Keep Taking the Tablets Newsletter

Issue 28 – April 2016

NHS Dorset Clinical Commissioning Group

Quick bites

- Medicines Health Regulatory Agency (MHRA) Drug Safety Update
- March 2016 Vaccine Update (Public Health England) – includes information on vaccine storage and cold chain; administering multiple vaccines in one session and pertussis vaccination schedule changes.
- NICE Quality Standard on medicines optimisation – covering the safe and effective use of medicines for all people who take medicines, including people who are receiving suboptimal benefit from medicines.
- A licensed nitrazepam liquid is now available – please prescribe as "nitrazepam 2.5mg/5ml oral suspension". It costs £10.60 for 150ml. Prescribing as "nitrazepam 2.5mg/5ml suspension **sugar free**" will mean that the expensive unlicensed special order product will still be supplied.

Medicines safety: Updated advice on the risk of DKA with SGLT2 inhibitors

The manufacturers of canagliflozin, dapagliflozin and empagliflozin have written to healthcare professionals regarding updated advice on the risk of diabetic ketoacidosis (DKA). There have been rare but serious, sometimes life-threatening and fatal cases of DKA linked with these treatments and clinicians are encouraged to continue reporting suspected adverse reactions through the yellow card system.

The advice notes that DKA must be considered in the event of non-specific symptoms such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness. Clinicians should inform patients of the signs and symptoms of metabolic acidosis and advise them to seek immediate medical advice if they develop. In patients who develop DKA, treatment with SGLT2 inhibitors should be stopped immediately and only restarted if another clear precipitating factor is identified and resolved.

Before starting treatment it is recommended that risk factors that predispose individuals to DKA are considered. These include:

- a low beta-cell function reserve (e.g. type 2 diabetes with a low C-peptide, latent autoimmune disease in adults or patients with a history of pancreatitis)
- conditions that lead to restricted food intake or severe dehydration
- sudden insulin reduction
- increased insulin requirements due to acute medical illness
- surgery
- alcohol abuse

International organisation for standardisation (ISO) standard for blood glucose meters coming into force

The ISO standard for blood glucose meters (15197:2013) comes into force on 1st June and means that non-compliant meters will no longer be marketed. Test strips for non-compliant meters will likely become difficult to source as remaining supplies are used up. A letter on behalf of the manufacturers to the Royal College of Pathologists is available to download and provides more information. The introduction of the standard should be used as an opportunity to review patients and consider changing them where appropriate to a formulary choice meter.

Prescribing data for 2015/16 indicates that relatively few patients locally will be affected by this change, other than a few patients using Freestyle testing strips (note Freestyle lite, Freestyle Optium and Freestyle Optium Blood B ketone test strips are all designated as ISO 15197:2013 compliant). A review of the current recommendation is underway and should be available later this year.

Revised NICE guidance on Type 2 diabetes in adults (published December 2015)

The revised NICE guideline on Type 2 diabetes in adults: management [NG28] was the headline topic at a recent NICE working group meeting. Key changes to note are that the guideline:

- Strengthens patient education programme recommendations and emphasises individualising patient choice, including stopping any ineffective medicines.
- Prioritises lifestyle advice, and signposts to NICE guidance on lifestyle advice.
- Advises involving people in decisions about their individual HbA1c levels and supporting them to achieve their own targets.
- Advises using DVLA guidance when offering self-monitoring of blood glucose levels.
- Advises offer metformin 1st line, but if contraindicated or not tolerated, to consider DPP-4 inhibitor, pioglitazone or sulphonylurea.
- Includes recommendations for sulphonylurea, DPP-4 inhibitors, SGLT-2 inhibitors, pioglitazone, GLP-1 mimetics in combinations if metformin alone insufficient.
- Strengthens support and education requirements for those requiring insulin. Advises offer NPH 1st line, then advises consider detemir or glargine, (and biosimilars) pre-mixed (biphasic) preparations; with SGLT-2 inhibitors if necessary.
- Provides guidance on gastroparesis, painful diabetic neuropathy, autonomic neuropa-thy, diabetic foot problems, diabetic kidney disease, erectile dysfunction.

DO NOT DOs included in the guideline:

- Do not offer antiplatelet therapy (aspirin or clopidogrel) as primary prevention for CVD. Signposts to NICE guidelines on CVS disease and MI.
- Do not combine an ACEi with an ARB to treat hypertension.
- Do not offer degludec, as it is not cost-effective.

NICE Evidence Summary: Chronic wounds – advanced dressings & antimicrobial dressings

Systematic reviews and meta-analyses have identified little good quality evidence from randomised controlled trials (RCTs) to support the use of advanced or antimicrobial dressings (such as iodine, honey or silver dressings) for chronic wounds. As well as being few in number, many of the RCTs have significant limitations and the evidence is generally of low quality. Further good quality research is needed to improve confidence in the evidence, and would probably change the implications for practice.

Dressing selection should be made after careful clinical assessment of the person's wound, their clinical condition, and their personal experience and preferences. If a specific dressing cannot be adequately justified on clinical grounds, it would seem appropriate for healthcare professionals to routinely choose the **least costly** dressing of the type that meets the required characteristics appropriate for the type of wound and its stage of healing (for example, size, adhesion, conformability and fluid handling properties).

The frequency of dressing change needs to be carefully considered and should be appropriate for the wound and dressing type. Prescribing the **minimum quantity** of dressings necessary to meet a person's needs can avoid wastage and stockpiling. Silver dressings should be used only when there are clinical signs or symptoms of infection. A review of the local wound formulary is underway and updates will be provided shortly. Until then please refer to the current version of the formulary on the Dorset CCG website.

For practices in West Dorset – CADAS prescribers visiting practice

If you are a practice in West Dorset and have CADAS prescribers visiting your practice to prescribe for patients receiving treatment for substance misuse, please have available for CADAS the blue (computer feed) instalment prescription forms to facilitate this process. This will prevent the need for CADAS prescribers to carry loose blank prescriptions around with them, which is a security risk. The CADAS prescriber and the practice should keep appropriate records of which prescriptions have been issued from practice stock for use in this way.

Smartcard prescribing permissions

An entry has been made on the Dorset CCG Risk Register concerning the smartcard prescribing permissions for GP practice staff. It has been identified that some non-prescribing members of practice teams have 'independent prescriber' rights on their smartcards and there have been many incidences over the past 12 months where we have seen prescriptions bearing the name of practice administration staff in place of a qualified prescriber's name. In addition to this it was recognised that there is a risk of prescriptions being fraudulently generated.

Dorset CCG have issued guidance on this topic, which was previously sent by email all GP practices during February 2016. The guidance recommends that 'independent prescriber' rights are removed from the smartcards of all non-prescribers, via the Dorset CCG Smartcard Team. Practices that make the decision not to follow this recommendation should complete a risk assessment for each non-prescriber that will be retaining 'independent prescriber' rights. Risk assessments should be kept on file at the practice.

Use of NSAIDs in children with chickenpox

The National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summaries (CKS) guidance on treating chickenpox recommends that NSAIDs are avoided in children with chickenpox. This is because of concerns that using NSAIDs in children with chickenpox may increase the risk of necrotizing soft-tissue infections and secondary infections caused by invasive streptococci. There is evidence to suggest an increased risk of skin adverse reactions in people with varicella who are being treated with NSAIDs.

The summaries of product characteristics and patient information leaflets provided by NSAID manufacturers differ in the information that they provide regarding use in the management of chickenpox. Practices are strongly advised to follow the NICE CKS guidance when dispensing prescriptions for NSAIDs in children and when supplying over the counter products for use in children with chickenpox. Paracetamol can be used to relieve pain and fever in children who are unwell with chickenpox.

NICE Medicines Evidence Commentary: Adverse events associated with off-label medicine use in adults

A large Canadian observational study in people prescribed new medicines found that using medicines for an off-label indication is associated with an increased risk of treatment discontinuation due to adverse drug events, particularly when strong scientific evidence is lacking. This study reinforces the importance of continuing to follow the GMC prescribing guidance and MHRA advice on unlicensed or off-label medicines, and the NICE medicines optimisation guidance which recommends shared-decision making in relation to medicines.

Requests for 7 day prescriptions for blister packs

Practices are reminded that any decision to provide seven-day prescriptions should be made solely on **clinical grounds**, i.e. for an unstable patient / changeable treatment. Issuing of seven-day prescriptions is appropriate in cases where it will benefit care or increase the safety of the patient, however use of seven day prescriptions purely to cover the dispenser's cost of supplying blister packs is not appropriate, as there is an obligation under the Disability Discrimination Act (DDA) for dispensers to make reasonable adjustments and supply auxiliary aids as appropriate.

Specialist medicines advice can be obtained from the Medicines Advice Service at Southampton General Hospital: **023 8120 6908** or **023 8120 6909** or e-mail medicinesinformation@uhs.nhs.uk