Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary - May 2017

Monthly News Update

Welcome to the KINES Monthly News Update for May 2017. Other recent 'KINES Updates' have discussed:

- prognostic models for the risks and benefits of prolonged use of dual antiplatelet therapy after a myocardial infarction, including the development of a new web resource
- the first study reporting cardiovascular outcomes with a proprotein convertase subtilisin–kexin type 9 (PCSK9) inhibitor (evolocumab)
- a US cohort study that received press attention, which investigated the use of antibiotics and risk of colorectal adenoma

Update from NICE:

- NICE has published updated guidance on eating disorders. The guideline is wide ranging and includes recommendations on specialist treatments for different disorders. Of relevance to primary care are recommendations on identification, assessment, referral (*if suspected, refer immediately to eating disorder service*), and monitoring (*GPs should offer a physical and mental health review at least annually to people with anorexia nervosa who are not receiving ongoing treatment for their eating disorder, including an ECG for people with purging behaviours or significant weight changes*).
- There has been an update to the type 2 diabetes guideline, specifically recommendations on the use of sodium–glucose cotransporter 2 (SGLT-2) inhibitors in initial drug treatment. Text has been added that treatment with an SGLT-2 may be appropriate for some adults if metformin is contraindicated or not tolerated. The treatment algorithm has also been updated.
- Final Technology Appraisal guidance has been published for: certolizumab and secukinumab for active psoriatic arthritis; daclizumab for relapsing–remitting multiple sclerosis; ixekizumab for moderate to severe plaque psoriasis; obeticholic acid for primary biliary cholangitis. All are recommended as treatment options, subject to various requirements specified in the individual guidelines. Pegylated liposomal irinotecan has not been recommended by NICE for the treatment of pancreatic cancer after gemcitabine.
- A consultation is currently open on new NICE guidance on antimicrobial prescribing for acute sinusitis. The draft guidance includes the recommendation to not prescribe an antibiotic to people presenting with symptoms for around 10 days or less. A high-dose nasal corticosteroid and either a 'no antibiotic' or 'delayed antibiotic' strategy may be considered for people who have had symptoms for 10 days or more. Choices of antibiotics are also listed for adults and children. Feedback can be submitted until the 23rd June.
- Finally, NICE has published quick and advanced guides to using the Healthcare Databases Advanced Search (HDAS) service, which provides access to a set of bibliographic databases. Guidance has also been provided on the search features available on the NICE Evidence Search.

Regulatory agency safety update:

- The MHRA has advised there have been rare reports of depression and suicidal thoughts in men using finasteride for male pattern hair loss. For this indication finasteride is marketed as Propecia and is used at a dose of 1 mg daily. Finasteride 5 mg (Proscar) is also used for the treatment and control of benign prostatic hyperplasia, and the product information for Proscar already lists depression as a possible adverse drug reaction (ADR). Patients should be advised to stop use of finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional.
- As part of a strategy to update information on older antibacterials to help address antimicrobial resistance, the European Medicines Agency (EMA) is recommending some changes to the prescribing information for vancomycin. Vancomycin by infusion can continue to be used for the treatment of serious infections, including meticillin-resistant *Staphylococcus aureus* (MRSA), and can also be used to prevent bacterial endocarditis. When taken by mouth, vancomycin should no longer be used for the treatment of staphylococcal enterocolitis or clearage of the gut in patients with a weakened immune system. **Use of oral vancomycin should be limited to the treatment of *Clostridium difficile* infections only**. These recommendations are subject to final approval by the European Commission (EC).

- The EMA's pharmacovigilance committee has concluded its review of factor VIII medicines for haemophilia finding there is no clear and consistent evidence of a difference in inhibitor development between plasma-derived and recombinant products. This review was prompted following the publication of a study in 2016, which had concluded that inhibitors develop more frequently with recombinant factor VIII products.
- Finally, the MHRA has published a new CPD-accredited e-learning module aimed at all healthcare professionals on the reporting suspected ADRs.

NHS England/Department of Health/Public Health England:

- There has been an update to Public Health England's (PHE) infection guidance for primary care, citing findings from a recent Canadian cohort study investigating antibiotics during pregnancy and the risk of spontaneous abortion. Under Principles of Treatment (page 5 of the main guidance document), the wording on antibiotic use in pregnancy has changed to:

  > "In pregnancy, take specimens to inform treatment; use this guidance alternative or seek expert advice. Penicillins, cephalosporins and erythromycin are not associated with increased risks. If possible, avoid tetracyclines, quinolones, aminoglycosides, azithromycin, clarithromycin, high dose metronidazole (2g stat) unless the benefits outweigh the risks. Short-term use of nitrofurantoin is not expected to cause foetal problems (theoretical risk of neonatal haemolysis). Trimethoprim is also unlikely to cause problems unless poor dietary folate intake, or taking another folate antagonist."

  Also on page 5, under 'acute sore throat: pregnant and penicillin allergy', erythromycin is recommended

- The latest Vaccine Update from PHE notes a recent decline in uptake of the shingles vaccine. The update reminds GPs to continue to offer the shingles vaccine to eligible patients from both current and previous cohorts to help prevent the significant burden of disease associated with shingles among older adults. Eligibility is summarised here.

Other news:

- There has been an update from NHS England about the operating model for the proposed Regional Medicines Optimisation Committees (RMOCs). Regarding time lines, the report states that delivery activity for RMOCs commenced in April 2017, with all 4 RMOCs expected to have had their inaugural meeting by the end June. The RMOCs will begin to take on the functions described in the operating model over the next 12 months.
- The General Pharmaceutical Council (GPhC) has launched a consultation on the revalidation of pharmacy professionals. It is proposed that each year pharmacy professionals would be required to: make 4 records for CPD (rather than the current 9), record a peer discussion with someone who understands their work and write a reflective account detailing how they meet the standards for pharmacy professionals. The consultation runs until the 17th July. Also, new standards for pharmacy professionals came into force this month.
- The Faculty for Sexual and Reproductive Health (FSRH) has published an update to guidance on Quick Starting Contraception, which includes advice on the immediate commencement of contraception. The guideline also includes clarification on starting hormonal contraception after oral emergency contraception.
- A new resource 'Pharmacy Guidance on Smoking and Mental Disorder' has been published. People with a mental disorder are less likely to receive smoking cessation interventions, and this resource provides information on medication dose reduction following smoking cessation and advice on smoking cessation and reduction pharmacotherapies for this patient group.
- The Royal College of Paediatrics and Child Health has produced updated guidance on stroke in childhood. Relevant to primary care, the guideline includes advice on diagnosis and referral pathways. Also, 'Enuresis: practical guidelines for primary care' has recently been published in the British Journal of General Practice. The guidelines have been developed in collaboration with a number of international societies.

Other news:

Launched

- A further brand of salmeterol/fluticasone propionate pressurised metered dose inhalers (pMDI) has been launched - Sereflo 25/125 and 25/250. The inhalers are licensed for patients with moderate to severe asthma not adequately controlled on a lower strength inhaled corticosteroid (ICS) combination product, and patients already adequately controlled on a mid- or high-strength ICS and a long-acting β2-agonist (LABA). The SPCs note an alternative salmeterol/fluticasone propionate product containing a lower ICS

Current options for salmeterol/fluticasone pMDIs:	Cost/inhaler *(120 puffs). MIMS May-17*
Lower ICS (25 µg salmeterol/50 µg fluticasone propionate)	
Seretide Evohaler 50	£18.00
Mid ICS (25 µg salmeterol/125 µg fluticasone propionate)	
Sereflo 25/125	£23.50
Sirdupla 25/125	£26.25
Seretide Evohaler 125	£35.00
Higher ICS (25 µg salmeterol/250 µg fluticasone propionate)	
Sereflo 25/250	£39.95
Sirdupla 25/250	£44.60
Seretide Evohaler 250	£59.48

dose would need to be used as initial maintenance therapy in adults with moderate persistent asthma. Also, use of a spacer is recommended only for Sereflo 25/250, with which the Volumatic device and the AeroChamber Plus are both compatible. If a spacer is required for use with Sereflo 25/125, an alternative inhaler should be prescribed. Sereflo is not licensed for use in children. The currently available salmeterol/fluticasone propionate aerosol inhalers are summarised in the table above.

- Cuderm is a new colloidal oatmeal skin care range, i.e. similar to Aveeno and Aproderm products. The manufacturer (Synergy Biologics) has advised that the products will be listed on EMIS from 1st June. Costs are provided in the table, with savings versus existing products ranging from ~5-24%.

Product	Cuderm	Aveeno	Aproderm
Cream 100 ml	£3.37	£4.25	-
Cream 500 ml	£6.11	£8.06	£6.47
Lotion 300 ml	£3.89	£4.11	-
Lotion 500 ml	£5.66	£7.13	-
Hand cream 75 ml	£3.25	£3.99	-
Wash 250 ml	£2.90	-	-
Wash 500 ml	-	£7.30	-

Costs: direct communication from manufacturer. May-17.

SPC changes / license extensions

- The license for Glucophage SR (sustained-release metformin) has been extended to include use in prevention of type 2 diabetes. The new indication is as follows:
    - Reduction in the risk or delay of the onset of type 2 diabetes in adult, overweight patients with impaired glucose tolerance and/or impaired fasting glucose, and/or increased HbA1C who are:
        - at high risk for developing overt type 2 diabetes mellitus (refer to section 5.1 of the SPC), and
        - still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months.

    Treatment with Glucophage SR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk. Lifestyle modifications should be continued when metformin is initiated, unless the patient is unable to do so because of medical reasons.

    Metformin is included as a treatment option in the NICE guideline on prevention of type 2 diabetes in high risk individuals. Prescribers should be aware that NICE recommends standard-release metformin first-line (n.b. *use is off-label*); sustained-release metformin is recommended as an alternative, where a person cannot tolerate a standard-release formulation.
    We note that CCGs may have other 'preferred' brands of sustained-release metformin.

On the Horizon:

- The first triple combination inhaler for chronic obstructive pulmonary disease (COPD) has been recommended for approval. The inhaler (brand name Trimbow; manufacturer Chiesi) contains the ICS beclometasone, the LABA formoterol and the long--acting muscarinic antagonist (LAMA) glycopyrronium. It will be available as a pMDI delivering a solution with a dose per actuation of 87/5/9 µg of the respective active substances and is to be taken twice daily. The indication is for maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA. This recommendation is subject to final EC approval.
- Two studies investigating this combination were recently published in The Lancet: TRILOGY (Trimbow *vs.* ICS/LABA) and TRINITY (Trimbow *vs.* tiotropium and ICS/LABA + tiotropium open triple therapy). Studies versus newer LABA/LAMA combinations are not available.

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

- The Scottish Medicines Consortium (SMC) has published the following advice this month:
    - Accepted for use in NHS Scotland: micronised progesterone (Utrogestan Vaginal; *assisted reproductive technology*); nepafenac (Nevenac; *postoperative macular oedema*)
    - Accepted for restricted use: belimumab (Benlysta; *add-on therapy in lupus*); idebenone (Raxone; *Leber's Hereditary Optic Neuropathy*)
    - Not recommended: alectinib hydrochloride (Alecensa; *lung cancer*); liraglutide (Saxenda; *weight management*); talimogene laherparepvec (Imlygic; *unresectable melanoma*)