Derbyshire Medicines Management Newsletter

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The purpose of the Medicines Management newsletter is to deliver succinct, evidence-based advice and information on primary care prescribing issues. Aimed at busy prescribers wanting to know key messages from the many publications in the previous month.

1. What's in the news

Articles relevant to primary care

1. Antipyretic therapy for children with fever - *NICE eyes on evidence*

A fever in a child is with temperature of around 38°C or higher, usually self-limiting and viral in origin. Ibuprofen and paracetamol are the most commonly used anti-pyretics used to ease the distress. In doing so the child is more likely to eat and drink, avoiding complications of dehydration and the effects of poor nutrition. They are sometimes used together because of their different mechanisms of action- both paracetamol and ibuprofen simultaneously (combined therapy) or start with one antipyretic and then administer the second medication if the fever does not subside (alternating therapy).

Current advice: The NICE guideline on feverish illness in children recommends using either paracetamol or ibuprofen alone to reduce body temperature in children with fever who appear distressed. Antipyretic agents should not be used with the sole aim of reducing body temperature in children with fever and should be continued only as long as the child appears distressed. When using paracetamol or ibuprofen in children with fever, consider alternating these agents if the child's distress is not alleviated or recurs before the next dose is due. The guideline recommends that paracetamol and ibuprofen should not be given simultaneously.

New evidence: A Cochrane systematic review by Wong et al. (2013) assessed whether combining paracetamol and ibuprofen or alternating the two drugs reduced child discomfort (for example, stress scores, number of doses of medications given and absences from day-care or school) and fever compared with either drug alone in febrile children. The analysis comprised 6 randomised controlled trials (n=915) in children aged 6 months to 14 years with new fever (37.8°C or more) of presumed infectious origin. The authors concluded that both alternating and combined antipyretic therapy may be more effective at reducing temperatures than monotherapy, but that the evidence for how these approaches affect child discomfort is inconclusive. The systematic review was limited by the variation among the included trials in medication dosage, regimens of administration, and frequency and type of assessment and by the small number of patients in the analyses

2. Revisions to SLS list (Drug Tariff Part XVIIIB) *(see PSNC)*

NHS legislation has been changed effective from the 1st August 2014 to remove generic sildenafil from the list of medicines that may be prescribed only where they meet the SLS requirements. This means that generically written NHS prescriptions for sildenafil no longer require the prescriber to annotate them with the letters "SLS". Practices will need to review their private prescribing of generic sildenafil (private prescriptions for generic sildenafil should no longer be written for NHS patients). Patients that do not meet NHS SLS criteria, and are receiving private prescriptions for other erectile dysfunction treatment, may wish to be reviewed and considered for a switch to generic sildenafil on the NHS. However, the brand Viagra has been added to the list, and so the SLS prescribing restrictions apply. Patients must meet the SLS criteria and prescriptions must be annotated 'SLS' in order to be prescribed on the NHS.

Generic sildenafil is the preferred first line treatment option for erectile dysfunction and is by far the most cost-effective option. Note that any new patients that are initiated on generic sildenafil, if they do not respond to this and require an alternative treatment, they will need to meet SLS criteria to have alternative treatment under the NHS, alternatively they will then have private prescriptions - therefore counselling patients of this at the start of treatment may be helpful.

JAPC recommend that 4 tablets are the usual monthly prescription quantity. Clinicians retain clinical freedom to consider larger quantities for patients where it is appropriate, whilst balancing the risks of potential misuse or street value of these medicines.

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2. Drug Safety Update relating to primary care prescribing (For more information see Drug Safety Update : MHRA) Volume 7, Issue 12, July 2014

Drugs and driving: blood concentration limits to be set for certain controlled drugs in a new legal offence

Advice is similar to QIPP, see section 4 below.

Transdermal fentanyl "patches": reminder of potential for life-threatening harm from accidental exposure, particularly in children

This is a reminder from previous advice in 2008 for prescribers to provide clear information to patients and caregivers regarding risk of accidental patch transfer and ingestion of patches, and need for appropriate disposal of patches. Patients and caregivers are advised to follow the instructions on the patch carton and in the accompanying leaflet. If a patch is transferred to another person, it should be removed and the individual should get medical help immediately. If a patch is swallowed, the individual should get medical help immediately

3. Local News and GP queries

GP query

Formoterol Easyhaler is the Derbyshire Long Acting Beta Agonist (LABA) preferred choice. A GP has queried the safety of the drug because EMIS (GP clinical system) flags up a drug interaction with azithromycin with formoterol. This interaction does not appear with salmeterol.

Answer from UKMI

Overall the effect of formoterol on QTc interval can be considered to be small, although there have been cases reported. The Easyhaler formoterol SPC gives the incidence of QTc prolongation as 'very rare'. The SPC for salmeterol similarly rates arrhythmias as 'very rare', although the SPC does not mention QTc interval prolongation, SPC's origin for salmeterol is much older than that for formoterol, and from a time when there was less concern about this type of side effect.
This is probably a class effect of beta-agonists and there is some evidence it is dose-related. The issue becomes of clinical significance where drugs such as these are given to patients who are at higher risk of arrhythmias, whether this is because of cardiac disease, COPD, hypoxaemia, hypokalaemia.

4. QiPP

Guidance for healthcare professionals on drug driving – *gov.uk press release*

The government has issued drug driving guidance to help healthcare professionals explain the new laws that come into force in March 2015. The guidance helps doctors and nurses start explaining the new rules in advance of the launch to reassure those patients who take prescription drugs that they will be able to drive safely without fear of being prosecuted Unlike the existing 'impairment' offence, the new law provides a medical defence for patients who are taking their medicine in accordance with instructions – either from a healthcare professional or printed in the accompanying leaflet – provided they are not impaired. The guidance also advises patients who take legitimately supplied medicines to keep evidence with them in case they are stopped by police.

GPs should note that clinical practice has not changed but may want to explain the new rules concerning this offence to patients and to advise patients to continue taking their medicines as prescribed.

The MHRA has issued the following -

Advice for healthcare professionals:

- Any condition that requires medicinal treatment may itself pose a risk to driving ability if left untreated. Therefore it is important to advise patients to continue their treatment.

Advice to give to patients taking any medicine:

- Continue taking your medicine as prescribed
- Check the leaflet that comes with your medicine for information on how your medicine may affect your driving ability
- It is against the law to drive if your driving ability is impaired by this medicine
- Do not drive while taking this medicine until you know how it affects you (especially just after starting or changing the dose of the medicine)
- Do not drive if you feel sleepy, dizzy, unable to concentrate or make decisions, or if you have blurred or double vision

New QOF menu for improving care in general practice – *NICE*

An updated Quality and Outcomes Framework has been developed for the 2015/16. This includes new indicators in diabetes, hypertension and mental health and also updated ones in chronic kidney disease and atrial fibrillation aligning to recent NICE clinical guideline publications.

5. NICE Evidence summaries: New medicines and unlicensed/off-label relating to primary care prescribing

New medicines

Facial erythema of rosacea: brimonidine tartrate gel (ESNM43)

NICE review of 2 short-term randomised controlled trials (RCTs: n=553) showed that brimonidine tartrate gel was statistically significantly more effective than vehicle gel in reducing erythema in people with a clinical diagnosis of rosacea and moderate to severe erythema. However, 'success rates' (defined as a 2-grade reduction in the severity of erythema as assessed by both patients and clinicians) were just 25% to 30% with brimonidine gel compared with about 10% for vehicle gel at day 29.

JAPC reviewed brimonidine gel (Mirvaso) in May 2014 and classified this as red (for hospital only) indicated for the symptomatic treatment of facial erythema of rosacea in adults where quality of life is severely impaired by the rosacea, and alternative treatments are not suitable.

Unlicensed/ off-label reviews

Chronic urticaria: off-label doses of cetirizine (ESUOM31)

Cetirizine is licensed for the relief of symptoms of chronic idiopathic urticaria at a dose of 10 mg daily in adults. Doses greater than 10mg is off-label.

Four small studies were included in the review, this included two small randomised controlled trials (RCTs) and 2 double-blind crossover studies (total n=76). Cetirizine at a 20 mg daily dose may improve severe chronic urticaria refractory to standard doses of antihistamines. Cetirizine 20 mg appears to be well tolerated and the benefits appear to outweigh the risks for some people whose impaired quality of life is significantly burdened by the condition.

Prescribers should note though that there is no data are available from high quality studies on the use of cetirizine at doses higher than 20 mg and the lack of information available on the use of off-label doses of cetirizine in children and young people under 16 years, or adults over 65 years.

6. Useful resources

BMJ	www.bmj.com
JAMA: The Journal of the American Medical Association	http://jama.ama-assn.org/
The Lancet	www.thelancet.com
The New England Journal of Medicine	http://content.nejm.org/
BMJ, JAMA and NEJM can be accessed in full-text directly through your NHS Athens Account via: National Library for Health: search via My Journals MyAthens: via National Library for Health Resources or Local Resources. Current Lancet articles are sometimes available with free registration from http://www.thelancet.com/content/register. Print copies of The Lancet are available at DCGH library.	www.library.nhs.uk or www.athens.ac.uk
If you have not already registered for an NHS Athens Account, please register at: NB: It is recommended that you register on a Trust (NHS) PC for speedy confirmation of your username a password. Once registered, your account can be accessed from any computer with online access.	https://register.athensams.net/nhs/nhseng/
UKMI Nathnac NHS evidence Electronic medicines compendium Clinical Knowledge Summaries Medicines Prescribing Centre (Formerly NPC) Medicines for children (patient information leaflets Drugs in lactation	http://www.ukmi.nhs.uk/ https://www.evidence.nhs.uk/search?om=%5B%7B%22srn%22%3A%5B%22%20ukmi%20%22%5D%7D%5D http://www.nathnac.org/ http://www.evidence.nhs.uk/ http://www.medicines.org.uk/emc/ www.cks.nhs.uk. http://www.nice.org.uk/mpc/ http://www.medicinesforchildren.org.uk/ http://www.midlandsmedicines.nhs.uk/content.asp?section=6&subsection=17&pageIdx=1
UK teratology services	http://www.uktis.org/index.html
Vaccine update- Vaccination newsletter for health professionals and immunisation practitioners	https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update