Derbyshire Medicines Management Newsletter

www.derbyshiremedicinesmanagement.nhs.uk

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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.

1. Round up of what's in the news

Omega-3 supplements do not prevent heart disease, stroke or death

NIHR signal. Published on 6 November 2018. doi: 10.3310/signal-000670

Omega-3 fatty acid supplements from fish oils or plants have little or no effect on the risk of heart disease, stroke or overall death rates. This finding contradicts a widespread belief that omega-3 supplements are protective. Previous evidence in favour of omega-3 supplements is mainly derived from trials at high risk of bias. The better evidence identified in this review does not demonstrate any health benefit.

This updated Cochrane review found 79 randomised controlled trials that compared increased omega-3 intake to usual or lower intake for at least 12 months. Most of the trials used supplements, but some used foods rich in omega-3 or offered dietary advice. Overall, 112,059 adults were included; participants included adults at low and high risk or with established cardiovascular disease. The trials took place in North America, Europe, Australia and Asia, with eight from the UK.

Twenty-five of the trials had a low risk of bias and can be considered highly trustworthy. The rest had a moderate or high risk of bias. Most of the studies assessed omega-3 supplementation with capsules but few examined the effects of other dietary sources, and so it is possible the health effects available from food sources differ.

The review provides robust evidence confirming current guidance that omega-3 supplements should not be used to prevent cardiovascular disease. However, few of the trials included in this review looked at food sources of omega-3. Other studies have demonstrated that intake of omega-3 is essential to human health, and it is possible that the intake of foods rich in omega-3 may have a place in a healthy balanced diet

NICE guidance CG181states there is no evidence that omega-3 fatty acid compounds help to prevent CVD. Local classification of omega-3 is BROWN after consultant recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins.

Antibiotics for exacerbations of chronic obstructive pulmonary disease

Cochrane Systematic Review - Intervention Version published: 29 October 2018

Vollenweider DJ, Frei A, Steurer-Stey CA, Garcia-Aymerich J, Puhan MA

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010257.pub2/full

The objective of this review was to assess effects of antibiotics on treatment failure as observed between seven days and one month after treatment initiation (primary outcome) for management of acute COPD exacerbations, as well as their effects on other patient-important outcomes (mortality, adverse events, length of hospital stay, time to next exacerbation).

The review included 19 trials with 2663 participants (11 with outpatients, seven with inpatients, and one with ICU patients).

Researchers have found that antibiotics have some effect on inpatients and outpatients, but these effects are small, and they are inconsistent for some outcomes (treatment failure) and absent for other outcomes (mortality, length of hospital stay). Analyses show a strong beneficial effect of antibiotics among ICU patients.

Recent NICE guidance still advocates the use of antibiotics for acute exacerbations of COPD. See local guidance for further details.

The blood-thinner apixaban is less likely to cause major bleeding than warfarin

NIHR signal. Published on 16 October 2018. doi: 10.3310/signal-000661

This cohort study analysed UK primary care data in two databases with 196,061 people prescribed warfarin or direct acting oral anticoagulants (DOACs) between 2011 and 2016. It linked patient-level data to the hospital records to see if complications had been recorded here.

Researchers followed patients on warfarin for on average six to 11 months and on DOACs for three to nine months.

This was a large representative study and should reflect real-world use, but it did not look at patient adherence to the prescribed medications.
Fewer people had intracranial bleeding on the direct acting oral anticoagulants apixaban, dabigatran and rivaroxaban than warfarin. However, the death rate was higher for people taking low dose apixaban and rivaroxaban compared with warfarin, emphasising the need to base decisions on multiple sources of evidence.

The study was observational and based on routinely collected data from general practice registries, so the selection of patients and unmeasured factors may have biased the results. However, the study is large and provides some reassurance about the use of direct-acting oral anticoagulants as an alternative to warfarin.
This study provides further safety data which will aid shared-decision making on the use of DOACs as an alternative to warfarin.
Locally the DOAC's have been classified in line with various NICE guidance and are available as treatment options alongside warfarin.

Deleted products 2018 | MIMS online October 2018

Add Ins	Nitro-Dur	Slow-Trasicor
Fosamax	Penbritin	Slow-Trasicor

2. Drug safety update primarily relating to primary care prescribing

(For more information see Drug Safety Update)

Relevant to primary care

Ritonavir-containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels

Monitor thyroid-stimulating hormone (TSH) in patients treated with levothyroxine for at least the first month after starting and ending ritonavir treatment.

Advice for healthcare professionals:

- reduced thyroxine levels have been reported in patients concomitantly taking ritonavir-containing products and levothyroxine
- monitor thyroid-stimulating hormone (TSH) in patients treated with levothyroxine for at least the first month after the start and end of ritonavir treatment
- report suspected adverse drug reactions resulting from interactions on a Yellow Card

Transdermal fentanyl patches: life-threatening and fatal opioid toxicity from accidental exposure, particularly in children

Provide clear information to patients and caregivers about how to minimise the risk of accidental exposure and the importance of appropriate disposal of patches. We continue to receive reports of unintentional opioid toxicity and overdose of fentanyl due to accidental exposure to patches.

Advice for healthcare professionals:

- always fully inform patients and their caregivers about directions for safe use for fentanyl patches, including the importance of:
- not exceeding the prescribed dose
- following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application
- not cutting patches and avoiding exposure of patches to heat including via hot water (bath, shower)
- ensuring that old patches are removed before applying a new one
- following instructions for safe storage and properly disposing of used patches or those which are not needed (see instructions below)
- ensure that patients and caregivers are aware of the signs and symptoms of fentanyl overdose (see below) and advise them to seek medical attention immediately (by dialing 999 and requesting an ambulance) if overdose is suspected
- in patients who experience serious adverse events, remove patches immediately and monitor for up to 24 hours after patch removal
- report any cases of accidental exposure where harm has occurred or suspected side effects via the Yellow Card Scheme

3. Local news and GP/pharmacist queries

GP QUERY

Question:

Sodium valproate usage and women of childbearing potential.

Data from the MHRA and from the meds management team refers to "women of childbearing potential". However, there is a warning system on SystmOne, but this only pops up for women aged 9-49yrs. We had originally done an in-house search based on women up to the age of 55yrs as there is obviously on-going risk of pregnancy (albeit small) after the age of 50yrs. Do you know if there is any clear guidance about our obligations/recommendations for women between 50-55yrs as these make up most of our cohort? It creates a bit of complexity in terms of designing a robust system to cover all women when only some get the automatic warnings/read codes applied by SystmOne. I'd be grateful for any advice about this.

Answer:
Unfortunately, there isn't clear national guidance as such. As you say, the official MHRA information refers to "child-bearing potential" which they define as "premenopausal female who is capable of becoming pregnant". NHS Digital asked system suppliers to provide search and audit functions and SystmOne has gone with the range 12 to 49 years. This age-range is also being used nationally by Pharmacy bodies (Community Pharmacy Patient Safety Group and Royal Pharmaceutical Society, in partnership with the other pharmacy bodies represented on the MHRA's Valproate Stakeholder Network) in the advice provided to Community Pharmacies and has also been adopted locally by Southern Derbyshire CCG in their work with practices. So in short, there isn't an official age range in the MHRA documents although 12 to 49 seems to be the range adopted by a number of national bodies. I agree it would potentially miss some older women who would still be at risk of pregnancy, although there would be wide variation in individual circumstances. I have raised with the CCG Medication Safety Pharmacist and she is aware of other practices that have taken the decision to increase the range higher in their practices.

In other local news:
Finalised food fortification video - devised by the North Derbyshire Dietitians can be accessed via the Derbyshire Medicines management website.

4. Medicines safety issues

Nil

5. Quality, Innovation, Productivity and Prevention (QIPP)

October 2018 – price concessions
Prescribers should note that the re-imbursement price on FP10 may not necessarily reflect the Drug Tariff price as a result of a drug shortage. These concessionary prices are set by the Department of Health to reflect actual market prices.
A concession only lasts until the end of the month in which it was granted. If there is an on-going supply problem, it is possible that a new concession will be granted by the Department of Health the following month, however this is not guaranteed

Drug	Pack size	Price concession	Drug tariff price
Amisulpride 100mg tablets	60	£8.25	£4.89
Amisulpride 200mg tablets	60	£13.40	£8.01
Amisulpride 50mg tablets	60	£5.22	£2.76
Buprenorphine 2mg sublingual tablets sugar free	7	£5.25	£0.95
Buprenorphine 8mg sublingual tablets sugar free	7	£15.40	£2.14
Orlistat 120mg capsules	84	£24.01	£17.40
Ramipril 5mg tablets	28	£5.54	£0.83
Topiramate 100mg tablets	60	£18.68	£14.64
Valsartan 160mg capsules	28	£11.95	£3.32
Valsartan 80mg capsules	28	£9.95	£2.89

QIPP TIP
Prescribers are reminded:

- **Conotrane cream** (dimeticone, benzalkonium chloride) for use as 1st line in lower risk patients.
- **Drapolene cream** (cetrimide, benzalkonium chloride) for use as 1st line in lower risk patients.
- **Medi Derma S** cream, film spray/applicator is for use in higher risk patients. This is the cost effective alternative barrier preparation to Cavilon.

These are only indicated in certain situations:

- Peri-wound protection: cream/film (spray, foam applicator) for protection from bodily fluids e.g. exudate
- Preventing incontinence dermatitis in high risk patients (e.g. very acidic urine, diarrhoea)
  - Not all incontinence patients will require a barrier cream; professional judgement is required.
  - If skin is dry/fragile an emollient cream or gel could be applied after cleansing (apply sparingly).
  - Barrier creams can clog incontinence pads if applied too thickly.
- Stomas: protecting broken or sore peristomal skin.
  - General barrier creams are NOT recommended as majority will reduce adhesion of bags/flanges.
  - Films/wipes reserved for selected patients only i.e. diabetics, palliative patients and difficult stomas
  - For acute prescription only

Silver Sulfadiazine Cream (Flamazine) - BROWN traffic light classification. Tissue Viability Nurses recommend to be used only as per wound care formulary, not to be used routinely for wound dressing

6. NICE summaries: New medicines (relating to primary care prescribing)

September 2018

Relevant for primary care: Chronic heart failure in adults: diagnosis and management. This guideline covers diagnosing and managing chronic heart failure in people aged 18 and over. It aims to improve diagnosis and treatment to increase the length and quality of life for people with heart failure.

Local heart failure guidance is currently under review to bring in line with NICE.

7. Useful resources

BMJ	www.thebmj.com
JAMA: The Journal of the American Medical Association	http://jama.ama-assn.org/
The Lancet	www.thelancet.com
The New England Journal of Medicine	http://content.nejm.org/
BMJ, JAMA and NEJM can be accessed in full-text directly through your NHS Athens Account via: National Library for Health: search via My Journals MyAthens: Via National Library for Health Resources or Local Resources. Current Lancet articles are sometimes available with free registration from http://www.thelancet.com/content/register. Print copies of The Lancet are available at DCGH library.	www.library.nhs.uk or www.athens.ac.uk
If you have not already registered for an NHS Athens Account, please register at: NB: It is recommended that you register on a Trust (NHS) PC for speedy confirmation of your username a password. Once registered, your account can be accessed from any computer with online access.	https://register.athensams.net/nhs/nhseng/
UKMI Nathnac NHS evidence Electronic medicines compendium Clinical Knowledge Summaries Medicines Prescribing Centre (Formerly NPC) Medicines for children (patient information leaflets Drugs in lactation	http://www.ukmi.nhs.uk/ https://www.evidence.nhs.uk/search?om=%5B%7B%22srn%22%3A%5B%22%20ukmi%20%22%5D%7D%5D http://www.nathnac.org/ http://www.evidence.nhs.uk/ http://www.medicines.org.uk/emc/ www.cks.nhs.uk. http://www.nice.org.uk/mpc/ http://www.medicinesforchildren.org.uk/ http://www.midlandsmedicines.nhs.uk/content.asp?section=6&subsection=17&pageIdx=1
UK teratology services	http://www.uktis.org/index.html
Vaccine update- Vaccination newsletter for health professionals and immunisation practitioners	https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update