat after 2 weeks and then monthly  
If dose and test results stable for 6 months consider reducing to 3 monthly.  
In patients heterozygote for TPMT, monitoring should continue at monthly intervals | - | Note: local gastroenterologists prescribe prophylactic co-trimoxazole whilst a patient is on 3 immunomodulating drugs at once. The risks of serious infection are considered to outweigh the risks. Patients only require treatment with co-trimoxazole for a short time, usually when crossing over from ciclosporin to azathioprine. |
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| Ciclosporin     | RA: 2.5mg/kg per day in 2 divided doses, increasing after 6 weeks by 25mg increments to a maximum of 4mg/kg per day.  
Dermatology: severe atopic dermatitis, severe psoriasis: 2.5-5 mg/kg per day in 2 divided doses titrated to skin response.  
Gastroenterology: ulcerative colitis (unlicensed indication) 5 – 6.5mg/kg per day in 2 divided doses for 3-6 month course. | Monthly until dose and results stable for 3 months, thereafter 3 monthly.  
Creatinine clearance or equivalent  
Fasting Lipids  
BP: ≤ 140/90 on 2 occasions at 2/52 apart. | FBC, U&E, LFT, Creatinine | Serum electrolytes incl K+ and creatinine.  
Every 2 weeks until dose and results stable for 3 months and then monthly. | Monthly until dose and results stable for 3 months thereafter 3 monthly | - | Check blood pressure at each attendance. Maintain BP ≤140/90  
Vigilance when NSAID added, particularly diclofenac-reduce diclofenac dose by 50%.  
Check fasting lipids every 6 months |
| Dapsone         | Dermatitis herpetiformis & other inflammatory dermatoses -neutrophilic vasculitis: start 50mg daily gradually increased to 300mg then reduced to usual maintenance dose of 25-50mg daily. | Fortnightly for 2 months then at least every 3 months. | FBC, LFTs  
G6PD levels in patients of Middle & Far Eastern origin. | Monthly until dose stable then 3 monthly | - | - |
| Gold I/M Sodium aurothiomalate (Myocrisin®) | RA: Test dose 10mg then 50mg weekly until a total dose 1000mg. Patients who respond increase  
FBC, U&E, LFT & Creatinine Urinalysis Administration of At time of each injection | - | - | At time of each injection | Ask about skin rash, mouth ulcers at each injection. |
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<th>Pre-treatment assessment</th>
<th>FBC (incl HB, WCC, platelets, neutrophils).</th>
<th>U&amp;E, Creatinine</th>
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<th>URINE DipStick Protein</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Hydroxycarbamide</td>
<td>Psoriasis (unlicensed): 500mg-2g daily</td>
<td>FBC (incl HB, WCC, platelets, neutrophils)</td>
<td>Monthly until stable (weekly if high dose/frail elderly). Thereafter at least every 3 months.</td>
<td>3 monthly</td>
<td>3 monthly</td>
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<td>See also Hydroxyxycarbamide Guidelines</td>
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<tr>
<td>Hydroxychloroquine</td>
<td>RA, systemic and discoid lupus erythematosus, 0.photosensitive dermatological conditions 200 – 400 mg daily. Max 6.5mg/kg/day</td>
<td>FBC, U&amp;E, LFT. Ask about visual impairment not corrected by glasses. Record near visual acuity of each eye. If abnormality detected refer first to an optometrist</td>
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<td>Annual review by an optometrist / check visual symptoms, visual acuity, blurred vision using reading chart. Discuss with ophthalmologist if treated &gt;5yrs Advise patients to report any visual disturbance</td>
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<tr>
<td>Leflunomide</td>
<td>RA &amp; psoriatic arthritis: 10mg – 20 mg daily. Maximum 20mg daily when monotherapy is used. (Loading dose of 100mg daily for 3 days may be used to speed onset of effect but can give GI side effects) Use 10mg daily in combination with other</td>
<td>FBC, U&amp;E, LFT, Creatinine. Blood Pressure on 2 occasions 2 weeks apart. If &gt; 140/90 treat before starting Rx Body weight</td>
<td>Every month for 6 months and, if stable, 2 monthly thereafter. If co-prescribed with another immunosuppressant or potential hepatotoxic agent then blood checks should be continued long-term, at least once a month</td>
<td>Every month for 6 months and, if stable, 2 monthly thereafter. If co-prescribed with another immunosuppressant or potential hepatotoxic agent then blood checks should be continued long-term, at least once a month</td>
<td>-</td>
<td>BP at each visit. If BP &gt;140/90 treat in line with NICE guidance. If BP remains uncontrolled, stop Leflunomide and consider washout Weigh at each visit. If &gt;10% weight loss with no other cause identified, reduce dose or stop and consider washout.</td>
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<td>Mercaptopurine</td>
<td>Inflammatory bowel disease, autoimmune chronic and active hepatitis (unlicensed indications): 0.75-1.5mg/kg per day</td>
<td>See azathioprine (azathioprine is a prodrug which is converted to mercaptopurine in vivo &amp; monitoring requirements are the same)</td>
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<tr>
<td>Methotrexate</td>
<td>RA, Psoriasis</td>
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<td>FBC, U&amp;E, LFT, CXR (within the last 6 months)</td>
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<td>Psoriatic arthritis, Crohn’s disease, connective tissue disease (SLE, myositis &amp; vasculitis), Felty’s Syndrome, inflammatory bowel disease (unlicensed indications): 7.5 – 25mg ONCE a week. Increase every 2-6 weeks to a maximum dose of 25mg ONCE weekly. Rarely max 30mg/week</td>
<td>Pulmonary Function Test in selected patients</td>
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<td></td>
<td>ONLY prescribe as 2.5mg strength tablets (not 10mg tablets)</td>
<td>P3NP (procollagen peptide assay) in dermatology patients</td>
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<td>s/c or i/m route may be given for patients unable to tolerate oral methotrexate</td>
<td>Every 2 weeks until dose and monitoring stable for 6 weeks; thereafter monthly</td>
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<td>Following discussion with the Specialist Team, it may be appropriate for selected patients to be monitored less frequently. i.e every 2 or 3 months</td>
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<td></td>
<td>Every 2 weeks until dose and monitoring stable for 6 weeks; thereafter monthly.</td>
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<td>Following discussion with the Specialist Team, it may be appropriate for selected patients to be monitored less frequently. i.e every 2 or 3 months</td>
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<td>New or increasing dyspnoea or dry cough – withhold and discuss urgently with the specialist team</td>
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<td>Specialists may recommend co-prescribing of methotrexate and NSAIDs/aspirin-clinically significant interactions are rare</td>
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<td>Avoid prescribing trimethoprim or cotrimoxazole to patients receiving Methotrexate – greatly increases risk of marrow aplasia.</td>
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<td>Folic acid given to minimise side effects is usually given 5mg-10mg once weekly, 3 days after methotrexate; however doses can vary.</td>
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<td><strong>Mycophenolate</strong></td>
<td>RA, LE, lupus nephritis, dermatomyositis, polymyositis, psoriasis, atopic dermatitis, autoimmune bullous dermatoses incl pemphigus. (unlicensed indications): Start 500mg daily increase weekly by 500mg to optimal or max. tolerated dose. Max – 3g/day.</td>
<td>FBC, U&amp;E, LFT &amp; CXR (within the last 6 months)</td>
<td>Weekly until dose stable for 4 weeks then fortnightly for 2 months. Monthly thereafter even after patient is stabilised on treatment.</td>
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<td>Advise patients to report any signs or symptoms of bone marrow suppression-inexplicable bruising or bleeding</td>
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<td><strong>D-Penicillamine</strong></td>
<td>RA, Wilson’s disease: Start 125 – 250mg/day increase by 125mg, 4 weekly initially to 500mg. Max dose 750mg/day in divided doses.</td>
<td>FBC, U&amp;E, Creatinine &amp; Urinary Protein</td>
<td>Every 2 weeks until stable for 3 months. Monthly thereafter.</td>
<td>-</td>
<td>-</td>
<td>Every 2 weeks until stable for 3 months. Monthly thereafter</td>
<td>Ask about skin rash or oral ulceration at every visit. Alteration of taste usually settles spontaneously.</td>
</tr>
<tr>
<td><strong>Sulfasalazine</strong></td>
<td>Ulcerative colitis, Crohn’s disease: 1g twice daily increasing to 4g daily in divided doses. RA: Start at 500mg/day increasing by 500mg weekly to maximum of 2-3 grams/daily Sero-negative spondyloarthropathy, psoriasis (unlicensed indications): Dose as in RA above</td>
<td>FBC, U&amp;E, LFT, Creatinine</td>
<td>Monthly for 3 months. If stable for 3 months, then 3 monthly. Repeat one month after dose increase. If stable after 1 year reduce to every 6 months. After 2 years monitoring can be discontinued.</td>
<td>-</td>
<td>Monthly for 3 months. If stable for 3 months, then 3 monthly. Repeat one month after dose increase. If stable after 1 year reduce to every 6 months. After 2 years monitoring can be discontinued.</td>
<td>Ask about skin rash, oral ulceration at each visit.</td>
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</tbody>
</table>
# Monitoring - Action to be taken

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>WBC &lt; 4.0 x 10^9/l</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Neutrophils &lt; 2.0 x 10^9/l</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Eosinophils &gt; 0.5 x 10^9/l</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Platelets &lt; 150 x 10^9/l</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Haemoglobin reduction of &gt; 3g/dl</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>AST, ALT &gt; 2 fold rise (from upper limit of reference range)</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Leflunomide- special rules: ALT/AST 2-3x upper limit normal – reduce dose to 10mg, recheck weekly. If normalized – continue 10mg; if remains elevated withdraw drug and discuss with specialist team. If ALT/AST &gt; 3x normal, stop drug, recheck within 72 hours. If still &gt; 3x, withdraw drug and consider washout.</td>
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</tr>
<tr>
<td>Albumin – unexplained fall (Methotrexate)</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>MCV &gt; 105 fl</td>
<td>Investigate and if B12 or folate low start supplementation</td>
</tr>
<tr>
<td>Creatinine &gt; 30% rise from baseline on 2 consecutive occasions</td>
<td>Repeat in 1 week if still &gt; 30% above baseline withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Potassium rise to above normal range</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Urinary protein on dipstick is 2+</td>
<td>Send a MSU for culture. If MSU confirms infection, treat appropriately. If sterile proteinuria – seek advice from specialist team</td>
</tr>
<tr>
<td>Blood pressure &gt; 140/90 mm Hg</td>
<td>Manage hypertension according to NICE hypertension guidance (Ciclosporin – discuss with specialist team)</td>
</tr>
<tr>
<td>Fasting lipids – significant rise</td>
<td>Withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Any unexplained illness e.g. nausea/dizziness/headache</td>
<td>If symptoms severe withhold until discussed with specialist team</td>
</tr>
<tr>
<td>Abnormal bruising or sore throat</td>
<td>Withhold until FBC result available</td>
</tr>
<tr>
<td>Unexplained acute widespread rash/ hair loss</td>
<td>Withhold – seek urgent specialist (preferably dermatological) advice</td>
</tr>
<tr>
<td>Oral ulceration</td>
<td>Withhold until discussed with specialist</td>
</tr>
<tr>
<td>New increasing dyspnoea or cough (methotrexate)</td>
<td>Withhold &amp; discuss urgently with specialist team</td>
</tr>
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</table>
BSR Statement on Vaccination in Adult Patients with Rheumatic Diseases
November 2011

Individuals with immunosuppression should be given inactivated vaccines in accordance with national recommendations. It is recommended that patients with autoimmune inflammatory rheumatic diseases should be offered pneumococcal and influenza vaccination. Vaccination should ideally be administered at least 2 weeks prior to immunosuppression. In individual cases it may be necessary to discuss vaccination with an appropriate local specialist in infectious disease and the patient’s General Practitioner. Further advice is available through the Department of Health’s “Green Book” on Immunisation against Infectious Disease.

The vast majority of these vaccinations are given in Primary Care and it is advised that robust local arrangements are instituted to raise awareness both to patients and their General Practitioners of the need for appropriate vaccinations.

BSR is currently updating its guidelines on Disease Modifying anti-Rheumatic Drugs which will include further information in relation to vaccinations in individuals receiving these medications.
References

British National Formulary 64. March 2012.


Electronic Medicines Compendium. Available at www.emc.medicines.org.uk


NPSA rapid response report on the risks of incorrect dosing of oral anti-cancer medicines (NPSA/2008/RRR001)

Guidelines for the management of IBD in adults- on behalf of the IBD section of the British Society of Gastroenterology GUT 2011; 60;5, 571-607.
