Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary December 2016

Monthly News Update

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

- an update on the recently launched, lower cost tiotropium dry powder inhaler **Braltus**
- the findings, and limitations, of the PRECISION study, which investigated the cardiovascular safety of celecoxib, ibuprofen and naproxen in the treatment of arthritis
- a randomised study investigating long-term oxygen treatment in patients with stable chronic obstructive pulmonary disease and moderate desaturation. Treatment did not extend the time to death or first admission, improve lung function or exercise capacity, and did not provide sustained benefit with regard to other measured outcomes.

Update from NICE:

- NICE has published updated guidance on **low back pain and sciatica**. Revisions include:
  - The use of risk stratification tools, such as Keele's **STarT Back**, to help inform shared decision-making about management options.
  - An emphasis on exercise and self-management as key interventions, and encouragement to continue with normal activities as far as possible.
  - Paracetamol alone is no longer a first-line pharmacological option for managing low back pain. Instead, NSAIDs should be considered, taking into account gastrointestinal, liver and cardio-renal toxicity, the person's risk factors, and the use of gastroprotective treatment. NSAIDs should be prescribed at the lowest effective dose for the shortest possible period of time. (*For sciatica treatment recommendations, see the neuropathic pain guideline.)*
  - Weak opioids (with or without paracetamol) should be considered for managing acute low back pain **only** if an NSAID is contraindicated, not tolerated or has been ineffective. **Opioids should no longer be offered for managing chronic low back pain.** Also, selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors, tricyclic antidepressants and anticonvulsants should not be offered.
  - Acupuncture is no longer recommended, and manual therapies (spinal manipulation, mobilisation or soft tissue techniques, such as massage) should only be used as part of a treatment package that also includes exercise. The guideline also recommends against the routine use of imaging, unless the result is likely to change management.
- Final guidance has now been published recommending the antiplatelet **ticagrelor** (60 mg twice daily) in combination with aspirin as an option for extended use (up to 3 years) to prevent further atherothrombotic events in adults who have had a myocardial infarction and who are at high risk of a further event.

Regulatory agency safety update:

- The MHRA has clarified that concomitant use of spironolactone with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) increases the risk of severe hyperkalaemia, particularly in patients with marked renal impairment, and **should be used with caution**. The same advice applies to the concomitant use of the aldosterone antagonist eplerenone with ACEi or ARB in heart failure. The previous MHRA update may have been interpreted by some readers to mean that spironolactone should not be used with an ACEi or ARB.
- The MHRA has warned clinicians that co-administration of a corticosteroid (including intranasal and inhaled steroids) with an HIV-treatment-boosting agent (i.e. ritonavir or cobicistat) may increase the risk of adrenal suppression due to a pharmacokinetic interaction. Co-administration is not recommended unless potential benefits are likely to outweigh the risks, in which case beclomethasone should be considered, and the patient monitored for systemic corticosteroid-related reaction.
- The European Medicines Agency (EMA) has confirmed a recommendation to screen all patients for hepatitis B before starting treatment with direct-acting antivirals for hepatitis C. Patients infected with both hepatitis B and C viruses must also be monitored and managed according to current clinical guidelines. These measures aim to minimise the risk of hepatitis B re-activation, which is thought to be a consequence of reduced levels of the hepatitis C virus, which, as a co-infection, is known to suppress hepatitis B.

NHS England/Department of Health/Public Health England:

- The SNOMED CT clinical vocabulary is to replace Read codes within the NHS. This change must be adopted by all GP service providers before April 2018, and will affect those who add or extract data to or from clinical systems. CCGs can register to receive a briefing document and access webinars about the transition via the NHS Digital website.
- NHS England has launched an update to the medicines optimisation (MO) dashboard. The dashboard is now presented using a similar platform to NHS RightCare's Atlas, and includes trend data. A number of changes have been made to the dashboard's comparators, including the addition of patient experience metrics. NHS RightCare has also recently published data packs for CCGs on long-term conditions.
- Due to a rise in influenza circulating in the community, the Chief Medical Office has announced that GPs and other prescribers in primary care can now prescribe antiviral medicines for the prophylaxis and treatment of influenza at NHS expense. Information on at risk groups and patient eligibility for treatment is available from Public Health England.

Other news:

- The General Pharmaceutical Council (GPhC) has launched a consultation on religion, personal values and beliefs in pharmacy practice, for the new standards for pharmacy professionals that are **due to come into effect in 2017.** The proposals would change the expectations of pharmacy professionals when their religion, personal values or beliefs might, in certain circumstances, impact on their ability to provide services, and shift the balance in favour of the needs and rights of the person in their care. The consultation runs until 7th March 2017.
- The General Pharmaceutical Council (GPhC) has agreed to changes to its Continuing Professional Development (CPD) framework. A random sample (a minimum of 2.5%) of pharmacy professionals will now have their CPD records called for review each year. Where a registrant has met the GPhC's CPD requirements, they will not be recalled for another review for at least two years.
- Professional Standards on the reporting, learning, sharing, taking action and review of incidents have been published. The standards are aimed at pharmacists, pharmacy technicians and pharmacy teams in the UK, and have been jointly developed by the Royal Pharmaceutical Society, the Association of Pharmacy Technicians UK and the Pharmacy Forum of Northern Ireland.

Other news:

Launched

- Following the expiry of tiotropium's patent earlier this year, **Braltus** (10 microgram tiotropium powder for inhalation) has been launched by Teva. Braltus provides the same 10 microgram delivered dose of tiotropium as Spiriva HandiHaler and has been priced around £8 to £9 less (*MIMS Dec-16, 30-day treatment costs*). To assist local discussions, Keele has recently published a 'KINES Rapid Update' on this new inhaler.

On the Horizon:

- The EMA's Committee for Medicinal Products for Human Use (CHMP) has issued 'positive opinions' for two more biologics this month:
  - Lifmior **- Pfizer's version of etanercept, which is considered identical to Enbrel**
  - Truxima - Celltrion's rituximab biosimilar
- The CHMP has also given a positive opinion for a change in the indication for empagliflozin, which acknowledges the drug's cardiovascular effects, as were seen in EMPA-REG OUTCOME study. *(A KINES Rapid Update, published in October 2015, discussed this study.)* Assuming the CHMP recommendation is adopted, the new indication will be:

  "for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
  - *as monotherapy when metformin is considered inappropriate due to intolerance*
  - *in addition to other medicinal products for the treatment of diabetes*

  For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1."
- The wording ratified by the CHMP is thus somewhat different to that recently approved by the FDA, which authorised a separate, additional indication for prevention of death due to cardiovascular disease (CVD) in adults with both type 2 diabetes and existing CVD.

SMC Update:

- The Scottish Medicines Consortium (SMC) has accepted the following new medicines for use in NHS Scotland:
  - cabazitaxel (Jevtana [for prostate cancer])
  - cefuroxime (Aprokam [for prophylaxis of postoperative endophthalmitis after cataract surgery]

  See above verdicts for full SMC advice, including restrictions.