LOTHIAN PRESCRIBING BULLETIN

Supporting prescribing excellence - informing colleagues in primary and secondary care

2013 Calendar enclosed

NHS Lothian

Issue No. 58

November 2012

In this issue …

Focus on interactions

Cytochrome P450 (CYP450) is a large group of iso-enzymes involved in the metabolism of many drugs. Inhibition of this enzyme can lead to decreased metabolism of other drugs metabolised by the same system which, may result in higher concentrations with potential for increasing risk of toxicity.

Simvastatin

Simvastatin is metabolised by CYP450 and is sensitive to the effects of CYP3A4 inhibitors. Amlodipine, diltiazem and verapamil inhibit CYP3A4 and amiodarone inhibits both CYP3A4 and CYP2C9. Recent review of data by the MHRA has led to a change in simvastatin prescribing information. This data highlights the increased risk of myopathy/rhabdomyolysis when simvastatin is given with these medicines which due to the interaction, increases the plasma concentration of simvastatin. Therefore the maximum dose of simvastatin when given with these medicines is restricted to 20mg/day. Atorvastatin is also metabolised by CYP450 but is less susceptible to interactions with CYP3A4 inhibitors.

Patients taking simvastatin 40mg *and* amlodipine, diltiazem, amiodarone or verapamil should be reviewed at their next scheduled appointment. Consider the following action taking individual factors into account:	
Primary prevention	**Secondary prevention**
reduce *simvastatin dose to 20mg, monitor*	***switch*** *to atorvastatin 40mg, monitor*
Ciclosporin, danazol and gemfibrozil have been added to the list of medicines contraindicated with concurrent use of simvastatin.	

Further information can be found at www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON180637

Clarithromycin

Clarithromycin, a macrolide antibiotic included in NHS Lothian guidance, is a cytochrome P450 enzyme inhibitor. It is associated with many clinically significant drug-drug interactions and many combinations are contraindicated. Clarithromycin is also associated with prolongation of QT interval which may lead to cardiac arrhythmias. This risk is increased if given with other drugs which also have this side-effect.

It is vital to check for interactions with existing therapy when considering prescribing clarithromycin.

Sources to check for interactions

- BNF - Appendix 1 Interactions
- Summary of product characteristics (SPC) of medicines. www.medicines.org.uk
- Pharmacists
- Medicines Information (0131 242 2920)

New guidance for intravenous acetylcysteine following paracetamol overdose

The Commission on Human Medicines (CHM) has issued revised guidance for use of acetylcysteine. The indication for intravenous acetylcysteine is now:

- If staggered overdose or doubt about timing acetylcysteine treatment is indicated ***irrespective*** of the plasma paracetamol level ***OR***
- If single ingestion: acetylcysteine treatment is indicated when a timed plasma paracetamol concentration is on or above a single treatment line on a new nomogram. ***This is regardless of previously used clinical risk factors*** for hepatotoxicity.

Other changes include the duration of administration of the first dose has been increased from 15 minutes to 1 hour and hypersensitivity is no longer a contraindication to acetylcysteine. Further information can be found at www.mhra.gov.uk//Safetyinformation/DrugSafetyUpdate/CON185624.

Remember: *paracetamol overdose is the commonest cause of acute liver failure in the UK.*

Marrying quality and cost - are you engaged?

The Primary Care Pharmacy (PCP) Team has developed and implemented a wide range of initiatives to maximise the cost effectiveness of prescribing, while maintaining a focus on quality and evidence based medicine. As a result of the ongoing efforts of prescribers and the prescribing teams, NHS Lothian continues to demonstrate excellent prescribing. Thank you for continuing to support these projects.

Non–clinical staff medication review training

Practice administrative staff are invited to attend training and support on repeat prescribing systems facilitated by pharmacy and eHealth. Some practices have selected this as a MED 6/10 action.

Promoting formulary 1st and 2nd line choices

This year's projects to audit and promote formulary choices include:

- Combination respiratory inhalers
- Wound management products
- Emollients.

There may be an opportunity for these to be undertaken by the PCP team. Practices are encouraged to use eLJF CLINICAL in promoting formulary choices.

Further information is available at www.ljf.scot.nhs.uk

Care homes ordering processes

The PCP team is working with practices, care homes and their community pharmacies to optimise repeat ordering systems and reduce avoidable waste. Audit packs have been developed and practices may have selected this as a MED 6/10 action.

General Practice Intervention Programme (GPIP) 2012

As in previous years, practices are being asked to ensure that patients receive the most cost-effective formulations available, e.g. omeprazole capsules not tablets. All GP practices in Lothian have been sent a protocol pack and searches have been developed to support this work. CH(C)P managers have agreed to make administrative payments to practices to undertake this work. Participation by practices in GPIP 2012 is the gateway to a further payment linked to Prescribing Indicator (PI) attainment.

Gluten-free foods

The provision of gluten-free foods on NHS prescription is limited to the borderline substances and specific therapeutic indications specified by the Advisory Committee on Borderline Substances (ACBS). There has been close collaboration with GI consultants, dietitians, patients and Coeliac UK to develop a policy and agree a list of staple gluten-free foods such as bread and flour which should meet the requirements for the majority of adult patients. To this end we have requested that GPs stop prescribing non-essential luxury foods, e.g. cakes and sweet biscuits unless on the written advice of a specialist dietitian. GPs are also asked to ensure that all other prescribing of gluten-free foods is strictly within the ACBS indications. The project is for adults only in the first instance. Please see Gluten-free Section on the LJF website.

Review of special order unlicensed medicines

As part of a larger NHS Lothian project, we are asking practices to review the appropriateness of all special order unlicensed products (specials). Guidance has recently been sent to community pharmacies outlining the NHS Lothian procurement process and expected costs which the health board will reimburse. Work is also ongoing to address specific interface issues between primary and secondary care around the use of pharmaceutical specials, including dermatological and ophthalmic unlicensed products. We are also encouraging practices to prescribe melatonin by brand name only (Bio-Melatonin® 3mg tablets or Circadin® MR 2mg tablets) as recommended in the Shared Care Protocol. Please see the article in LPB Issue 55.

If you have any suggestions or would like further information on any of these projects, please contact your Primary Care Pharmacist.

Yellow Card Centre Scotland - Lothian update

The total number of Yellow Card reports received for suspected Adverse Drug Reactions (ADRs) across the UK increased by 3% from 2009/10 to 2010/11. During this same period the total Scottish and Lothian Reports decreased by 9% and 8% respectively, which may be of concern. Yellow Card Reports are essential in detecting unknown ADRs and identifying any unknown potential safety risks to patients.

The mission of Yellow Card Centre (YCC) Scotland is to enhance and safeguard the public's health in Scotland by seeking to minimise the adverse effects of medicines. To meet this objective YCC Scotland will seek:

***(i)** to raise the profile of adverse drug reactions (ADRs) as an important health issue amongst both professionals and the public in Scotland*

***(ii)** to enhance the quality and quantity of spontaneous ADR reports*

***(iii)** to improve education about ADRs for undergraduates and clinicians*

***(iv)** to promote research that helps to better understand the causes, effects and avoidance of ADRs.*

A breakdown of the reports received from Lothian compared to the whole of Scotland in 2010/2011 can be seen in the table below:

	Number Received	Total Black Triangle (% of total)	Total Serious Reactions (% of total)	Total Paediatric Reports (% of total)	Total Herbal Reports (% of total)
Scotland	1008	363 (31%)	641 (55%)	121 (12%)	62 (5%)
NHS Lothian	195	63 (32%)	114 (58%)	9 (5%)	3 (1%)

The reporting rate of 23 per 100,000 population in NHS Lothian, is slightly higher than the Scottish average but ranks 6th overall in reporting rate for all Scottish Health Boards. The top reporting professional groups in NHS Lothian were GPs and hospital doctors. There were a number of yellow card reports where the professional affiliation was not stated on the report so classification of reporter qualification was not possible. Patients were added as recognised reporters to the Yellow Card Scheme in 2008, and they account for 10% of the reports received for both Scotland and NHS Lothian (2010/11).

Key messages:

- **All healthcare professionals are asked to report via the Yellow Card Scheme www.yellowcard.gov.uk:**
  - **all suspected serious reactions for all medicines**
  - **any suspected reactions for medicines under intensive monitoring (i.e. currently referred to as ▼Black Triangle medicines but will change to a European Monitoring Scheme within the next year)**
- **From July 2012 any adverse events with medicines related to incorrect prescribing or incorrect administration of a medicine should be reported via the Yellow Card Scheme.**
- **All healthcare professionals should specify their professional affiliation and location (hospital or community) on the Yellow Card report.**
- **Patients should be encouraged and supported by healthcare professionals to complete Yellow Card reports for suspected ADRs.**
- **If at any time you are uncertain or have questions whether a Yellow Card report should be submitted, the staff at YCC Scotland would be happy to discuss. Educational materials or training on ADRs and reporting are also available from YCC Scotland. The contact details are:**

0131 242 2919 or alternatively via www.yccscotland.scot.nhs.uk

Domperidone to augment lactation – new guidance

Breastfeeding is recognised worldwide to have many health benefits for mother and baby.[1] Low breast milk supply is a common reason for discontinuing breastfeeding. Timely assessment of breastfeeding and expressing technique can identify reasons for milk insufficiency. Effective and optimal non-pharmacological support will usually improve breast milk supply. In women who still have a shortfall in milk supply despite this support, domperidone has been used for 30 years across many countries and there is supportive evidence that domperidone is effective for this off label indication.[2] It is considered to be the galactagogue of choice due to its better safety and efficacy profile compared with other agents.

Key messages:

- **Mothers should receive expert help and support with breastfeeding technique from midwife, health visiting team or at a Breastfeeding Clinic or GP as soon as possible.**
  www.nhslothian.scot.nhs.uk/Services/A-Z/BreastfeedingSupport/Pages/default.aspx
- **Domperidone must only be used after non-pharmacological support has failed to improve milk supply. It must be used with and not instead of this support and with regular monitoring thereafter.**
- **NHS Lothian prescribing guidance can be found in LJF section 7.1.**
  The full guideline can be viewed at the NHS Lothian intranet > Healthcare > A-Z > Reproductive Medicine.
- **Inpatients will receive supply from hospital pharmacy. All other breastfeeding mothers will be referred to GPs using the agreed referral letter.**
- **Possible risks and benefits of off label use of domperidone and other treatment options must be discussed with mothers by those recommending treatment.**

References:

1. Horta BL *et al*. Evidence on the long-term effects of breastfeeding. WHO 2007 www.who.int accessed 12/10/2012
2. UKMi Q&A 73-3. Drug treatment of inadequate lactation. 20 April 2010. www.nelm.nhs.uk accessed 12/10/2012.

Thanks to Sherry Wright, Lead Pharmacist, Reproductive Medicine for contributing this article.

Individual Patient Treatment Requests

It is the responsibility of the managing clinician(s) to decide if the patient meets the criteria for an IPTR application. **"*The patient's clinical circumstances (condition and characteristics) and potential response to treatment with the medicine must be significantly different to the general population of patients covered by the medicine's licence or the population of patients included in clinical trials for the medicine's licensed indication appraised by the SMC, AND it is the clinician's professional opinion that the patient is likely to gain significantly more benefit from the treatment than might normally be expected from patients for whom NHS policy is not to use the medicine*."**
IPTR policy and procedures. Version 1.3. NHS Lothian. February 2012.

NHS Boards in Scotland have processes for considering individual patient treatment requests (IPTRs), in line with Scottish Government circulars CEL(2010)17 and CMO(2012)1. These apply to any clinician requesting the treatment of a patient with a medicine that is '*not recommended*' for use in the NHS by the Scottish Medicines Consortium (SMC). The Lothian IPTR Panel also considers individual requests for surgical procedures not recommended by NHS Lothian policy. Where an urgent decision is required, the Medical Director is the direct contact.

If the clinician in charge of the patient's care considers that the patient's clinical circumstances do not merit consideration for an IPTR request, then the clinician should discuss other SMC/LJF approved treatment options with the patient. Where no such medicine is available, the clinician should provide the best supportive care. If the patient wishes to obtain treatment from the independent healthcare sector, clinicians should follow the guidance on arrangements for NHS patients receiving healthcare services through private healthcare arrangements – see CMO(2009)3.

Supplement: Recent SMC and Lothian Formulary Committee Recommendations

The supplement can be accessed via the LJF website www.ljf.scot.nhs.uk in 'Prescribing Bulletins'.

Correspondence address:
Medicines Management Team (MMT)
Pentland House
47 Robb's Loan
Edinburgh
EH14 1TY Tel: 0131 537 8510
Email: prescribing@nhslothian.scot.nhs.uk