

Prescribing and Medicines Optimisation Guidance

Issue: 57

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Medicines Safety Week

1st -7th November 2021

#MedSafetyWeek

This year's sixth international medicines safety week focuses on vaccines and the importance of reporting adverse side effects. [LINK](#)

What healthcare professionals can do to support MedSafetyWeek

- don't delay in reporting suspected adverse reactions to the [Yellow Card scheme](#) or via the Yellow Card app (download from the [Apple App Store](#) or [Google Play Store](#))
- report suspected reactions to COVID-19 vaccines and medicines to the [Coronavirus Yellow Card reporting site](#) or Yellow Card app
- for each vaccine administered, accurately record in clinical health records details such as the vaccine and product name, batch number, expiry date, the dose, number of vaccinations (if multiple), and site of administration
- include the brand and batch number when reporting suspected adverse reactions to vaccines to the Yellow Card scheme
- for suspected reactions following a third or booster dose of a COVID-19 vaccine, please provide details of any suspected reactions following previous COVID-19 vaccinations, including which vaccine was previously received
- talk to your colleagues about being vigilant for new or rare suspected reactions with vaccines or medicines and reporting them to the MHRA
- follow the MHRA on its social media channels and show your support by retweeting, commenting, liking, and sharing material with your social media contacts using #MHRAYellowcard, #MedSafetyWeek, #ReportSideEffects, and #patientsafety

1. UHS / Wessex AHSN: Medicines Safety portal

The Medicines Safety Portal is a collaboration between the Southampton Medicines Advice Service at University Hospital Southampton (UHS) and Wessex AHSN and can be accessed here: [LINK](#)

This site aims to help GPs, pharmacists and nurses in primary care to use medicines safely. The clinical topics section has e-learning showing how to protect patients from selected

prescription medicines that sometimes cause harm. These include anticholinergics, low dose methotrexate, NSAIDs and sulfonylureas.

2. Recap on some national medication safety issues

a) Steroid Emergency Cards- NPSA alert (Aug 2020)

Guidance entitled: **Exogenous steroids, adrenal insufficiency and adrenal crisis-who is at risk and how should they be managed safely** ([LINK](#)) was produced in response to the national patient safety alert (NatPSA) of August 2020 ([Link](#)) promoting the use of a new Steroid Emergency Card to support the early recognition and treatment of adrenal crisis in adults. The NatPSA advised on a series of actions to be completed no later than 13 May 2021.

Ardens and PrescQIPP have provided supporting templates/ searches. However, both have needed clinical review to filter out the relevant patients to receive this new information card. Much work has been undertaken locally to implement this alert.

b) Valproate medicines and Pregnancy Prevention Programme (MHRA Updated Nov 2020) ([Link](#))

Valproate (Epilim, Depakote and other generic brands) is associated with a significant risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy.

The Pregnancy Prevention Programme (PPP) aims to minimise pregnancy exposure during treatment with valproate. Its guidance was updated in November 2020 ([Link](#)).

The Annual Risk Acknowledgement Form for valproate was also revised and updated in January 2020. See [LINK](#). It now has a stepped approach and step one includes making the decision as to whether the patient needs to be on the PPP. There is the option for the specialist to declare a “permanent” reason why the prevention programme is not appropriate on the revised form.

It is advisable to regularly run practice searches to ensure any new, applicable girls and women prescribed valproate are picked up and reviewed for inclusion in the Pregnancy Prevention Programme.

c) Clozapine reminder

1. **Ensure systems are in place for hospital-prescribed medicines such as clozapine to be added to GP clinical systems.** This will minimise the following potential risks: Inadvertent co-prescribing of interacting medications, the potential to miss side effects or not attribute them to clozapine therapy and finally to prevent clozapine being missed on admission, to another hospital.

2. Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus (MHRA 2017) [LINK](#)

- the antipsychotic drug clozapine has been associated with varying degrees of impairment of intestinal peristalsis; this effect can range from constipation, which is very common, to very rare intestinal obstruction, faecal impaction, and paralytic ileus
- exercise particular care in patients receiving other drugs known to cause constipation (especially those with anticholinergic properties), patients with a history of colonic disease or lower abdominal surgery, and in patients aged 60 years and older.

d) Inappropriate anticoagulation of patients with a mechanical heart valve. NPSA alert July 2021 ([Link](#))

Early in the Covid-19 pandemic, published guidance supported clinical teams to review patients treated with a vitamin K antagonist (VKA) e.g. warfarin and where appropriate change their medication to an alternative anticoagulant (e.g. a low molecular weight heparin (LMWH) or a direct oral anticoagulant (DOAC)). This was partly to reduce the frequency of clinic attendance for monitoring, and thus reduce the risk to patients. The guidance listed exceptions where specific patients should not be switched from a VKA, including patients with a mechanical heart valve.

However, incidents have been reported of patients with a mechanical heart valve being switched to a LMWH or a DOAC. This NPSA alert asks GPs and other NHS providers of anticoagulation services to identify any patients who have a record of a mechanical heart valve and are receiving a DOAC, and to urgently review these patients to ensure they are on the most appropriate anticoagulation therapy and monitoring.

e) Emollients and risk of severe and fatal burns: new resources available. MHRA Aug 2020 [LINK](#)

Since 2010 more than 50 deaths and serious injuries have been linked to the use of emollient skin creams. MHRA first took regulatory action in 2008 for products containing more than 50% paraffins. In 2018, following new evidence, the MHRA recommended that labelling and product information for a wider range of emollient products (paraffin-based and paraffin-free) should include a warning about the fire hazard, with clear advice not to smoke or go near naked flames and information about the risk of severe burn injury or death when clothing, bedding and dressings with emollients dried on them are accidentally ignited. Since then, these recommendations have been adopted and can be found on products available in the UK. The above link takes you to many resources available to support patient education around fire safety and emollient use.

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Previous bulletins can be found at: <https://gp-portal.westhampshireccg.nhs.uk/medicines/covid-19-medicines-information/covid-19-medicines-optimisation-bulletins/>