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.

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## 1. Medicines Digest and what's in the news

**EMA to review efficacy of emergency contraceptives**

The European Medicines Agency (EMA) has launched a review of emergency contraceptives in light of new data suggesting that high bodyweight could impair their effectiveness. The review will include emergency contraceptives that contain either levonorgestrel or ulipristal acetate. Information on reduced efficacy due to high bodyweight was recently added to the summary of product characteristics (SPC) of Norlevo, a levonorgestrel-containing emergency contraceptive not licensed in the UK. The SPC states: “In clinical trials, contraceptive efficacy was reduced in women weighing 75kg or more, and levonorgestrel was not effective in women who weighed more than 80kg”. The SPCs for emergency contraceptives available in the UK (e.g. Levonelle, ellaOne) do not make reference to the impact of bodyweight on efficacy. In 2012, the Clinical Effectiveness Unit (CEU) of the Faculty of Sexual Health and Reproductive Health Care reviewed the evidence for the effectiveness of levonorgestrel emergency contraception in obese women (body mass index >30kg/m²) and commented that more evidence was needed before specific recommendations can be made.

**Comment:** This review has implications for the use of emergency contraceptives in overweight and obese women. However, healthcare professionals should continue with their current prescribing practice, pending the review’s completion and the EMA’s recommendations.

**Glucocorticoids linked to mortality in rheumatoid arthritis**

The use of glucocorticoids in rheumatoid arthritis is associated with a dose-dependent increase in all-cause and cardiovascular (CV) mortality, a cohort study reports. Researchers followed 779 patients with rheumatoid arthritis for an average of nearly 10 years, totalling 7,203 person-years of observation.

**Comment:** This study provides a valuable analysis of the risks associated with glucocorticoid use in patients with rheumatoid arthritis. There are limitations to this type of study but the association of a dose-dependent link to all-cause mortality is interesting and may be helpful in guiding dosing decisions. Current guidance suggests using short-term courses of glucocorticoids for acute flares of rheumatoid arthritis and only continuing treatment long-term when all other treatment options have been offered.

**New patient safety alert system in England**

NHS England has established a new three-tier system of patient safety alerts, which all English NHS organisations are required to implement. NHS Trusts will be monitored for compliance with the system, and results will be published, starting in April 2014.

The three-tier system replaces the Patient Safety Alerts and Rapid Response Reports previously issued by the National Patient Safety Agency. Alerts will now come from the Department of Health’s Central Alerting System. Examples of issues covered by the system include:

- alerts for new or under-recognised patient safety issues
- alerts for widespread, common and challenging patient safety issues
- alerts aimed at improving systems for clinical governance, reporting and learning

The new system is designed to allow for alerts to be issued sooner after a risk has been identified. The first-stage warning will ask local NHS bodies to identify whether the risk is applicable in their area, and to share any existing processes or practices they have put in place to mitigate the risk. The second stage will share examples of best practice and resources
across the country. The third stage will ask all NHS bodies to confirm that they have (where applicable) put risk mitigation measures in place using the resources supplied in stage two. NHS England has circulated a document with a 10-point checklist, so that NHS bodies can be sure that they have taken all the steps needed to be ready for the implementation of the new system.

Comment: The new alerting system is based on systems used by other high-risk industries, such as aviation. However, its success will rely on ensuring that alerts are targeted and relevant to avoid the risk of ‘alert fatigue’. Prescribers need to be aware that alerts now come through a new system, and may require different actions at the different levels of alert.

**Draft lipid modification guideline reduces threshold for prescribing statins**

The National Institute for Health and Care Excellence (NICE) has overhauled its recommendations on the use of statins, in a draft version of updated guidance on lipid modification. The draft recommendations halve the threshold for prescribing statins, which could result in millions more people being offered statins. NICE says that it has broadened the recommendations on statins to include more people as the effectiveness of these medicines is well established and their cost has fallen. Currently, NICE recommends that only people with a 20% or greater 10-year risk of developing cardiovascular disease (CVD) are offered statins. However, the draft guidance now recommends offering statins to people who have a 10% or greater 10-year risk. For people whose risk is 10% or more, the advice is to offer atorvastatin 20mg daily for primary prevention of CVD. In people with established CVD, the draft guideline recommends starting statin treatment with atorvastatin 80mg daily. A lower dose can be used if any of the following apply: potential drug interactions, risk of adverse effects, patient preference. Prescribers should aim for at least a 40% reduction in non-high-density lipoprotein (non-HDL) cholesterol after the first 3 months of treatment. In addition to the recommendations about statins, NICE also emphasises the need for lifestyle changes, especially stopping smoking, eating healthily, losing excess weight, drinking less alcohol and doing more exercise.

Comment: The draft guidance marks a significant change in the threshold for intervention as well as the choice of statin. Such changes are not based on new clinical studies but analyses of existing data, DTB share some of the concerns of critics of the proposed recommendations who have pointed out the risks of mass medicalisation, including the potential for adverse effects from statin treatment. This view is echoed the CCGs of Derbyshire and who have registered to comment on the NICE draft. In addition, it has been noted that trials of statin therapy have not used risk scoring systems as an enrolment criterion. Of particular concern is whether systems are in place to provide clear explanation of the potential benefits and harms of statin treatment to ensure that people are able to make an informed decision. NICE is due to publish the final guidance in July 2014. Prescribers across Derbyshire should continue to follow local guidelines on lipid management until NICEs final publication followed by a decision by JAPC.

**Metformin OK in CKD?**

Metformin has been used as a first line agent in the management of type 2 diabetes for over 40 years. It is inexpensive, effective (twelve patients need to be treated for 10 years to prevent one diabetes-related endpoint), and in contrast to other drugs used to treat diabetes, does not usually cause hypoglycaemia or weight gain. It is generally well tolerated, although it can produce mild gastrointestinal effects that usually settle with time. Data from observational studies have been used to explore the association of lactic acidosis with metformin. For example, a Cochrane systematic review compared over 70,000 patient years of metformin exposure with a matched group receiving other hypoglycaemic agents and found no evidence of excess lactic acidosis. The upper estimate of incidence was in fact lower for those in the metformin group than in the non-metformin group. The authors concluded that “there is no evidence at present that metformin is associated with an increased risk for lactic acidosis when prescribed under the study conditions”. More recently, a UK case-control study also found higher rates of lactic acidosis in those on sulphonylureas (4.8/100,000 person-years) compared with metformin (3.3/100,000 person-years). Metformin is excreted unchanged by the kidney and therefore lower doses are needed as kidney function falls. Unfortunately for clinicians, advice and guidance on the use of metformin in renal disease from the British National Formulary (BNF), the National Institute for Health and Care Excellence (NICE) and the Summary of Product Characteristics (SPC) rather unhelpfully uses different terminology, measures of kidney function and thresholds. The SPC states that metformin is contraindicated in renal failure or renal dysfunction (creatinine clearance <60mL/min). The BNF advises ‘caution’ in renal impairment and that the drug should be avoided in ‘significant renal impairment’. NICE recommends that the dose is reviewed when estimated glomerular filtration rate (eGFR) <45mL/min/1.73m² (or if serum creatinine >130μmol/L) and stopped when eGFR <30mL/min/1.73m² (or if serum creatinine >150μmol/L). In addition, NICE advises that metformin should be withdrawn when there is a high risk of tissue hypoxia or acute kidney injury. Practical advice from the Renal Drug Handbook includes using 25–50% of the standard dose when GFR is 40–50mL/min, 25% of the standard dose when the GFR is 10–40mL/min and avoiding metformin when GFR <10mL/min, with annual monitoring of eGFR in people with normal renal function and 2–4 times a year in those with an eGFR at the lower end of normal and in older people.

Balancing the benefits and risks of metformin and other hypoglycaemic agents it could be argued that metformin is one of the most effective hypoglycaemic agents, and that it has a valuable role even in patients with chronic kidney disease. There is a growing conviction amongst nephrologists and diabetologists that the current contraindication is too restrictive. It is time for standardisation of the prescribing advice on the use of metformin to maximise its use in people with renal disease supported by the development of a decision aid to enable patients to make an informed choice based on the risks and benefits of such treatment.


Overview: Asthma is a chronic inflammatory condition in which the airways are hyper-responsive and constrict easily in
response to a wide range of stimuli. Physical exercise may trigger symptoms such as cough, chest tightness and shortness of breath in people with asthma that is not adequately controlled (exercise-induced asthma). Physical exercise can also trigger asthma symptoms and induce bronchial obstruction in people without clinical asthma (exercise-induced bronchoconstriction).

Current advice: The British guideline on the management of asthma (Scottish Intercollegiate Guidelines Network and British Thoracic Society) states that for most people, exercise-induced asthma indicates poorly controlled asthma. People who experience exercise-induced asthma should undergo review of their regular asthma treatment, including inhaled corticosteroids. If exercise is a specific problem in people taking inhaled corticosteroids whose asthma is otherwise well controlled, the British guideline recommends considering adding one of the following treatments: leukotriene receptor antagonists; long-acting beta-2 agonists (LABAs); chromones; oral beta-2 agonists; or theophyllines.

An inhaled short-acting beta-2 agonist (SABA) immediately before exercise is also recommended.

In a Drug Safety Update, the Medicines and Healthcare Products Regulatory Agency recommended that LABAs should not be prescribed for the relief of exercise-induced asthma symptoms in the absence of regular inhaled corticosteroids.

New evidence: A Cochrane systematic review by Bonini et al. (2013) has assessed the effects of SABAs and LABAs compared with placebo in the prevention of exercise-induced asthma. The review included 53 double-blind placebo-controlled randomised trials. In the 45 studies that looked at short-term (single-dose) administration of an inhaled beta-2 agonist (n=799), FEV1 fell significantly less in people who took a beta-2 agonist before the exercise challenge than in those who took a placebo (mean difference=−17.67%, 95% CI −19.51 to −15.84%, p=0.00001). Subgroup analysis for both LABAs (21 studies) and SABAs (40 studies) produced similar results. The total number of adverse events was similar with beta-2 agonists and placebo (45 versus 54, p=0.56). The 8 studies that looked at long-term administration of an inhaled beta-2 agonist had a small number of participants (n=206) and differed in their study designs, which meant meta-analysis was not possible. However, overall evaluation of the long-term studies suggested a bronchoprotective effect for the first-dose of a beta-2 agonist, but that long-term use of both SABAs and LABAs induced the onset of tolerance and decreased the duration of drug effect, even after a short treatment period. The long-term studies had insufficient data on the safety of regular long-term use of beta-2 agonists for exercise induced asthma.

Commentary: Exercise-induced symptoms are a common problem in patients with asthma, and SABAs are frequently used before exercise as a preventive measure. This Cochrane review concluded that a single dose of a SABA before exercise is associated with a short-term benefit (reduction in mean fall of FEV1). However, the evidence is of low-to-medium quality. In addition, the review found that long-term use of SABAs induced tolerance.

The review also included studies that looked at the effect of LABAs before exercise. Although there was also a short-term protective effect with LABAs, evidence from safety data does not support the use of LABAs in this way. In asthma, LABAs should only be prescribed in conjunction with inhaled corticosteroids.

For any patient experiencing frequent exercise-induced asthma symptoms, two things should be considered before simply advising that pre-exercise SABA should be the mainstay of treatment. First, consider whether the symptoms indicate poorly controlled asthma and if a review of the patient's regular asthma treatment would be more appropriate. Second, bear in mind whether the symptoms are caused by dysfunctional breathing during exercise, in which case the management is very different.

Antihypertensive Medications and Serious Fall Injuries in a Nationally Representative Sample of Older Adults

Importance

The effect of serious injuries, such as hip fracture and head injury, on mortality and function is comparable to that of cardiovascular events. Concerns have been raised about the risk of fall injuries in older adults taking antihypertensive medications. The low risk of fall injuries reported in clinical trials of healthy older adults may not reflect the risk in older adults with multiple chronic conditions.

Objective

To determine whether antihypertensive medication use was associated with experiencing a serious fall injury in a nationally representative sample of older adults.

Design, Participants, and Setting

Competing risk analysis as performed with propensity score adjustment and matching in the nationally representative Medicare Current Beneficiary Survey cohort during a 3-year follow-up through 2009. Participants included 4961 community living adults older than 70 years with hypertension.

Exposures

Antihypertensive medication intensity based on the standardized daily dose for each antihypertensive medication class that participants used.

Main Outcomes and Measures

Serious fall injuries, including hip and other major fractures, traumatic brain injuries, and joint dislocations, ascertained through Centres for Medicare & Medicaid Services claims.

Results

Of the 4961 participants, 14.1% received no antihypertensive medications; 54.6% were in the moderate-intensity and 31.3% in the high-intensity antihypertensive groups. During follow-up, 446 participants (9.0%) experienced serious fall injuries, and 837 (16.9%) died. The adjusted hazard ratios for serious fall injury were 1.40 (95% CI, 1.03–1.90) in the moderate-intensity and 1.28 (95% CI, 0.91–1.80) in the high-intensity antihypertensive groups compared with nonusers. Although the difference in adjusted hazard ratios across the groups did not reach statistical significance, results were similar in the propensity score–matched subcohort. Among 503 participants with a previous fall injury, the adjusted hazard ratios were 2.17 (95% CI, 0.98–4.80) for the moderate-intensity and 2.31 (95% CI, 1.01–5.29) for the high-intensity.
anthypertensive groups. Conclusions and Relevance Antihypertensive medications were associated with an increased risk of serious fall injuries, particularly among those with previous fall injuries. The potential harms versus benefits of antihypertensive medications should be weighed in deciding to continue treatment with antihypertensive medications in older adults with multiple chronic conditions.


2. Drug Safety Update relating to primary care prescribing

(For more information see Drug Safety Update : MHRA ) Volume 7, Issue 9, April 2014

Tumour necrosis factor alpha inhibitors: risk of tuberculosis—screen all patients before starting treatment and monitor them closely

There is an increased risk of tuberculosis, or reactivation of latent tuberculosis, during treatment with tumour necrosis factor alpha (TNF-alpha) inhibitors. Tuberculosis in patients receiving TNF-alpha inhibitors can be life-threatening, and deaths from tuberculosis have occurred in these patients. TNF-alpha inhibitors are therefore contraindicated in patients with active tuberculosis or other severe infections. Screen patients for active and latent tuberculosis before starting treatment with a TNF-alpha inhibitor. Monitor them closely for infectious diseases including tuberculosis before, during, and after treatment. Although anti-TNF drugs will be initiated and monitored by specialists GPs should be aware of this advice if patients present with symptoms of TB (e.g. persistent cough, weight loss, low-grade fever)

MHRA (letter sent to healthcare professionals April 2014 CAS – View Alert)

Domperidone: risk of cardiac side effects - restricted indication, new contraindications, and reduced dose and duration of use

Summary: Domperidone is associated with a small increased risk of serious cardiac side effects. Its use is now restricted to the relief of symptoms of nausea and vomiting and the dosage and duration of use have been reduced. Domperidone is now contraindicated in those with underlying cardiac conditions and other risk factor

Background: The review was triggered following continued reports of cardiac side effects and a small increased risk of serious cardiac side effects was confirmed. A higher risk was observed in patients older than 60 years, adults taking daily oral doses of more than 30mg, and those taking QT-prolonging medicines or CYP3A4 inhibitors concomitantly.

Advice for healthcare professionals

Indication

- Domperidone is now restricted to use in the relief of symptoms of nausea and vomiting
  - It should be used at the lowest effective dose for the shortest possible time
    - The maximum treatment duration should not exceed one week
    - Patients currently receiving long-term treatment with domperidone should be reassessed at a routine appointment to advise on treatment continuation, dose change, or cessation
    - For adults and adolescents over 12 years of age and weighing 35kg or more, the recommended maximum dose in 24 hours is 30mg (dose interval: 10mg up to three times a day)
    - In children under 12 years of age and weighing less than 35kg, the recommended maximum dose in 24 hours is 0.75mg/kg body weight (dose interval: 0.25mg/kg body weight up to three times a day)

- Oral liquid formulations of domperidone should only be given via an appropriately designed, graduated oral syringe to ensure dose accuracy

Contraindications Domperidone is contraindicated in people:

- with conditions where the cardiac conduction is, or could be, impaired
- with underlying cardiac diseases such as congestive heart failure
- receiving other medications known to prolong QT or potent CYP3A4 inhibitors (the Derbyshire medicines management website recommends using CredibleMeds as a useful resource)
- with severe hepatic impairment

Patients with these conditions should have their treatment reviewed at their next routine appointment and be switched to an alternative treatment if required

Mims deletions: April 2014

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3. Local News and GP queries

GP query

There is a supply problem with Caverject, the dual chamber formulation is out of stock until 2016

Answer

The Derbyshire Guideline Group has agreed to add Viridal Duo to the local formulary as a cost effective alternative (when prescribed as continuation packs) to Caverject Vials. Replacement injectors can be obtained free of charge- Tel 0800 731 2698 and can be delivered to local pharmacy/ GP practice or patients’ homes.

This Newsletter has been produced by Slak Dhadli – slakahan.dhadli@southernderbyshireccg.nhs.uk
**Derbyshire Medicines Management – Improved Website Launched!**
Following the Derbyshire Medicines Management consultation on its website we are pleased to announce that an improved website has now been launched. The web address and the general look of the website remains the same however you will notice some significant improvements, these include:

- Clear ‘traffic light system’ navigation
- Improved search engine to help you find information quickly and easily
- Electronic inappropriate request form
- Easy to find medicines information
- Headline latest and current news
- Alerts utilising Twitter feeds - coming soon!!
- Improved reliability
- Up to date content

If you have any comments about the website please feel free to inform us using the feedback form on the website.

4. **QiPP**

**Newly Published Ophthalmic Specials Guidance**
Analysis of primary care prescription data for the first nine months of 2013 has revealed that over 30,000 prescriptions for unlicensed eye preparations were dispensed in England and Wales at a cost of almost £3 million. The UK Ophthalmic Pharmacy Group (UK OPG) believes that this is not an effective or cost efficient use of NHS resources. The Royal College of Ophthalmologists and the UK Ophthalmic Pharmacy Group are concerned about the suitability and the cost of certain unlicensed ophthalmic preparations prescribed and dispensed in primary care. The General Medical Council’s advises that unlicensed medicines may be prescribed ‘on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.’

Following on from the advice by the GMC, the College and the UK OPG have produced the **Ophthalmic Specials Guidance**

**Child amoxicillin dose increase (Primary care talk April 2014)**
The online BNF and BNFC now list higher doses of oral amoxicillin for children in line with Health Protection Agency (HPA) guidance. The paper BNF (67th edition, March 2014) does not list the new dose. The current recommended doses are:

- Child 1 month to 1 year: 125mg three times daily, increased if necessary up to 30mg/kg three times daily.
- Child 1-5 years: 250mg three times daily, increased if necessary up to 30mg/kg three times daily.
- Child 5-12 years: 500mg three times daily, increased if necessary up to 30mg/kg (max 1g) three times daily.
- Child 12-18 years: 500mg three times daily; in severe infection 1g three times daily.

The HPA guidance for managing infections in primary care is freely available online at: www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1279888711402

**Interchangeability of oral mesalazine**
The online BNF has made changes to the recommendations on interchangeability of oral mesalazine preparations. It now states there is no evidence to show that any one oral preparation of mesalazine is more effective than another; however, the delivery characteristics of oral mesalazine preparations may vary. If it is necessary to switch a patient to a different brand of mesalazine, advise the patient to report any changes in symptoms

**Drug monitoring in primary care**
The UKMi document Suggestsions for drug monitoring in adults in primary care has been updated. This comprehensive document suggests tests to perform before a drug is started, while the patient is being stabilised on therapy, and on-going monitoring for longer-term therapy. Actions to take if results are abnormal are also listed. Each entry is fully referenced. http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20monitoring%20document%20Feb%202014.pdf

Whilst this is a good reference source, clinicians should follow local monitoring guidelines (e.g. in shared care) where they exist.

**Brazilia 2014 travel advice**
National Travel Health Network and Centre (NaTHNaC) and Public Health England have published a fact sheet with health advice for football fans travelling to Brazil for the World Cup. www.nathnacl.org/pro/news/worldcup_060314.htm

Advice on vaccines, malaria and other health risks for Brazil are on NaTHNaC | Brazil: Country Information page. Useful travel advice and tips on travelling to Brazil are available on the Foreign and Commonwealth Office information page. https://www.gov.uk/government/news/world-cup-2014

This Newsletter has been produced by Slak Dhadli – slakahan.dhadli@southernderbyshireccg.nhs.uk
5. **NICE Evidence summaries: New medicines and unlicensed/off-label medicines** relating to primary care prescribing (NICE evidence summaries can be found [here](#)).

### New medicines

**ESNM35 Type 2 diabetes: empagliflozin**

**Summary**

As part of a dual or triple therapy regimen in people with type 2 diabetes, the selective sodium-glucose cotransporter-2 (SGLT-2) inhibitor empagliflozin reduces glycated haemoglobin (HbA1c) levels by about 6 mmol/mol (0.5-0.6 percentage points) compared with placebo over 24 weeks. No serious safety concerns have been identified so far; however, there are no long-term safety data and no data on the effect on empagliflozin on the long-term complications of type 2 diabetes. Although use as monotherapy is one of the proposed indications for empagliflozin, it is unlikely to be used as first-line monotherapy in practice.

**Comment:** Locally JAPC has agreed to dapagliflozin from this new drug class after specialist initiation which should be prescribed in line with its NICE TA 288 in combination therapy for treating type 2 diabetes after DPP4s are considered inappropriate.

**ESNM37 Partial seizures in children and young people with epilepsy: zonisamide as adjunctive therapy**

**Summary**

In a double-blind, randomised controlled trial (RCT) in 207 children and young people aged 6-17 years with partial seizures, zonisamide (as adjunctive treatment) statistically significantly increased the number of participants achieving at least a 50% reduction in seizure frequency from baseline compared with placebo. Although the general safety profile for zonisamide in children and young people is similar to that in adults, certain adverse events raise concerns because they may have greater implications in children than in adults.

**Comment:** JAPC decided some months ago to classify all anti-epileptic drugs usually after specialist initiation from secondary care or under the guidance from tertiary centres. See local formulary on the medicines management website for classification.

**ESNM34 Asthma: fluticasone furoate/vilanterol (Relvar Ellipta) combination inhaler**

**Summary**

Relvar Ellipta is a combination inhaler containing 2 active ingredients not previously available for the treatment of asthma: fluticasone furoate (an inhaled corticosteroid [ICS]) and vilanterol (a long-acting beta-2 agonist [LABA]). There are no published studies that compare fluticasone furoate/vilanterol with a currently available ICS/LABA combination inhaler or currently available ICS monotherapy for a patient-orientated primary outcome such as exacerbation rate.

**Comment:** Classified as BLACK by JAPC in March 2014

### Unlicensed reviews

**ESUOM29 Difficult-to-treat scabies: oral ivermectin**

**Summary**

Oral ivermectin appears to be effective for treating people with classical or crusted scabies. However, differences in treatment regimens and the length of follow-up make interpreting comparisons with topical treatments difficult. Transient exacerbation of pruritus may occur at the beginning of treatment.

**Comment:** This drug has not formally been assessed by JAPC. Primary care prescribers should seek the advice of the medicines management team before being prescribing.

**ESUOM30 Pouchitis: rifaximin**

**Summary**

One small randomised controlled trial (RCT) and 2 small non-comparative observational studies provide limited evidence that rifaximin alone or in combination with ciprofloxacin can improve symptoms or induce remission in people with pouchitis that is refractory to other antibiotics. One small non-comparative observational study provides limited evidence that rifaximin monotherapy can help maintain remission in people with chronic pouchitis that has responded to other antibiotics.

**Comment:** Rifaxamin has only been agreed onto the Derbyshire formulary in the management of hepatic encephalopathy following specialist initiation only.
### 6. Useful resources

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<td>BMJ, JAMA and NEJM can be accessed in full-text directly through your NHS Athens Account via:</td>
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