re:ACTION No.38

An occasional bulletin from the Yellow Card Centre West Midlands

December 2009

http://www.yccwm.org.uk

If you would like to receive this bulletin by email contact: yccwm@swbh.nhs.uk

HPV vaccination

Infection with human papillomavirus (HPV) is one of the most common sexually transmitted infections. Genital infection with a high-risk HPV virus is responsible for nearly 3000 cases of cervical cancer every year in the UK. Immunizing girls before they become infected could eventually prevent up to 400 deaths every year in the UK.

Routine immunization for HPV started across the UK on 1 September 2008 for 12 to 13 year-old girls (school year 8). The vaccine (Cervarix® ▼), protects against infection with HPV types 16 and 18.

In September a young girl died in Coventry, a few hours after HPV vaccination. It was quickly established that she had died from a serious underlying malignancy. However, in the space of three days considerable media interest provoked public concern about the safety of the vaccine.

The Medicines and Healthcare products Regulatory Agency (MHRA) issued a drug alert to the healthcare community advising them of the recall of the human papillomavirus (HPV) vaccination batch quarantined following the death of the girl. The manufacturer, GlaxoSmithKline (GSK), voluntarily recalled the vaccination batch used as a precautionary measure while further investigations were undertaken. However, the safety of the vaccine is not in question, and no link exists between the vaccine and the death of the girl.

Good reporting of adverse events suspected to be caused by vaccines improves the knowledge of the safety of vaccines, and increases public confidence in vaccine safety surveillance systems.

In the case of HPV vaccine, a "black triangle" ▼ drug under intensive surveillance, all reactions in patients of any age should be reported. For other established vaccines, only reports of serious reactions are required in adults. However, any reaction occurring in a child should be reported to the Yellow Card scheme, no matter how trivial.

Varenicline (Champix® ▼)

Gunnell, D. *BMJ* 2009;**339**:b3805

The MHRA issued warnings about a possible association between the smoking cessation therapy varenicline (Champix® ▼) and suicidal behaviour based on spontaneous reports in December 2007. Further reports of suicide to the Yellow Card Scheme followed these warnings.

A recent pharmacoepidemiological study in the BMJ has found no evidence of an association between varenicline and fatal or non-fatal self-harm. Compared with nicotine-replacement therapy the hazard ratio for fatal and non-fatal self-harm was 1.12 (95% CI 0.59–2.32), increased risk of depression (0.88 [95% CI 0.77–1.00]), and suicidal thoughts (1.43 [95% CI 0.53–3.85]). However, the study was unable to exclude a two-fold increased risk of fatal or non-fatal self-harm. The study's limitations included a limited number of episodes of self-harm, and other possible sources of confounding.

Reports of neuropsychiatric reactions to varenicline continue to appear. Alhatem and Black (*Clinical Neuropharmacology* 2009;32:117-118) report the case of a 34-year-old man with bipolar affective disorder and adult attention-deficit hyperactivity disorder, who became manic following initiation of varenicline. His mania subsided following the discontinuation of varenicline.

Smoking cessation is of benefit to both individuals and public health, but patients can experience adverse effects both from the withdrawal of nicotine, and smoking cessation treatments. Advice for healthcare professionals remains that care should continue be taken, particularly when patients have other potential predisposing factors for neuropsychiatric reactions. Varenicline is a "black triangle" drug (▼), and all cases reports of suspected adverse effects may be reported regardless of severity.

Uncomfortable Ulcers?

Coget-Ehrlich N. *Nouvelles Dermatologiques* 2009;**28**:307–308
Chan SK et al. *BJOG: An International Journal of Obstetrics and Gynaecology* 2009;**116**:1403–1405
Fraser SJ et al. *BJOG: An International Journal of Obstetrics and Gynaecology* 2009;**116**:1400–1402

Several recent case reports remind us of the propensity of nicorandil (Ikorel®) to cause ulceration in mucous membranes, and draw attention to genital ulcers. Genital, oral and anal ulceration are rare listed adverse effects of nicorandil, and the MHRA have previously draw attention to this rare adverse effect (*Drug Safety Update*, June 2008)

Coget-Ehrlich reported an 82 year-old man with heart failure who developed a severe penile ulcer over 3–4 weeks. The ulcer healed over a two month period following discontinuation of the nicorandil.

Painful vulval ulceration associated with nicorandil was reported by Chan SK *et al* (2 cases) and Fraser *et al* (5 cases). Many patients had been taking nicorandil for years, and developed concurrent chronic vulval ulceration. The ulcers healed when nicorandil was eventually recognised as the possible cause and withdrawn. In one case, longstanding unexplained oral and corneal ulcerations also subsided. Although rare, ulceration caused by nicorandil can be debilitating and painful. Healthcare professionals with patients presenting with unexplained ulcers should be aware of the potential for nicorandil to cause mucous membrane, skin, and GI tract ulceration. Nicorandil-induced ulcers are refractory to treatment, responding only to withdrawal of the drug. Withdrawal should only take place under medical supervision. We welcome reports of unusual reactions that have disabling effects on patients.

Drug Safety Update

http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm

Readers are reminded that the publication *Drug Safety Update* is published on a monthly basis by the MHRA, and provides concise and useful advice on current issues of drug safety for healthcare professionals. You can sign up for email alerts at the above address.

Sharing our expertise

If you require a speaker for a lunchtime meeting or continuing professional development programme, why not contact us?

Our centre is keen to promote the Yellow Card scheme, and can provide training on adverse drug reactions and the Yellow Card scheme.

If you would like to discuss this with us, please ring 0121 507 5672 or email yccwm@swbh.nhs.uk.

"If in doubt write one out."

The Yellow Card Centre West Midlands

We encourage the reporting of Yellow Card reports for all suspected adverse reactions to new (▼) drugs, vaccines and unlicensed herbal remedies, all suspected reactions to all drugs in children, and all serious or unusual reactions to well-established drugs. You do not have to be certain that a drug caused a reaction in order to report.

Please send reports to: MHRA, CHM, Freepost, London, SW8 5BR. Or Use http://www.yellowcard.gov.uk

No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact us:

Phone: 0121 5075672 **Email**: yccwm@swbh.nhs.uk
Address: Yellow Card Centre West Midlands, City Hospital, Dudley Road, Birmingham, B18 7QH.

VACCINES ON THE INTENSIVELY MONITORED DRUGS LIST

Approved name	Trade name	Indication
Pandemic influenza vaccine (H1N1)	▼ Celvapan ®	Pandemic influenza prophylaxis
Pandemic influenza vaccine (H1N1)	▼ Pandemrix ®	Pandemic influenza prophylaxis
Measles, Mumps, and Rubella	▼ M–M–RvaxPro®	Measles, mumps & rubella prophylaxis

Please send any comments to:
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