PRESCRIBING SUPPORT TEAM AUDIT: METHOTREXATE (April 2010)

DATE OF AUTHORISATION: ______________________

AUTHORISING GP: ______________________________________

PRESCRIBING SUPPORT TECHNICIAN: ______________________

SUMMARY

Methotrexate is an antineoplastic that acts as an antimetabolite of folic acid. It also has immunosuppressant properties and is most commonly used in general practice as a disease modifying anti-rheumatic drug for the treatment of moderate to severe rheumatoid arthritis and psoriasis\(^1\). Methotrexate is of value in the treatment of psoriasis but because of the risks associated with this use, it should only be given when the disease is severe and has not responded to other forms of treatment. Therapy of rheumatoid arthritis is conventionally begun with an analgesic and an NSAID for symptomatic relief, to which a disease-modifying anti-rheumatic drug (DMARD) is subsequently added in an attempt to retard the disease process. It is now clear that irreversible joint damage commonly occurs in early disease and rheumatologists now generally add the DMARD shortly after rheumatoid arthritis has been diagnosed. Methotrexate is widely used, and is the DMARD of first choice in many patients. Systematic review has confirmed that methotrexate has significant benefit in the short-term treatment of the disease.

In terms of cost methotrexate is an inexpensive drug however the National Patient Safety Agency (NPSA) issued an alert in July 2004 highlighting the potential hazards of this drug to NHS trusts\(^2\). They requested that NHS organisations should take steps to ensure that this drug is prescribed and monitored safely and that patients receive the core patient information leaflets and monitoring documents produced by the NPSA. NHS organisations were also charged with self-assessing locally the safe prescribing, safe dispensing and safe administration checklists. This audit
looks at safe prescribing and monitoring of oral methotrexate in general practices.

OBJECTIVE

To ensure that the prescribing of oral methotrexate in general practices in Dumfries and Galloway follows NPSA guidelines and to highlight any anomalies to practices.

RATIONALE

Methotrexate is a safe and effective medication if taken at the right dose and with the appropriate monitoring. Methotrexate overdose can cause serious long term complications or death. Due to risk of blood dyscrasias, patients should be advised to report all symptoms and signs suggestive of infection, especially sore throat to their doctor and have full blood count, renal and liver function tests before starting treatment, and repeated every week until therapy is stabilized. Blood monitoring should be continued every 2 to 3 months thereafter. Practices should be aware of patients who attend with symptoms such as breathlessness, persistent dry cough, vomiting and diarrhoea as these can all be signs of methotrexate intolerance.

Methotrexate is normally taken as a once weekly dosage and so it is vitally important that patients are fully aware of the dosage and frequency of administration to avoid overdosing. Directions such as ‘as directed’ should be avoided and specific directions should be stated on prescriptions.

Methotrexate is available in 2.5mg and 10mg tablets which look very similar in form and packaging. It is advisable to prescribe only one strength, preferably 2.5mg tablets to avoid confusion between tablets and potential overdose. Individual practices should decide whether they wish to prescribe only one strength of tablets to patients. Patient should be aware of how many tablets to take at each dosing. Patient should also avoid taking interacting medications such as aspirin or NSAIDS and should be informed about over the counter usage. It is also advisable that no more than one month supply is issued at a time.

Repeat prescriptions should be retained separately for prescriber review prior to authorization.

The anti-folate side-effect of methotrexate can be reduced by taking folic acid the day after methotrexate is taken. Patient should be able to distinguish between folic acid and methotrexate packaging and know when and how to take it. Prescriptions directions should be specific.
METHOD

A computer search to identify patients currently receiving acute and repeat prescriptions for methotrexate will be carried out.

The auditor will record on the data collection form, the following information regarding each patient identified by the search; the indication for methotrexate, the date of initiation, the date of the last blood results, dosage and frequency, strength of tablets issued, directions on the prescription, quantity supplied per prescription, if folic acid is co-prescribed and if so the directions on the prescription, whether patients have received patient information booklet and blood monitoring information.

Where information is not available in the patient’s electronic records, the notes will be checked by the Prescribing Support Technician and missing information recorded on the data collection form. This information will be verified by the GP and added to the electronic notes by administrative staff.

The Prescribing Support Technician will then use the NPSA guidance (see Appendix 1) to identify patients who require referral back to the GP for one of the following interventions to be made:

1. Directions on the prescription to be made clear i.e. not ‘as directed’
2. Weekly dosage to be added to prescription
3. Quantity supplied to be reduced to one months supply maximum
4. Strength of tablets to be changed to 2.5mg
5. Patient requires blood monitoring performed
6. Patient required review of other medication due to a potentially harmful drug interaction with methotrexate.
7. Folic acid is not co-prescribed.

A note will be made in the patient’s computer record detailing the action taken by Prescribing Support Technician

The local community pharmacy/pharmacies will be informed about the activity and given a copy of the NPSA guidance.

EXCLUSION CRITERIA

None

SUGGESTED CRITERIA FOR REFERRAL TO PRACTICE

Any criteria specified by the practice.
**CHANGES TO REPEAT PRESCRIBING**

1. The audit must be checked and agreed with a GP in the practice prior to work being undertaken by the Prescribing Support Technician.

2. Agreement is made between the Practice and the Prescribing Support Technician on a suitable date for implementation.

3. It is recommended that the prescribing support technician/LHP Pharmacist notify local community pharmacies of the impending change in prescribing of methotrexate.

4. The Prescribing Support Technician conducts a search of the Practice Clinical System to identify patients currently prescribed methotrexate as authorised on the Prescribing Review form.

5. The patient list is checked to ensure that all patients are still undergoing treatment (recently deceased or recent discontinuation of methotrexate).

6. Patients are assessed, with respect to potential referral to GP or who require documentation of clinical information held on paper notes only.

7. No patient may be changed beyond the scope of the SPC unless authorised by the prescriber.

8. All changes to prescribing must be recorded within the prescribing field and, wherever possible, an indication recorded for the medication added.

9. Each patient should be informed of any changes made in accordance with the Practice’s preferred mode of communication. The Prescribing Support Team recommends personalised written communication sent from the Practice. Additional information e.g. patient leaflets may be included wherever possible.

10. If the patient is in residential care or has their medication otherwise supervised, e.g. Dosette dispensing, information regarding any changes should also be communicated to the relevant service providers.

11. The Prescribing Support technician will communicate information about the review to relevant personnel within the practice e.g. receptionists, nurses and will, if appropriate, create on-screen reminders on the Clinical System.

12. A project file is retained by the Practice containing a list of patients involved, patient letter templates and any individual information sent, a copy of the protocol and prescribing review form and contact details for the Prescribing Support Team.
13. The Prescribing Support Technician may record statistics of the review for report purposes and analysis of the review. No information regarding individual patients leaves the practice.

14. A follow-up audit will take place within 6 months.
REFERENCES

   www.medicinescomplete.com (Athens password required)
   www.rheumatology.org.uk
Dear Patient,

As part of our ongoing commitment to patient care, NHS Dumfries & Galloway is currently reviewing patients on methotrexate 10mg tablets.

Oral methotrexate is a safe and effective medication if taken at the right dose and right time (i.e. once a week) with appropriate monitoring by your doctor. However, the NPSA (National Patient Safety Agency) have become aware of occasional errors with methotrexate dosing which may cause serious harm to the patient. Concerns have arisen due to the similarity of the 2.5mg and 10mg strengths and this has caused the NPSA to urge all doctors to prescribe only one strength of these tablets. In addition, the local policy here in Dumfries and Galloway is to discontinue the use of 10mg tablets entirely. Similarly, DGRI Pharmacy Department now stock only 2.5mg tablets. From now on, you will receive a prescription for 2.5mg tablets only. Depending on your dose of methotrexate, your weekly dose of 2.5mg tablets will be as follows:

<table>
<thead>
<tr>
<th>Weekly Methotrexate Dose</th>
<th>Number of 2.5mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5mg</td>
<td>1</td>
</tr>
<tr>
<td>5mg</td>
<td>2</td>
</tr>
<tr>
<td>7.5mg</td>
<td>3</td>
</tr>
<tr>
<td>10mg</td>
<td>4</td>
</tr>
<tr>
<td>12.5mg</td>
<td>5</td>
</tr>
<tr>
<td>15mg</td>
<td>6</td>
</tr>
<tr>
<td>17.5mg</td>
<td>7</td>
</tr>
<tr>
<td>20mg</td>
<td>8</td>
</tr>
</tbody>
</table>

If you have any concerns about this change, or need any further information, you can contact the Prescribing Support Team (on xxxxxx) or your own GP.

Yours sincerely,