Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary October 2016

Monthly News Update

Welcome to the KINES Monthly News Update for October 2016. Other recent 'KINES Rapid Updates' have covered:

- a Cochrane systematic review of studies looking at vitamin D supplementation in addition to standard asthma treatment to reduce exacerbations
- a study evaluating the STARWAVe clinical rule for children presenting to primary care with a respiratory tract infection
- a systematic review of studies comparing biosimilar TNF-alpha inhibitors with their reference products, which supports the biosimilarity and interchangeability of the products.
- a review interpreting the evidence for the safety and efficacy of statins

Update from NICE:

- In final draft technology appraisal guidance, NICE has recommended the type 2-diabetes treatment dapagliflozin in a triple therapy regimen only in combination with metformin and a sulfonylurea (SU). *(n.b. The other sodium-glucose co-transporter 2 inhibitors, empagliflozin and canagliflozin, are recommended in a triple therapy regimen with either metformin and an SU, or metformin and a thiazolidinedione [i.e. pioglitazone]).* Final guidance on dapagliflozin is due to be published in November.
- NICE has published an evidence summary for the HIV treatment Truvada for use as pre-exposure prophylaxis (PrEP) in adults at high risk of HIV infection. In the trials reviewed, Truvada reduced the risk of acquiring HIV infection by 44% to 86% compared with placebo/no prophylaxis. Issues to consider relate to uptake and adherence, sexual behaviour, drug resistance, safety, prioritisation for prophylaxis and cost-effectiveness. See NHS England for the latest announcement regarding commissioning of PrEP
- A draft version of the NICE 'Medicines Optimisation: Key Therapeutic Topics' document for 2017 is now available for comment. Please submit any feedback by the 22nd November 2016 to adminteam@nice.org.uk.

Regulatory agency safety update:

- An alert has been issued for Adalat LA, as there is a possibility that some packs of Adalat LA 60mg Tablets batch BXH84X5 may have been incorrectly repackaged into 30 mg cartons. Pharmacists are asked to check their stock of Adalat LA 30mg Tablets for any packs containing batch BXH84X5.
- The MHRA has advised parents of young children not to use unlicensed homeopathic teething products, which are available to purchase online, due to concerns over potential side effects. This advice relates only to US-manufactured products that are not known to be available in the UK, but may be advertised online.
- Prescribers are being alerted to the updated prescribing information for the selective Cox-2 inhibitor etoricoxib (Arcoxia), in particular the new lower recommended starting dose of 60 mg once daily for patients with rheumatoid arthritis and ankylosing spondylitis, with the option to increase to a maximum of 90 mg once daily. The lower 60 mg dose has been shown to effective in clinical trials. In light of cardiovascular and other risks with etoricoxib, the lowest effective dose should be used.
- The MHRA has published a toolkit on the risks of valproate medicines in female patients. It aims to provide improved information on the risks of taking valproate medicines in pregnancy, use of which is associated with up to a 4 in 10 risk of developmental disorders and approximately a 1 in 10 risk of birth defects.
- The EMA's Committee for Medicinal Products for Human Use (CHMP) has completed a review of metformin-medicines, concluding they can be used in patients with moderately reduced kidney function (GFR 30-59 ml/min/1.73m^2) for the treatment of type 2 diabetes. Product information, which varies between EU countries, will be updated. The contraindication for patients with severely reduced kidney function will remain (eGFR less than 30 ml/min/1.73m^2). This is in agreement with NICE guidance which recommends that the dose should be reviewed if eGFR is less than 45 ml/min/1.73m^2 and to avoid if eGFR is less than 30ml/min/1.73m^2.
- A number of measures have been recommended to improve the correct dosing of Keppra (levetiracetam) oral solution, following cases of accidental overdose. Advice to healthcare professional includes writing the dose in both 'mg' and 'ml' equivalences, providing advice on how to measure the prescribed dose, and reminding the patient/carer to only use the syringe included in the medicine's package. See EMA announcement for full advice.

NHS England/Department of Health/Public Health England:

- Public Health England (PHE) has updated the '*Helicobacter pylori* in dyspepsia: test and treat' quick reference guidance for primary care for consultation and local adaptation. A 2-page summary table is also available.
- Reducing the burden of tuberculosis (TB) is a priority for PHE, and new guidance has been published that outlines the actions that can be taken to further reduce the incidence of, and health inequalities associated with, TB. Advice to CCGs includes raising awareness of a number of resources, including TB alert, the RCGP TB-e-learning module for primary acre and the new latent TB toolkit.
- The specification for the 2017-19 Quality Premium for CCGs has been published. This scheme will cover a 2 year period; the maximum payment that can be achieved will again be set at £5 per head of population. There are several measures that relate directly to prescribing:
  - a reduction in inappropriate antibiotic prescribing for urinary tract infections, which will look at reductions in the trimethoprim:nitrofurantoin ratio, and a reduction the number of trimethoprim items prescribed to patients aged 70 years or greater. (Both will work towards increasing the use of nitrofurantoin as a first-line choice for UTIs, whilst reducing the use of trimethoprim, which is reported to have a significantly higher rate of non-susceptibility in at-risk groups.)
  - a sustained reduction of inappropriate antibiotic prescribing in primary care, which will expect CCGs to ensure items per STAR-PU are equal to or below England 2013/14 mean values of 1.161.
- The October 2016 Vaccine update is a special edition focussing on flu vaccination. Age eligibility groups for children are reiterated, as are the general principles for ordering live attenuated influenza vaccine. For information on supply of influenza vaccines in Scotland, Wales and Northern Ireland guidance from the respective health departments should be referred to.
- NHS England has developed two new toolkits to help promote GP online services to the public. Promotional materials are also available.

Other news:

- Specialist Pharmacy Service has published a Medication Safety Officer Handbook, which provides information and lists resources supporting individuals working in this role. Also, the Royal Pharmaceutical Society has published guidance for pharmacists on the additional monitoring of medicines (the Black Triangle scheme).
- The BMJ has published an article "*What a patient with a learning disability would like you to know*". It is by Emily Smith who has Down's syndrome, and concerns two very different interactions with healthcare professionals. On a related topic, the Centre for Postgraduate Education has released an e-learning programme on learning disabilities.
- A recent article in Pulse discusses new developments in the legal challenges over pregabalin. This follows a recent Court of Appeal's judgement which upheld an earlier High Court decision that Pfizer's patent claims for some forms of pain were invalid. An NHS England spokesperson is quoted as saying that NHS England is awaiting the final court order, "will consider what steps, if any, are appropriate at that stage" and that "pregabalin guidance (*see link*) remains in place until new guidance is issued."

Other news:

SPC revisions

- The SPC for bevacizumab (Avastin) now states that dose reduction for adverse reactions is not recommended. If indicated, therapy should either be permanently discontinued or temporarily suspended.

Launched

- Opicapone (Ongentys; Bial Pharma UK Ltd) has been launched as adjunctive therapy for Parkinson's. It is a third-generation catechol-O-methyltransferase inhibitor, and is indicated as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations. NICE is in the process of developing an evidence summary for this treatment (date of publication to be confirmed).

On the Horizon:

- The EMA's Committee for Medicinal Products for Human Use (CHMP) has issued a 'positive opinion' Rekovelle (follitropin delta) for controlled ovarian stimulation.
- Final European approval has been granted for eluxadoline (Triberzi) for irritable bowel syndrome with diarrhoea. Allergan anticipates launching eluxadoline in Europe during 2017. Final approval has also been issued for Bayer's Kyleena, a 5-year, low-dose levonorgestrel-releasing intrauterine device.

SMC/AWMSG Update *(Please see links for full SMC and AWMSG advice.)*:

- The Scottish Medicines Consortium (SMC) has accepted the following new medicines for routine use by NHS Scotland: lenvatinib (Lenvima), aflibercept (Eylea), progesterone (Lutigest), rilpivirine/emtricitabine/tenofovir alafenamide (Odefsey). Budesonide (Cortiment) and nivolumab (Opdivo) for non-squamous NSCLC, are accepted for restricted use.
- The All Wales Medicines Strategy Group (AWMSG) has recommended the following as options for use in NHS Wales: emtricitabine/tenofovir alafenamide (Descovy); golimumab (Simponi); rilpivirine (Edurant). Green tea leaf extract (Catephen) and brivaracetam (Briviact) are recommended for restricted use.