Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary November 2016

Monthly News Update

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

- the 2017 update to the GOLD COPD guideline, which includes changes to disease categorisation and treatment algorithms
- an analysis of antipsychotic prescribing in care homes, which has reported little improvement in the 4 years following the launch of the National Dementia Strategy
- the findings that underpinned Public Health England's new recommendations on vitamin D

Update from NICE:

- NICE has recommended the sodium-glucose co-transporter 2 inhibitor dapagliflozin (Forxiga) in a triple therapy regimen for treating type 2 diabetes, but only in combination with metformin and a sulfonylurea. NICE has also recommended nivolumab (Opdivo) as an option for previously treated advanced renal cell carcinoma, when provided with the discount agreed in the patient access scheme.
- In draft guidance, NICE is recommending the antiplatelet ticagrelor (60 mg daily) for extended use, as an option to prevent further atherothrombotic events in adults who have had a myocardial infarction and who are at high risk of a further event. Treatment may be continued for up to 3 years. Final guidance is expected next month.
- NICE has launched an e-learning tool on the management of food allergies and anaphylactic reactions. It has been developed to support implementation of the related NICE quality standards on food allergy and anaphylaxis.
- Finally, NICE has published an evidence summary on the (off-label) use of rituximab in minimal change disease and focal segmental glomerulosclerosis, both of which are types of glomerulonephritis.

Regulatory agency safety update:

- The MHRA has issued a drug safety update on the exacerbation of rosacea symptoms in patients treated with brimonidine gel (Mirvaso), which is licensed for the treatment of facial erythema of rosacea. In clinical trials, symptom exacerbation was seen in 16% of patients using brimonidine gel; most patients recovered on stopping treatment. The MHRA advice is that patients should start treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment. Patients should be advised not to exceed the maximum (1 g of gel - approximately 5 pea-sized amounts) and warned to stop treatment and consult their doctor if worsening of rosacea symptoms occurs.
- An MHRA medical advice alert has requested that systems are in the place to remind diabetic patients:
  - to only use devices that have been recommended or prescribed for them by their diabetes specialist
  - not to stop or change their prescribed insulin management regimen without seeking the advice of their diabetes specialist, and
  - to contact their diabetes specialist if invited by a manufacturer to test a new device e.g. via social media.

NHS England/Department of Health/Public Health England:

- The November Vaccine Update from Public Health England (PHE) is calling on healthcare professionals to offer the shingles vaccination to all eligible patients, as uptake has been falling recently. It's been reported that there some uncertainty about who can receive this vaccine; eligibility can be checked on this poster.
- Updated PHE guidance on the management of pertussis within a healthcare setting has been published. Changes include revised definitions of priority groups (in particular the definition of a vulnerable infant), revised exclusion periods (reduced from 5 days to 48 hours after antibiotics) and updated flow diagrams for management of cases and close contacts. An update to PHE's Respiratory tract infections control document is also available, summarising advice on the prevention and control of acute respiratory infections within healthcare settings.
- A new leaflet for parents/carers explaining 'off-label' vaccines is available. 'Off-label' vaccines are vaccines that have been briefly stored outside the recommended storage temperature, but that can still be used. The NHS has a duty to advise parents/carers where such vaccines are being offered or have been used.

Other news:

- A new survey has highlighted the poor awareness in women taking sodium valproate about the risks of this medicine in pregnancy. The risk of developmental disorders is up to 4 in 10 and the risk of birth defects is approximately 1 in 10 in women who take valproate while pregnant. An MHRA toolkit is available to help clinicians discuss these issues with patients.
- The British Heart Foundation has launched a new resource to improve the detection and management of high blood pressure. The resource presents data for CCGs, with a commentary on what could be improved locally.
- The 2016 English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) report has been published. A notable finding is the rising rates of bloodstream infections caused by *Escherichia coli* and *Klebsiella pneumoniae,* now seen as a key government priority. Also, in light of high levels of resistance, the report comments that trimethoprim can no longer be advised as the first-line empiric antibiotic treatment for urinary tract infections in England. Both issues are included as measures in the recently announced Quality Premium scheme for CCGs for 2017/19.
- An update to the British guideline on the management of asthma is available. This is a minor update and includes some changes to the tables categorising inhaled corticosteroids by dose, as well as some other corrections.
- The latest summary of Prescribing Costs in Hospitals and the Community in England has been published. The cost of medicines in hospitals continues to rise at a greater rate than in primary care (up by 13.6% and 4% respectively from 2014/15), driven by the introduction of new medicines and the greater use of specialist medicines. Hospital medicines now account for 45.2% of total NHS spend on medicines.

  *The 'top 10 by spend' medicines positively appraised by NICE are shown in the table for each sector. We note the recent launch of infliximab, insulin glargine and etanercept biosimilars; rituximab biosimilars are likely to be available next year. Rosuvastatin's patent will expire late 2017. *Whilst rosuvastatin has been listed as 'positively appraised' by NICE, atorvastatin is the only high-intensity statin specifically named in the NICE lipid modification guideline, and that the full guideline states "Given the considerably higher cost of using rosuvastatin, it would need to be considerably more effective than atorvastatin for there to be a possibility that its use could be cost-effective. In the absence of trial evidence of greater effectiveness the guideline development group are therefore unable to recommend the use of rosuvastatin'. (Ref: 2016 NICE Key Therapeutic Topic on lipid-modifying drugs.)*

'Top 10' medicines positively appraised by NICE by spend (2015/16)	
In Hospitals (£million)	**In Primary care (£million)**
Adalimumab - £391	Rivaroxaban - £94
Ranizumab - £249	Insulin glargine - £80
Etanercept - £218	Buprenorphine (*exc. combinations*) - £72
Aflibercept (*soln for injection*) - £198	Atorvastatin - £51
Infliximab - £178	Ezetimibe - £51
Rituximab - £156	Apixaban - £48
Trastuzumab - £152	Liraglutide - £47
Lenalidomide - £142	Rosuvastatin* - £47
Enzlutamide - £86	Insulin detemir - £44
Imatinib - £82	Aripiprazole - £43

- Specialist Pharmacy Services (SPS) has published Prescribing Outlook National Developments (2016), a resource to support medicines optimisation and budget planning for 2017/19. A Prescribing Outlook cost calculator has also recently been produced by SPS.

Drug update:

Launched

- Cinqaero (reslizumab) 10 mg/ml concentrate for solution for infusion is a new monoclonal antibody treatment for the management of severe asthma. It is licensed as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment. NICE is developing technology appraisal guidance for this treatment, which is due to be published in April 2017. The initial appraisal consultation document indicates NICE is minded to not recommend the treatment, requesting further information from the manufacturer.

SPC revisions

- The Summary of Product Characteristics (SPC) for Novorapid (insulin aspart) formulations has been updated to reflect that NovoRapid is now licensed for use in children aged 1 year and above.

On the Horizon:

- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a 'positive opinion' for Suliqua, a combination of insulin glargine and lixisenatide for the treatment of type 2 diabetes. Three biosimilars were also given 'positive opinions' by the CHMP this month:
  - Lusduna - Merck's biosimilar insulin glargine, which will potentially be the second biosimilar of insulin glargine to become available, the first being Abasaglar.
  - Movymia and Terrosa - both are teriparatide biosimilars for the treatment of osteoporosis (note - the UK patent for teriparatide is not expected to expire until April 2021 [ref]).

SMC/AWMSG Update (Please see *SMC* and *AWMSG* for full advice, including restrictions)

- The Scottish Medicines Consortium (SMC) has accepted the following new medicines for use in NHS Scotland: olaparib (Lynparza); nivolumab (Opdivo); sofosbuvir/velpatasvir (Epclusa); migalastat (Galafold) and dequalinium chloride (Fluomizin).
- The All Wales Medicines Strategy Group (AWMSG) has recommended the following as options for use in NHS Wales: levofloxacin (Quinsair); dequalinium chloride (Fluomizin); sofosbuvir/velpatasvir (Epclusa); emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey).