Health and Social Care Board

Medicines Safety Matters

Newsletter for Prescribers & Community Pharmacists

Vol 4 Issue 1 Jan 2014

Inside this issue:

Something missing?

A patient came to serious harm and required admission to hospital when he did not receive his full supply of regular repeat medicines during a respite stay in another town.

The patient who had complex needs, routinely had his medicines dispensed weekly in a compliance aid and was not familiar with their names. The patient did not bring his medicines from home and asked the local community pharmacist to arrange a supply for him.
The pharmacist contacted the GP practice as requested.

However, prescriptions for some of the patient's regular medicines were not issued by the GP practice, including a number of important medicines which were omitted from the compliance aid leading to a hospital admission.
A similar incident was also reported recently where a new patient presented with prescriptions and asked the community pharmacist to dispense his medicines into a compliance aid. The patient's carer returned the following day to advise that some medicines were missing. When this was investigated it was discovered that all of the patient's prescriptions had not been collected from the GP practice.

Advice for GP Practices:
When taking requests for repeat medicines:

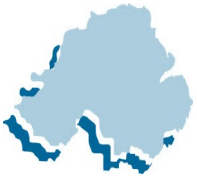
- Confirm if all repeat and regular acute medicines are required.
- Ensure medication requests following hospital discharge are dealt with in their entirety by a prescriber
- Notify the GP if non-compliance is identified or suspected. Be vigilant to any regular acute medicines which may have dropped into 'past' screens.
- Advise patients when **all** of the prescriptions requested will be ready for collection
- Take extra care with high risk patients/ medicines e.g. patients on weekly dispensing.

Advice for Community Pharmacies:

- In cases such as these when it is necessary to request prescriptions on behalf of a patient, check all available resources to ensure prescriptions for all current and required medicines have been received e.g.
  - Patient
  - GP practice
  - PMRs
- When dispensing medicines into a compliance aid for a new patient, check all available resources to ensure prescriptions for all the current medicines have been received
- Query items known to be missing from prescriptions directly with the GP.

Local knowledge

All the articles in the Medicines Safety Matters newsletters are based on local events reported to the Medicines Governance Team at the Health Board. Without your continued support and contribution, we would not be able to raise awareness of the risks or to share advice on preventing re-occurrences with readers.



Dabigatran (Pradaxa®) not suitable for compliance aids

Hospitals have reported a number of occasions where dabigatran has been dispensed into compliance aids in community.

These reports indicate that the special storage requirements for dabigatran (Pradaxa®) are not commonly known.

Dabigatran is susceptible to hydrolysis and the product markedly loses potency when it is removed from the original packaging and is exposed to moisture. Capsules must not be removed from the packaging until the time of administration. The capsules must not be opened to administer the pellets.

Unlike warfarin, dabigatran does not require INR monitoring. There is no blood test to show that it is working effectively and the outcome of any undetected loss of potency could have **serious** consequences for patients.

Advice for prescribers & pharmacists:

The following points may be helpful in assessing the adherence support needs of patients taking Pradaxa®:

- Firstly, assess whether a compliance aid is appropriate*
- It may be possible to dispense the Pradaxa® capsules in the original pack to be used alongside the compliance aid.
- The Pradaxa® Medication Device can be used to help patients/carers push the capsules from the blister pack. It is important to ensure that the user is trained on how to use the device (see below).
- Alternative newer oral anticoagulant agents (NOACs), rivaroxaban (Xarelto®) and apixaban (Eliquis®) are not moisture sensitive and are stable in compliance aids. See Product SPC for full details.

Pradaxa® Storage Requirements:

- Store & dispense in the original bottle or blister pack & only remove at the time of use
- Do not store or dispense in compliance aids, pill boxes etc.
- Capsules in the bottle presentation must be used within 60 days of opening:

◊ Do not open the bottle unnecessarily when dispensing
◊ Always date the bottle when it is opened
◊ If more than one bottle is dispensed, advise patients to only open one at a time. Pharmacists can number the bottles to help patients keep track of which bottle they have opened.

- Pharmacists should ensure that patients are aware of the special storage requirements.

See SPC for full details
http://www.medicines.org.uk/emc/

The Pradaxa® Medication Device is designed for use with Pradaxa® blister strips. The serrated edge of the case pierces the foil of the blister strip to allow access to the capsule. Healthcare professionals can order the devices from Boehringer Ingelheim Customer Services or via a company representative.

*The Royal Pharmaceutical Society report "Improving patient outcomes - the better use of multi-compartment compliance aids (MCAs)" states that whilst MCAs are appropriate for some individuals, their use should be viewed as only one possible medicines adherence solution and that the use of original packs of medicines with appropriate support should be the preferred option in most individuals.
http://www.rpharms.com/unsecure-support-resources/improving-patient-outcomes-through-the-better-use-of-mcas.asp

Immunosuppressants - check for interactions

Tacrolimus (Prograf® & Advagraf®) is licensed for immunosuppression post organ transplant and is classed as an amber medicine in N.I. It can therefore be prescribed/dispensed in either secondary or primary care in line with the shared care guideline (SCG).

In a recent incident, a patient with a bilateral lung transplant who was taking Prograf® (supplied by hospital) mycophenolate mofetil and prednisolone was prescribed clarithromycin tablets as part of the triple therapy regimen for *H.pylori* eradication.

The interaction between tacrolimus and clarithromycin was missed on the GP clinical system and as the pharmacy had never dispensed any prescriptions for Prograf®, there was no record of the drug in the PMR and they were unaware of the risk to the patient.

The patient took the clarithromycin for one week and was subsequently admitted to hospital for monitoring due to a raised tacrolimus levels and abnormal renal function tests.

Test your knowledge of tacrolimus & sirolimus interactions

In patients prescribed these drugs:

a	Erythromycin is a safe alternative to clarithromycin	T	F
b	Verapamil & diltiazem increase plasma levels	T	F
c	Nicardipine does not affect plasma levels	T	F
d	NSAIDs should be used with extreme caution	T	F
e	Herbal preparations containing St John's Wort increase plasma levels	T	F
f	Phenytoin decreases plasma levels	T	F
g	Oral fluconazole can be used safely	T	F
h	Patients are advised to avoid grapefruit juice	T	F

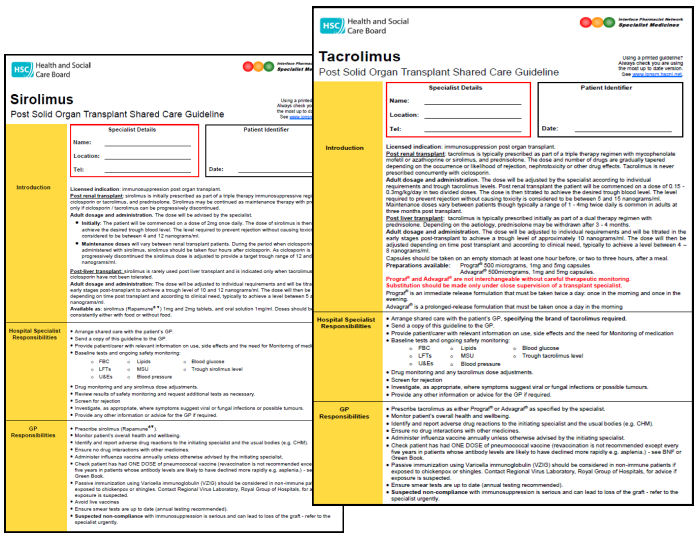
Answers on back page

Advice for prescribers:

- Clinically significant interactions that are flagged on the GP clinical system should be noted
- Save a copy of the SCG into the patient's clinical record for information
- Ensure that all transplant patients, including those who have received their transplant outside N.I., are highlighted on the clinical record as requiring extra vigilance with all prescribing decisions due to the nature of their drug treatments
- The supply route for all amber medicines should be clearly visible on the patient's record to prevent duplication of supply
- Ensure medication requests on hospital letters are dealt with in their entirety and checked by a prescriber
- Any medication supplied by secondary care should be added to a patient's record for information only. The dose field may be entered as "Hospital supply only" to prevent accidental prescription and dispensing in primary care. This will allow interactions, allergies etc. to be identified when concurrent medicines are prescribed and ensures a complete medication history is available on ECR.

Advice for pharmacists:

- Exercise extra vigilance with all prescriptions for transplant patients due to the number of medicines interacting with treatment regimens



The shared care guidelines (SCG) for tacrolimus & sirolimus highlight important interactions that should be avoided. Update your knowledge by reviewing these resources. http://www.ipnsm.hscni.net

Valproate - warnings for use in pregnancy

A recent report about a patient who became pregnant whilst taking valproic acid (Depakote®) has highlighted the issue of the safety of this drug in pregnancy. In November 2013, the MHRA issued updated advice on the use of sodium valproate in pregnancy based on new evidence of neurodevelopmental delay in children following maternal use.

In summary, the advice states that:

- Sodium valproate should not be used **during pregnancy and in women of childbearing potential** unless clearly necessary
- Women of childbearing potential should not start treatment with sodium valproate without specialist advice
- Adequate counselling should be made available to all women of childbearing potential to weigh the risk of teratogenic and neurodevelopmental effects against the benefits of treatment.

The majority of patients with epilepsy or bipolar disorders will already be under specialist review. However, there may be patients who are taking sodium valproate for the prevention of **migraine** (unlicensed indication) who are not reviewed in secondary care.

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON336719

Prescribers must ensure that the use of valproate containing medicines in women of child bearing age and in pregnancy is in line with MHRA advice.
Ensure searches on clinical systems pick up all forms of sodium valproate e.g. Epilim®, Depakote®, Convulex®, Episenta®, sodium valproate, valproic acid.

Further information:

The BNF identifies drugs which may have harmful effects in pregnancy and indicates the trimester of risk www.bnf.org

UK Teratology Information Service (UKTIS)
UKTIS is commissioned on behalf of UK Health Departments to provide a national service on all aspects of the toxicity of drugs and chemicals in pregnancy. Information is provided to health professionals via a telephone information service and online through TOXBASE®. In 2014, UKTIS are launching a range of patient information leaflets about the best use of medicines in pregnancy.www.uktis.org.

UK Patient Epilepsy and Pregnancy Register
Database collects information on the treatment of epilepsy in pregnancy and on the health of the baby after delivery.
http://www.epilepsyandpregnancy.co.uk/

Medicines safety - CPD

The '**Managing High Risk Medicines'** workshop has been attended by more than 300 community pharmacy and GP practice staff at venues across N.I. Feedback has been positive with learning from local incidents cited as being particularly useful. Participants also enjoyed sharing ideas and learning from their colleagues in other pharmacies and GP practices. Two further dates are available.

27th February	Seagoe Hotel Portadown
6th March	Silver Birches Hotel Omagh
	7.30 - 9.30pm

Any GP or practice nurse wishing to attend should register to do so at www.medicinesni.com
Open access to pharmacists.

The Royal College of Nursing online learning resource **'Safety in Numbers'** aims to help nurses improve their numeracy skills. The course includes sections on:

- Information and credits
- Maths matters
- Tackling number problems
- Metric (SI) units
- Dosage for solid medicines (tablets)
- Dosage for liquid medicines
- Flow rate and IV drugs

Registration with RCN is required
https://www.rcn.org.uk/

Quiz answers	
a	False
b	True
c	False
d	True
e	False
f	True
g	False
h	True

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Medicines Safety Matters on the web: http://www.hscboard.hscni.net/medicinesmanagement/index.html