BRITISH ASSOCIATION OF DERMATOLOGISTS'
RESPONSE TO NPSA DOCUMENTS ON METHOTREXATE
JULY 2005

1. The BAD is pleased that the NPSA has taken up the issue of improving safety for patients taking low-dose methotrexate.

2. The BAD is pleased at the opportunity the review of the original NPSA documents from 29th July 2004 has given rheumatologists, dermatologists and gastroenterologists to work collaboratively to achieve an acceptable consensus. The BAD feels that the results of this collaboration are considerably improved documents.

3. The BAD nevertheless still has some concerns which it was not possible to reconcile fully during the consultation process. These relate only in part to the two documents which were reviewed.

4. The BAD remains very concerned at the NPSA's view about methotrexate 10 mg tablets. The BAD considers that the failure to make a recommendation that these should be used only in exceptional circumstances leaves patients open to significant risk of dosage error and can quote recent cases where this has only by good fortune been averted (see Appendix 1-3). Our concerns can be summarised:

    a. Patients taking oral corticosteroids are commonly asked to take six or eight prednisolone 5 mg tablets on a daily basis and are able to do so without questioning the appropriateness of this. The argument that patients should not be asked to take a similar number of methotrexate 2.5 mg tablets once a week should not dominate the major and easily avoidable safety risk from using two tablet strengths.

    b. The introduction of an oval tablet to distinguish the methotrexate 10 mg tablet from the 2.5 mg tablet is not a sufficient distinction for patients to appreciate that they may be different. Patients commonly receive generic drugs in a variety of guises and are used to finding that packaging and tablet/capsule appearance may change from prescription to prescription.

    c. It is good practice to titrate methotrexate dosage up or down according to disease response to ensure that patients do not take more methotrexate than is needed to control their disease. The simple relationship between weekly tablet number and weekly dose is lost if two tablet strengths are used. Thus a patient moving up and down between 7.5mg and 12.5 mg weekly would be taking three x 2.5 mg, then 1 x 10 mg, then 1 x 10 mg + 1 x 2.5 mg or 5 x 2.5 mg, the latter depending on how the prescription had been prepared.

d. When hospital specialists advise patients on dose changes but do not themselves prepare the prescription, assumptions may be made about the number of tablets to be taken which do not tally with the way the prescription is then actually written. Even if the dose is written in a monitoring booklet there is ample scope for the prescription to be written differently and patients then to be confused (see Appendix 4).

We feel that the advantages of having 10 mg tablets available for patients receiving low dose methotrexate are far outweighed by the potential for serious dosage error. We feel that prescription of 10 mg tablets should be regarded as exceptional outside the sphere of oncology and that safeguards should be introduced to ensure that appropriate warnings are in place on electronic prescribing systems to ensure that this is clear to all prescribers.

5. Whereas the BAD is pleased that alerts have been incorporated into electronic prescribing systems, it is concerned at the way in which methotrexate doses are now presented to prescribers. The changes make prescription of one 10 mg tablet the norm for a 10 mg dose and make it more cumbersome for prescribers who wish to avoid the use of 10 mg tablets to do so (see Appendix 4). At present the only automatically presented options for 2.5 mg tablets are 2.5, 5 and 7.5 mg doses. A 10 mg dose defaults to the option of a single 10 mg tablet. We feel that the drop-down list for prescribers should include the whole range of doses to 10x2.5 mg = 25 mg weekly.

6. The BAD is concerned at the wordiness and size of the proposed Monitoring Booklet. We feel that the IMPORTANT safety messages will be clearer if the amount of text contained in the draft were reduced. It had prepared a mockup of an A6 booklet (see Appendix 5 and separate PDF file <<BAD RECOMMENDED A6 NPSA 593 MONITORING BOOKLET 130705.PDF>>) with comments. The BAD feels that it would be usable and practicable and the BAD membership, on being questioned, felt it to be far preferable to the proposed A5 document. If the NPSA were unhappy that some of the information in the Patient Information Leaflet were not replicated precisely in the Booklet then one solution might be to prepare the PIL as a companion A6 booklet, both of which would be issued to patients. This would have the advantage that if the monitoring booklet, which the patients are expected to carry around with them, were lost, they would have a greater chance of retrieving information about the drug from the PIL booklet which could be kept in the home.

7. The BAD has responded to the specific questions asked by the NPSA in their document <<BAD answers to NPSA questions re methotrexate 110705.doc>>. Further comments and corrections to textual errors are shown in the two PDF files
<< BAD RECOMMENDED A6 NPSA 593 MONITORING BOOKLET 130705.PDF>> and
<<BAD SUGGESTED CORRECTIONS AND AMENDMENTS TO NPSA PIL 603 130705.PDF>>

8. List of files submitted by BAD
    1. BAD RESPONSE TO NPSA RE METHOTREXATE 110705.DOC (current document)
    2. BAD ANSWERS TO NPSA QUESTIONS RE METHOTREXATE 110705.DOC

3. BAD RECOMMENDED A6 NPSA 593 MONITORING BOOKLET 130705.PDF
4. BAD SUGGESTED CORRECTIONS AND AMENDMENTS TO NPSA PIL 603 130705.PDF

9. The BAD is grateful to the NPSA for the opportunity to comment on these documents. It has considered these documents with great care and hopes that its comments and suggestions will be regarded as the fruit of very careful thought and deliberation.

Therapy, Guidelines and Audit Sub-Committee
British Association of Dermatologists
4 Fitzroy Square
London W1P 5HQ

JULY 2005

Appendix 1

Comments relating to 10 mg tablets by BAD Consultant Membership following circulation of revised NPSA documents in April 2005

10 mg tablets

- The 10mg tablets should be deleted - absolutely.
- If the NPSA is serious about its patient safety remit, then banning 10 mg tablets for low dose MTX (reserved for use as an antineoplastic drug) is the action they should be taking
- I cannot understand their reluctance to restrict the tablet size to 2.5 mgs. It makes no sense at all to insist that a 10mg tablet is also available and the justification given for this seems a trivial matter when compared to the potential benefits. In the laudable drive to improve safety it is baffling that this simple measure is being rejected.
- I am also concerned about the potential for error with 10mg tablets- we agreed with our rheumatologists that only 2.5mg tablets would be prescribed.
- I feel very strongly about this as it is not a rare error in methotrexate use
- 10 mg methotrexate tablets are a recipe for disaster

Appendix 2

Extract from letter dated 21st October 2004 sent by Dr Robert Chalmers, nominated BAD representative to NPSA meeting with BAD and BSR 15th November 2004 and BAD representative on joint BAD/BSR working group on methotrexate, to Professor Kuntal Chakravarty, Chairman BSR Guidelines Committee

Dear Kuntal

I made, I thought forcefully, a number of recommendations which I felt would help to improve patient safety, specifically:

- The 10 mg tablet should be treated as a controlled drug and issued only if specified in the prescription

We do not seem to have a problem with patients taking a handful of prednisolone tablets. I feel that patients have more of an idea of the dose required at different times to control their psoriasis if they are accustomed to a single tablet strength (2.5 mg) and it empowers them to titrate their dose within agreed limits depending on the activity of their psoriasis. Most importantly the availability of the 10 mg tablet introduces an unnecessary and potentially disastrous risk of overdose. My feelings on this are long held but can be illustrated by a recent incident in which I prescribed, as usual 2.5mg x 8 = 20 mg MTX for a patient stabilised on that dose for some while. As he did not have any money with him to pay for his prescription at the hospital pharmacy, he asked his GP to write a prescription which the latter did correctly as 20 mg weekly. He was dispensed 10 mg tablets: only after he had taken two 80 mg doses and realised he was running short of tablets did he realise he had made a mistake. Fortunately he came to no harm. The argument that a change in tablet shape is sufficient to alert patients to the difference is insufficient. With generic prescribing, patients are used to receiving a variety of different forms of their medication in which the tablets or capsules may look different (and be packaged in boxes printed in Greek or Spanish). They are not necessarily going to pick up the subtleties of a different tablet shape.

As stated previously, I look forward to working with you as the nominated BSR lead for MTX guidelines as we set about the task of producing our own guidelines.

With best wishes

Robert

Robert J G Chalmers MB FRCP
Consultant Dermatologist

E-mail r.chalmers@man.ac.uk

Appendix 3

Letter received from Dr EJ Cater, Benchill Medical Centre, 127 Woodhouse Lane, Benchill, Wythenshawe, Manchester, M22 9WP on 12th July 2005 by British Association of Dermatologists' Therapy Guidelines and Audit Sub-Committee

Dr A.D. Ormerod
Chairman
Therapy Guidelines and Audit Sub-Committee
British Association of Dermatologists
4 Fitzroy Square
London W1P 5HQ

12th July 2005

Dear Dr. Ormerod

Confusion between 2.5 mg and 10 mg methotrexate tablets

I am a GP practising in a large group practice in Manchester and understand that you are currently reviewing safety issues around the prescription of Methotrexate for Dermatological and Rheumatological conditions in response to guidance issued last year by the National Patient Safety Agency. I feel that I can contribute to the debate about these as a result of a critical incident involving our practice.

I have recently encountered a problem in the current prescribing system that put a patient of my practice at significant risk. She is prescribed Methotrexate by her rheumatologist and, in December 2004, he advised the practice of an increase in her dose from 15mg weekly to 17.5mg weekly. She had been taking her previous dose in 2.5mg tablets, as is generally recommended, and the Rheumatologist advised the patient to increase her dose from six to seven tablets each week. He sent a change of treatment advice slip to the practice stating that the dose be increased from 15mg to 17.5mg weekly; the patient had not had a repeat prescription of Methotrexate for some months but it was confirmed that she had been receiving this from the hospital. Our usual practice is for our Prescription Clerk (who is very experienced and careful) to enter such prescription changes on the patient's computerised prescription record so that repeat prescriptions can be issued. Unfortunately, the 17.5mg dose was prescribed as 1x10mg tablet and 3x2.5mg tablet and the patient took 4x10mg and 3x2.5mg tablets (47.5 mg) for her first changed dose (i.e. "7 tablets" as directed by her consultant). She did not realise her mistake until she came to take her dose a week later when she found she did not have enough tablets to last the usual four weeks. She requested a repeat prescription but was told this was not yet due; she then realised what she had done. Fortunately, she remained well and, apart from a transient rise in her MCV, no effect was shown in her blood.

I did not encounter this lady until recently when she came to consult me on another, unrelated, issue. I noticed that her repeat prescription record contained 10mg and 2.5mg Methotrexate tablets and asked her about this; she gave me the above explanation and confirmed that she was now taking the correct dose. I explained that she should only be given 2.5mg tablets and changed her prescription accordingly. She told me that the two tablets look very similar in every respect except for a small difference in shape which she had not noticed when she took her first dose. She is an intelligent lady but, as patients are used to receiving medication prescribed generically and, therefore, often of different shapes, sizes and colours for identical ingredient and strength, even if she had noticed the small difference, would probably not have considered it significant. She, of course, ought to have checked the labels but, in common with many, if not most, patients "knew" what she should be taking, so took the 7 tablets without checking.

I investigated this further and found that the way prescribing Methotrexate is set up on the computer (ostensibly to *avoid* errors!) is misleading and lead directly to this error. Our computers are set up to use EMIS which automatically makes relevant updates and changes, I do not think this "Alert" window is specific to EMIS however.

When an attempt to add a prescription for Methotrexate is made, an alert window appears in red and, to continue, the prescriber must select "continue" as the natural default is to abandon the prescription. The next window to appear is for 2.5mg tablets and three possible prescription options are given:

"2.5mg (1 tablet) to be taken weekly Quantity for one month: 4 tablets"
"5mg (2 tablets) to be taken weekly Quantity for one month: 8 tablets"
"7.5mg (3tablets) to be taken weekly Quantity for one month: 12 tablets"

No other options are available for the 2.5mg tablets. The next window is for 10mg tablets which gives two options:

"10mg (1tablet) to be taken weekly Quantity for one month: 4 tablets"
"20mg (2tablets) to be taken weekly Quantity for one month: 8 tablets"

Anyone attempting to put a prescription for Methotrexate on the computer (whether a doctor, nurse or prescription clerk) would therefore repeat the error made by our clerk unless they were aware of the specific problem with Methotrexate. The "Alert" windows are so directive, rigid and visually arresting that, unless the prescriber was confident enough to ignore the windows and prescribe the dose as a multiple of 2.5mg tablets, this error is bound to be repeated again and again. Fortunately, our prescription clerk learnt from the experience and now complains that it is very difficult to prescribe Methotrexate correctly because of the "Alert" windows. I have audited all our patients who are prescribed Methotrexate by the practice and, fortunately have found no other problems.

I feel very strongly that this should be addressed because I have heard of other such errors and cannot believe that they are rare. Prescribed correctly, Methotrexate is a cheap, safe and effective drug but can have catastrophic ill-effects if not. I believe that either the "Alert" window should be changed so that only 2.5mg tablets are chosen, or that 10mg Methotrexate tablets should be restricted to use by oncologists. I, among others, think that

the latter is the only really safe solution and hope that you will give this serious consideration.

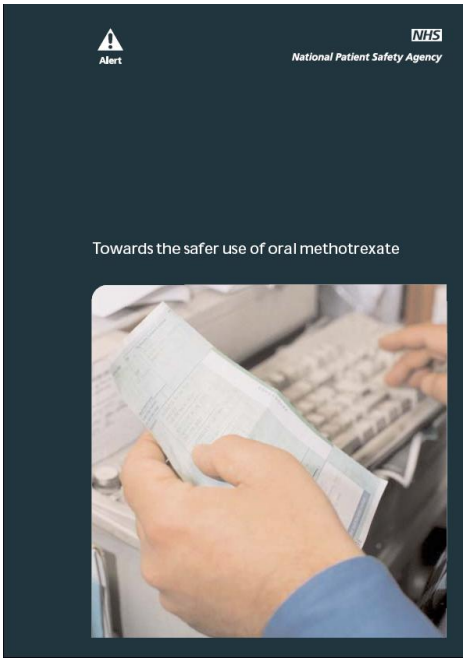
Yours faithfully

Dr Elizabeth Cater

Benchill Medical Centre
127 Woodhouse Lane
Benchill
Wythenshawe
Manchester
M22 9WP

Appendix 4

Extract from p.28 of Towards the safer use of methotrexate published by NPSA 29th July 2004



2.3 Standardising dosage

In the short-term the functionality should be simple, specifically, that the picking list should standardise the dosing prescribing/administration solutions for methotrexate tablets.

The standard dosages are as follows:

Methotrexate tablets 2.5mg:	Methotrexate tablets 10mg:
2.5mg (one tablet) to be taken weekly	10mg (one tablet) to be taken weekly
5mg (two tablets) to be taken weekly	20mg (two tablets) to be taken weekly
7.5mg (three tablets) to be taken weekly	(No dose greater than 20mg will be presented for the 10mg dose)

2.3.1 Non-standard dosage

It should be possible, but not easy, to over-ride these dose options to prescribe greater multiples of 2.5mg, as some localities have chosen to use one strength, 2.5mg, of the tablet. It is recommended that the user is prompted to record clinical evidence of over-ridden dosages.

It should only be possible to prescribe a daily dose in *exceptional* circumstances. Again, the user should be prompted to record clinical evidence to support this change.

Appendix 5 Suggested A6 format

1

METHOTREXATE SHARED CARE RECORD

This booklet belongs to:

Date of birth:
Hospital/Clinic: Record no:
Consultant/specialist:

Contact details for the healthcare staff looking after you

Telephone Helpline/Specialist nurse:
General practitioner:
GP surgery address:

GP surgery telephone:
Community pharmacy:
Pharmacy address:

Pharmacy telephone:
If found, please return this booklet to:

2

When to take your medication

Choose a day of the week to take your oral methotrexate and stick to it. You will also normally be prescribed folic acid (a vitamin supplement). You will be told when to take folic acid. Note down the instructions.

If you miss your methotrexate dose on your normal day, don't worry. You can take it sometime over the next two days. For example, if your normal day for taking your methotrexate is Monday, you can take it on Tuesday or Wednesday. Do not take the dose if you are three or more days late. A flare-up of the disease during this time is unlikely. In both cases, take your next dose on your usual day the following week.

Write down your chosen day of the week and this will help you remember which day to take your dose.

Day of the week for taking methotrexate:

3

When you should take folic acid:

Why you need regular blood tests

It is important that you do not miss your blood tests as these can detect problems before they cause you any harm.

You must not take methotrexate unless you are having regular blood tests and are being monitored regularly by your specialist team.

Things you must tell medical staff

If you need medical treatment, whether as an emergency or not, the staff treating you will need to know that you are taking methotrexate. You must also tell the doctor, nurse or pharmacist if you are taking other medicines including over-the-counter drugs, supplements or herbal remedies. You should

4

not use these without first checking that they are safe to use with methotrexate.

NHS Direct
If you seek help from NHS Direct, you must tell them you are taking methotrexate.

What problems must I look out for?

***Your Methotrexate Patient Information Leaflet gives more information on possible side effects from treatment*:**

Contact your doctor or the nurse helpline if you develop any unexplained new symptoms after starting methotrexate.

Possible Side effects that mean you should stop your methotrexate and tell your doctor immediately:

- Unexplained shortness of breath (breathlessness)
- If the whites of your eyes become yellow or you develop severe itching
- Fevers, chills or severe sore throat/mouth

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- Severe mouth ulcers, bleeding gums, bruising, fatigue or skin ulcers
- Severe sickness or upset stomach
- If you think you may be at risk of chicken-pox or if you get shingles

Other advice

Drinking alcohol
If you are taking methotrexate you should ensure that your alcohol intake is well within the limits agreed with your doctor and certainly no more than national recommended limits (2-3 units per day for women and 3-4 units per day for men). See the Patient Information Leaflet for further details.

Having a baby
Women should not take methotrexate if they are breast-feeding, pregnant or wish to become pregnant. If you think you might be pregnant do not take methotrexate. Men should not attempt to father a baby while taking methotrexate.

6

Wait at least three months after stopping treatment, before trying for a baby. See the Patient Information Leaflet for further details.

Immunisations
It is important that any doctor or nurse you see is aware that you are on methotrexate and that you or your close relatives should not receive any live vaccines such as MMR or rubella (German measles). However, flu vaccine and Pneumovax® are safe.

Antibiotics
You should not take trimethoprim or co-trimoxazole (Septrin®) whilst taking methotrexate.

Record of your dose
Keep a record of your dose by filling in details of your dose and the number of tablets you should take. If your dose changes, for example after a blood test, record the new dose here. Take this new dose, and not the dose shown on the bottle or carton label.

7

Show this record to your pharmacist each time you get more methotrexate tablets.

Date of dose instruct-ion	Weekly dose in mg	Number of tablets to be taken			
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	
		2.5 mg		10 mg	

8

Methotrexate blood test monitoring record

Test date									
MTX dose (mg)									
Hb									
MCV									
WBC									
Platelets									
Neutrophils									
Lymphocytes									
ALT /AST									

9

Urea									
Creatinine									
CRP									
ESR or PV									
PIIINP									
Next test date									

Blank rows may be used for special tests. Not every test is required in every patient or at every visit.

10

Methotrexate blood test monitoring record

Test date									
MTX dose (mg)									
Hb									
MCV									
WBC									
Platelets									
Neutrophils									
Lymphocytes									
ALT /AST									

11

Urea									
Creatinine									
CRP									
ESR or PV									
PIIINP									
Next test date									

Blank rows may be used for special tests. Not every test is required in every patient or at every visit.

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Methotrexate blood test monitoring record

Test date									
MTX dose (mg)									
Hb									
MCV									
WBC									
Platelets									
Neutrophils									
Lymphocytes									
ALT /AST									

13

Urea									
Creatinine									
CRP									
ESR or PV									
PIIINP									
Next test date									

Blank rows may be used for special tests. Not every test is required in every patient or at every visit.

14

Methotrexate blood test monitoring record

Test date									
MTX dose (mg)									
Hb									
MCV									
WBC									
Platelets									
Neutrophils									
Lymphocytes									
ALT /AST									

15

Urea									
Creatinine									
CRP									
ESR or PV									
PIIINP									
Next test date									

Blank rows may be used for special tests. Not every test is required in every patient or at every visit.

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Monitoring schedul

When you start methotrexate you will require blood tests every one to two weeks. For some people stabilised on treatment, blood tests may be needed as little as once every 12 weeks. The tests which need to be monitored vary according to the condition which is being treated. The haemoglobin, white cell count and platelets must, however, always be measured.

What the terms mean

It is common for people with chronic conditions to have blood results that are abnormal as a result of the condition itself. For instance, people with rheumatoid arthritis are often slightly anaemic. So although your treatment can cause anaemia (low haemoglobin), there are other explanations as well. Keeping results of your blood tests will help you to know what is 'normal' for you and you will get to know more about this as you continue your treatment.

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Term and normal values	Explanation
Hb Male 13.5-17.5 g/dl Female 12-16 g/dl	Haemoglobin is the oxygen-carrying protein inside red blood cells: low levels may show that you are anaemic
MCV 80-100 fl	The average volume of a red blood cell: two potential causes of abnormally large red blood cells are methotrexate toxicity and a deficiency of folic acid
WBC 4.0-11.0 x 10^9/l	White blood cells are important in fighting infections. The count can rise as a result of infection or from taking steroids: a low count may indicate that methotrexate is harming the bone marrow
Platelets 150-400 x 10^9/l	Platelets are essential for normal blood clotting: a low count may indicate that methotrexate is harming the bone marrow

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Lymphocytes 1.5-4.0 x 10^9/l	A type of white blood cell that has an important role in protecting your body from infections
Neutrophils 2.0-7.5 x 10^9/l	A type of white blood cell used to kill and digest micro-organisms
ALT/AST usually less than 50 u/l	ALT/AST are measures used to monitor liver inflammation. Rising blood ALT/AST levels may indicate liver damage
Urea 2.5-8.0 mmol/l **and creatinine** 60-125 µmol/l	These are tests that help to show how your kidneys are working. You will normally have these checked before you start treatment and from time to time (usually 3 - 6 monthly) when you are reviewed
CRP, ESR & PV	Indicators of inflammation which may be raised from active joint disease or infection
Other tests	Your doctor or nurse will explain the need for other monitoring tests which may be needed

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Where can I get more information?

NHS Direct Tel: 0845 4647
www.nhsdirect.nhs.uk

NHS Direct Wales Tel: 0845 4647
www.nhsdirect.wales.nhs.uk

Arthritis Research Campaign (ARC)
www.arc.org.uk

Arthritis Care Tel: 020 7380 6500
www.arthritiscare.org.uk

Arthritis Research Campaign
Tel: 0870 850 5000 www.arc.org.uk

National Rheumatoid Arthritis Society
Tel: 0845 458 3969 www.rheumatoid.org.uk

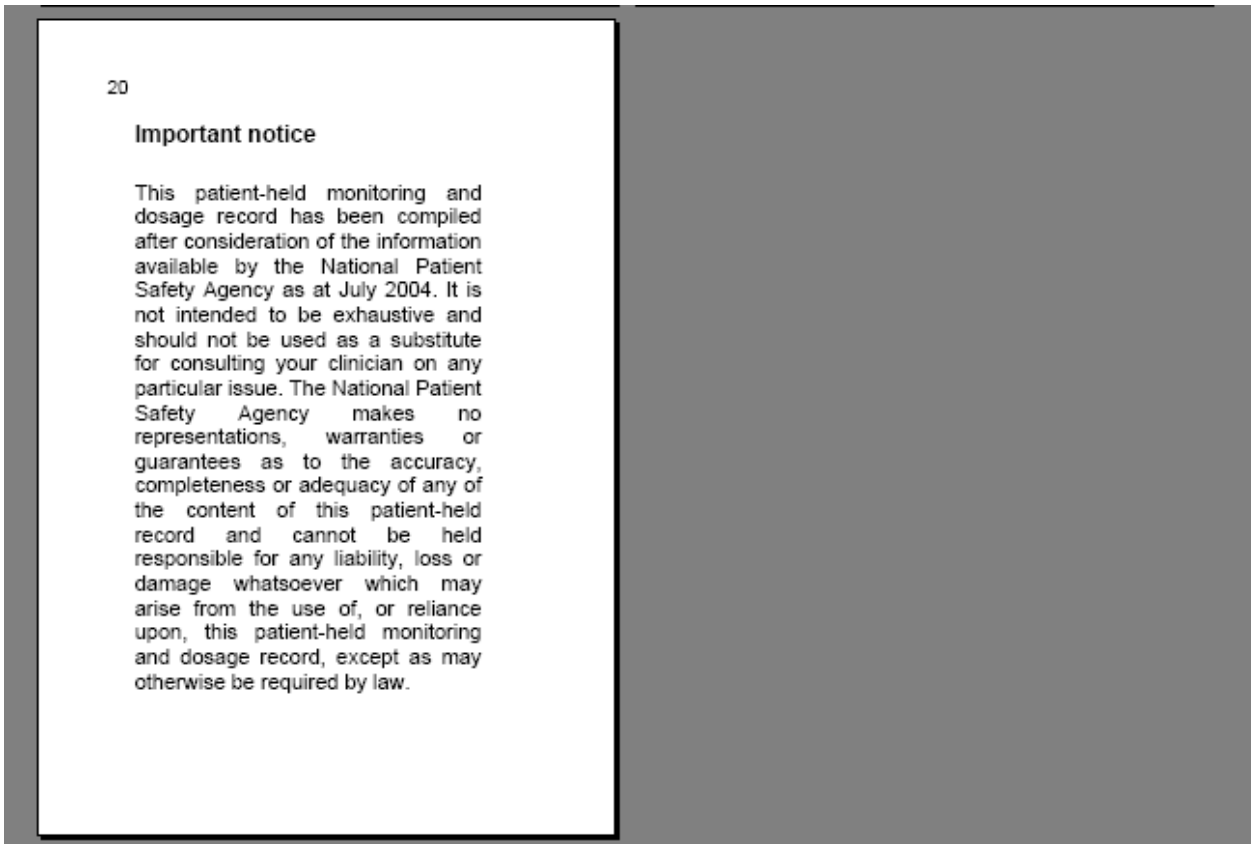
The Psoriasis Association Tel: 0845 676 0076
www.psoriasis-association.org.uk

The Psoriasis Arthropathy Alliance
Tel: 0870 770 3212 www.paalliance.org

The British Association of Dermatologists
www.bad.org.uk/public

The National Library for Health Skin conditions Library www.library.nhs.uk/skin

The National Association for Colitis and Crohn's disease. Tel: 0845 130 2233 www.nacc.org.uk



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Important notice

This patient-held monitoring and dosage record has been compiled after consideration of the information available by the National Patient Safety Agency as at July 2004. It is not intended to be exhaustive and should not be used as a substitute for consulting your clinician on any particular issue. The National Patient Safety Agency makes no representations, warranties or guarantees as to the accuracy, completeness or adequacy of any of the content of this patient-held record and cannot be held responsible for any liability, loss or damage whatsoever which may arise from the use of, or reliance upon, this patient-held monitoring and dosage record, except as may otherwise be required by law.

Please see separate PDF file to view comments

Summary of Comments on Microsoft Word - BSR BAD NPSA 593 response Pt monitoring booklet 2503005 A6…

Page: 1

Author: BAD
Subject: Note
Date: 13/07/2005 23:22:31
Mockup A6 format of Patient Booklet

The NPSA has suggested a format of A4 or 5, which we would suggest is not something that patients are likely to carry around with them on a long-term basis.

We have therefore produced this mockup of an A6 format which we feel would be more satisfactory.

Page: 2

Author: BAD
Subject: Note
Date: 13/07/2005 23:23:06
We have changed from the BSR wording which specifies a once weekly dose.

Author: BAD
Subject: Note
Date: 13/07/2005 23:23:58
More precise instructions given

Author: BAD
Subject: Note
Date: 13/07/2005 23:37:47
"the following week" added

Page: 3

Author: BAD
Subject: Note
Date: 13/07/2005 23:25:04
This is made much more open so that it is easy to write in either "on Fridays" or "daily" etc.

Author: BAD
Subject: Note
Date: 13/07/2005 23:25:27
We feel that this section can be condensed as shown here

Author: BAD
Subject: Note
Date: 13/07/2005 23:25:51
The final clause added to explain the need for regular blood tests.

Author: BAD
Subject: Note
Date: 13/07/2005 23:26:13
We have condensed this section

Page: 4

Author: BAD
Subject: Note
Date: 13/07/2005 23:29:51
We have simplified this and feel that there is confusion as to what may be significant in the way these sections are laid out in the A5 NPSA 593 document.

Page: 5

Author: BAD
Subject: Note
Date: 13/07/2005 23:30:53
This section has been streamlined.

Page: 6

Author: BAD
Subject: Note
Date: 13/07/2005 23:31:51
We have changed to Immunisations. Live polio vaccine is no longer used in the UK and we have changed to MMR.

Page: 7

Author: BAD
Subject: Note
Date: 13/07/2005 23:33:09
The original document from the NPSA took no account of the different tablet strengths and just stated "No of tablets" without referring to dose.

The BAD has argued all along that the danger of confusion between the 2.5mg and 10 mg tablet was one of the greatest potential hazards of MTX . The NPSA has argued that this is an issue which can be solved by altering the shape of the 10 mg tablet (which has been done). The BAD would still strongly argue that it is necessary to use 10 mg tablets only in exceptional circumstances and that a presumption should be made that 2.5 mg tablets will be dispensed unless there is a specific instruction to dispense 10 mg. We would prefer to see the 10 mg tablet treated as a controlled drug.

If this cannot be achieved then we suggest that the 10 mg option should be greyed out.

Page: 8

Author: BAD
Subject: Note
Date: 13/07/2005 23:33:30
We have laid out a booklet with four pages of entries which would take a total of 24 blood test entries (2 years for monthly; up to 6 years if tested 3 monthly).

Page: 9

Author: BAD
Subject: Note
Date: 13/07/2005 23:33:56
PIIINP added for dermatology users

Page: 16

Author: BAD
Subject: Note
Date: 13/07/2005 23:34:49
We have added this section as it is not clear that more frequent tests may be required initially.

Author: BAD
Subject: Note
Date: 13/07/2005 23:35:16
We have condensed this section.

Page: 18

Author: BAD
Subject: Note
Date: 13/07/2005 23:35:47
There are differences in practice between rheumatologists and dermatologists. The former normally look at renal function only every six months. Deteriorating renal function may result in haematological toxicity due to reduced MTX excretion. We have agreed a compromise stating 3-6 monthly.

Author: BAD
Subject: Note
Date: 13/07/2005 23:36:31
PIIINP is mentioned in the NPSA 593 document and should perhaps be included here

Page: 19

Author: BAD
Subject: Note
Date: 13/07/2005 23:36:55
This is taken from the Patient Information Leaflet. We felt it would be appropriate to include it in the patient-held booklet.