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Patients get good reports

Patients and clinicians may report suspected adverse drug reactions (ADRs). To investigate whether patients and clinicians report the same concerns Topaz et al examined electronic health records (completed by clinicians) and social media reports (completed by patients), of potential ADRs to aspirin and atorvastatin. Most of the concerns expressed on social media were consistent with ADRs recorded on electronic health records. Interestingly rarer ADRs, like aspirin-induced hypoglycaemia, were only found on social media. Reports from patients are valuable, and all healthcare professionals should encourage them.

[Drug Safety 2016;39:241-50]

Valproate medicines: important new contraindications



This medicine can seriously harm an unborn baby. Always use effective contraception during your treatment.

If you are thinking about becoming pregnant, or you become pregnant, talk to your doctor straight away.

Do not stop taking this medicine unless your doctor tells you to.

WARNING FOR WOMEN AND GIRLS

Valproate medicines are now contraindicated in women of child bearing age unless the conditions of a Pregnancy Prevention Programme are met, and only if other treatments are ineffective or not tolerated. Drug Safety Update sets out the specific actions that GPs, pharmacists and specialists should take. Healthcare professionals will also be receiving further information in the post.

[<https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met>]

Disturbing visuals: corticosteroids linked to central serous chorioretinopathy

Central serous chorioretinopathy is a rare retinal disorder that can cause blurred or distorted vision and sometimes leads to retinal detachment. It typically affects only one eye.

Although the exact mechanism is unknown there are several possible risk factors. One recognized factor is the use of systemic corticosteroids. Reports of chorioretinopathy with the use of local corticosteroids, including inhaled, intranasal, epidural, intra-articular, dermal, and peri-ocular steroids have gradually emerged.

MHRA advises that patients treated with local corticosteroids should report any visual problems. If symptoms do develop, consider referring the patient to an ophthalmologist to establish the cause.

[<https://www.gov.uk/drug-safety-update/corticosteroids-rare-risk-of-central-serous-chorioretinopathy-with-local-as-well-as-systemic-administration>]

Not for the faint-hearted: topical brimonidine and systemic cardiovascular effects

Rosacea is common, and the facial flushing can be treated with the α_2 -agonist brimonidine gel. This can be absorbed and cause bradycardia, hypotension, and dizziness; some patients have required admission to hospital. Damaged skin makes the reaction more likely, especially after laser treatment, perhaps because of increased absorption. To minimise the risk of systemic reactions, advise patients not to apply brimonidine gel to irritated or damaged skin.

[<https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin>]

Finasteride: some men down

Finasteride 1 mg is indicated for the treatment of male pattern baldness and the 5 mg dose for benign prostatic hypertrophy. Depression is a listed adverse effect of finasteride. There are now reports of depression and suicidal thoughts with the 1 mg dose in men without a previous history of depression. A review of the evidence has suggested that depression is more significant, so MHRA has updated its advice.

Patients should stop taking finasteride 1 mg at once if they become depressed, and inform a healthcare professional. Clinicians are also reminded that depression is a listed side effect to the 5 mg dose of finasteride.

If you do encounter a patient with a suspected psychiatric adverse reaction please submit a YellowCard, or ask that the patient does so.

[<https://www.gov.uk/drug-safety-update/finasteride-rare-reports-of-depression-and-suicidal-thoughts>]

Calciphylaxis: warfarin causing vascular calcification and skin necrosis

Calciphylaxis is a rare but serious condition of vascular calcification and cutaneous necrosis. This is usually observed in patients with end-stage renal disease on dialysis, and it is often fatal.

Cases of calciphylaxis are now reported in patients taking warfarin. Most patients had pre-existing renal disease, although there also were reports in patients with normal renal function. It seems probable that warfarin can, rarely, cause calciphylaxis. If a patient taking warfarin develops calciphylaxis, then consider whether the warfarin treatment should be stopped.

[Am J Med 2014;127:253-4;
<http://www.medsafe.govt.nz/profs/PUArticles/September2017/WarfarinAndCalciphylaxis.htm>]

Dangerous liaison!

Patients taking warfarin should not use miconazole oral gel bought over-the-counter. Miconazole inhibits the enzyme CYP2C9, and so increases the effect of warfarin. A coroner sent a Report to Prevent Future Deaths to MHRA in March 2016 raising concerns of this interaction and also the lack of knowledge around this interaction. Altogether 175 Yellow Card reports have cited this interaction. Most (135) report an increased INR, 23 concern contusion, and 19 describe haematuria. Three patients died.

You can still prescribe miconazole gel to patients on warfarin, but they should be monitored closely, and advised to seek medical help if there are signs bruising or bleeding.

[Pharmaceutical Journal,1 April 2012.]

Thank you

The monitoring of drug safety depends on the goodwill of those who report suspected adverse drug reactions to the Yellow Card Scheme, and we are very grateful for their efforts.

The efforts of the doctors, nurses, pharmacists and patients in the West Midlands has made the past year one of our most successful years in terms of collecting reports.

Each card adds a little more to our knowledge of drug safety. Please visit our website www.yccwm.org.uk or follow us on twitter <https://twitter.com/yellowcardwm> and remember our motto:

“If in doubt, fill one out.”

The Yellow Card Centre West Midlands

It's quickest to send a Yellow Card to the MHRA online: www.mhra.gov.uk/yellowcard or via the app; you can download the app from the iTunes App Store and Google Play for your IOS or Android device. Alternatively please send reports to: 'FREEPOST YELLOW CARD' (no stamp or any other address details are needed). If you would like a supply of pre-addressed and reply-paid Yellow Cards, please contact us:

Phone: 0121 507 5672 **Email:** swb-tr.SWBH-YCCWestMidlands@nhs.net

Address: Yellow Card Centre West Midlands, Pharmacy, City Hospital, Dudley Road, Birmingham, B18 7QH.

Please send any comments to:

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