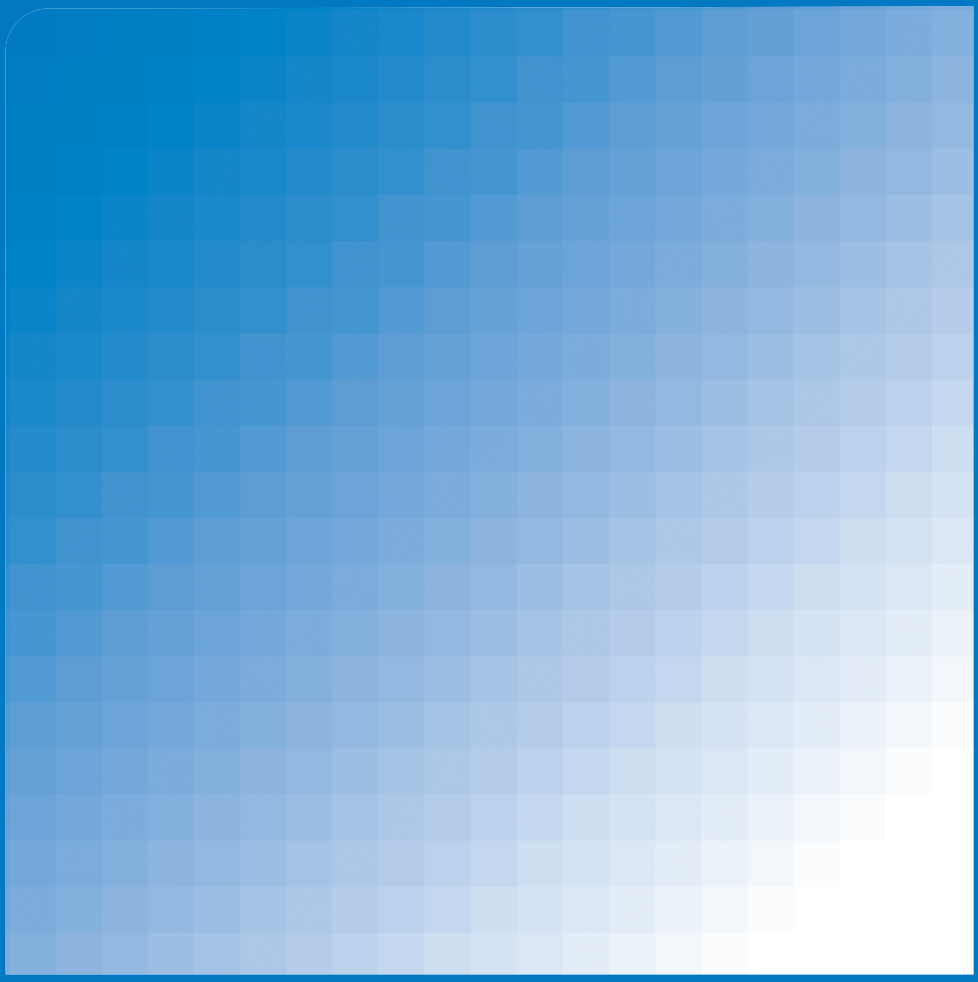
NHS
National Patient Safety Agency

IT requirement specification
Safety alert

Oral methotrexate 2.5mg and 10mg tablets



Synopsis

This document sets out the IT requirements for addressing methotrexate-related patient safety incidents that occur in general practice.

It specifically focuses on why GPs misprescribe methotrexate and how the GP (prescribing decision) support systems should be enhanced to minimise the risk of further errors occurring.

The specification provides a further safety check when reviewing the prescription prior to dispensing and supply. It is recommended that the same safety specification is incorporated into community pharmacy and dispensing doctor pharmacy systems.

As the use of IT develops within secondary care, safety alerts for primary care will also be relevant to this sector and should therefore be incorporated within hospital IT prescribing, dispensing and administration systems.

Contents

1 Overview of requirements

This requirement specification addresses one of the objectives of reducing or removing harm associated with dosing errors with oral methotrexate: namely, making changes to IT systems to flag methotrexate alerts and prevent erroneous prescribing and supply.

It seeks to address the central concern that methotrexate is a toxic drug with unusual dosing. Over a period of 10 years (1993-2002) there were 137 patient safety incidents associated with methotrexate in England, of which there were 25 patient deaths and 26 cases of serious, long-term harm associated directly with the use of oral methotrexate tablets. Sixty-seven per cent of these cases were due to, or partly due to, overdose of the drug because a daily dose had been prescribed, usually by the patient's GP. Furthermore, as the patients were harmed, it can be concluded that pharmacy systems also failed in preventing the supply of such over-dosages.

1.1 Out of scope

The software will not be rolled-out by the NPSA to GPs and other customers of the suppliers who are not in scope. This is the role of the system suppliers and system users.

1.2 In scope

This project will deliver an IT specification package to the system suppliers that will be sufficiently easy to implement so that it will have an insignificant impact on their development resources.

The development and testing of the specification was undertaken in full collaboration with EMIS and First DataBank Europe; initially to the drug databases and subsequently tested with user groups from EMIS and First DataBank Europe customers.

The requirements of the specification include the following safety features:

- picking list options including drug form and strength;
- alerts which are timely, appropriate, and not easily overridden;
- barriers to dual therapy and to prevent the drug being used too frequently;
- links to clinical audit and monitoring.

2 Point of drug selection

2.1 Distinguishing toxic drugs

A number of GP prescribing and pharmacy dispensary systems offer a picking list of drugs.

The presentation of the picking list should use the following style guide to show the distinction between 'high alert' and non-high alert drugs.

The primary objective of a visual graphic is to distinguish toxic from non-toxic drugs. It does so in the following ways:

- the words 'high alert', 'alert' or 'toxic' must appear in front of the drug name;
- a distinguishable icon, displayed in red, should appear (the NPSA accepts that colour might not initially be achievable for some systems);
- all high alert/toxic drugs should appear at either the end (preferably), or the beginning of the alphabetical picking list;
- when methotrexate is selected, the system should display an additional user message reminding the user that the dosage is weekly rather than daily and that the drug requires regular monitoring.

2.2 Initial alert

When 'methotrexate tablet' is selected, the additional user message should appear in the centre of the screen. It should state: ***This is an NPSA High Risk Process.*** The following steps are then to be taken by the user:

- *Confirm they have selected methotrexate tablets at strength xx mg*
- ***Proceed:*** If selected, the user's support system is invoked to prescribe the drug.
- ***Do not proceed:*** If selected, the user is returned to the screen prior to this secondary alert.

2.3 Standardising dosage

In the short-term, the dosing functionality should be simple.

The picking list should offer standardised dosing (**quantity and number of tablets**), whenever methotrexate tablets are selected for prescription.

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
10mg (four tablets) to be taken weekly	
12.5mg (five tablets) to be taken weekly	
15mg (six tablets) to be taken weekly	
17.5mg (seven tablets) to be taken weekly	
20mg (eight tablets) to be taken weekly	
22.5mg (nine tablets) to be taken weekly	
25mg (ten tablets) to be taken weekly	

2.3.1 Non-standard dosage

It should be possible, but not easy, to override these dose options to prescribe greater multiples of the 2.5mg tablets.

It is recommended that the user is prompted to record clinical evidence of overridden 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.

2.4 Avoiding prescribing errors: dual therapy

It is currently possible to prescribe two forms of methotrexate simultaneously. This is not recommended except in exceptional circumstances.

The NPSA specifically wants to prevent the prescribing of methotrexate by either two different routes (oral and SC), or two different formulations (tablets and injection) at the same time; i.e., to prevent duplicate ingredient prescribing.

Dual therapy may occur as a result of an error and so an alert of the sort described in paragraph 2.2 should be displayed asking the user to confirm. If it is not confirmed, the user is returned to the previous screen.

2.5 Avoiding prescribing errors: premature repeat prescription

Repeat prescriptions of methotrexate should require interaction with the individual patient history record held on the GP's system.

Some GP systems contain a field for 'Number of repeats' or 'Frequency of repeats'.

If possible, the GP system would recognise a repeat for methotrexate and display a corresponding alert if the prescription were to be generated more than one month before the previous prescription supply should have been exhausted.

2.6 Other GP support systems

GP support systems that do not offer a picking list of drugs will, it is expected, change in line with standardisation through NHS Connecting for Health and the introduction of the Contract Change Notice, which comes in to effect in 2006.

3 Compliance with standards and points for review

All the changes outlined here have been subject to a risk assessment to ensure that the end products are intuitive, reasonable, and do not lead to additional or new error. They have been risk-assessed as a package and **all the changes** should be implemented at once. Implementation of a selection of the changes can, and has, directly led to patients being harmed.