Drug Alert – Engerix B

The Medicines and Healthcare Products Regulatory Agency (MHRA) issued Drug Alert No 10 - Class 2 (EL (09) A/10) on 6th April 2009 relating to a batch of Engerix B vaccine. All stock of the affected batch is being recalled due to exposure to unacceptably low temperatures during distribution. This may render the vaccine ineffective.

DETAILS OF AFFECTED VACCINE

Product
Engerix B 1.0ml pre-filled syringe (Hepatitis B surface antigen 20 micrograms/ml) by GlaxoSmithKline UK

Batch number
AHVB591BB

Expiry date
28/02/2011

Pack Size
10 syringes/carton

First distributed
09/03/09

ACTIONS FOR HEALTHCARE STAFF

Contact all patients known to have received vaccine from the affected batch (from 9th March onwards) and recall for revaccination.

Quarantine all unused stock and return for credit. GSK will contact all customers and make arrangements for collection and replacement stock. There are adequate stocks of replacement syringes available.

Report any adverse effects to GSK Safety Department on 0800 221 441 (although there are no expected safety concerns about the affected batch or revaccination)

Inform recipients that they should contact GSK Customer Contact Centre on 0800 100 9997 with any general enquiries.

HPV uptake

Provisional data from Information Services Division show a very good uptake of this vaccine among girls at school. The uptake rate for first dose of HPV in NHSGG&C is 93.1% compared to a national rate of 92.2%. The uptake rate for the 2nd dose is 88.3% compared to a national rate of 87.8% although it is expected that this will increase further during the mop-up exercise later in this and subsequent school years. Girls born between 1st September 1990 and 28th February 1993 who have left school and/or missed any doses at school can access this vaccine by phoning the helpline 0800 015 0345 between 10am and 4pm.

Hib (nearly caught) catch-up

Primary care staff will recall that in August 2007 the Scottish Government announced a national time-limited campaign of giving an additional dose of Hib vaccine to children born between 4th April 2003 and 3rd September 2005. This campaign started on 5th November 2007 and was to continue until 3rd March 2009.

Recent data from the Child Health Screening Department show that over 4000 children in NHS Greater Glasgow and Clyde within this cohort have still not received pre-school booster with Hib. These children are listed on the ‘Treatment Centre Queue Print’ sent by the Screening Department to affected practices on a regular basis. To ensure that these children receive pre-school booster with Hib, the time-limited campaign has been extended by six months to the end of September 2009 (see PGD update below)

Practices are asked to check Queue Prints for these children and ensure that they are offered vaccine as soon as possible and preferably before the end of September.

Practice staff who have any enquiries about these children or want to run additional clinics and/or invite more children into existing clinics should contact the Child Health Screening Department on 0141 277 7616.

Pre-school booster

Supplies of Hib-free pre-school booster are now available for children who have completed their Hib-vaccine course. Holding centres will be supplying Infanrix-IPV routinely for pre-school booster

Ordering stock for Hib catch-up

Please note that when ordering Infanrix-IPV+Hib for the remaining ‘catch-up’ children, staff must now write plus Hib on the vaccine-order form (having first checked existing stock in the fridge). Centres will, otherwise, supply the Hib-free booster.

PGD update

Staff should note that the PGD for HPV has been amended to allow staff flexibility in spacing the 3 doses of HPV where scheduling difficulties arise (PGD ref no 2009/670).

A new PGD for Infanrix-IPV has also been circulated (PGD ref no 2009/669).

A 6-month extension to the Infanrix-IPV+Hib PGD has been arranged to cover those children not yet called for the catch-up Hib (see above).
**New local measles test**

The incidence of measles is increasing in other parts of the UK which makes it more likely that cases will be observed in NHSGG&C. For this reason, the West of Scotland Specialist Virology Centre (WoSSVC) will provide a rapid diagnostic service for suspected measles cases that are classed ‘probable’ in nature. This will allow the PHPU to act quickly to prevent the spread of illness.

Any GP who suspects that a patient has measles should call the PHPU on 201 4917 to discuss the case.

The following flowchart helps identify ‘probable’ cases:

- **Fever and characteristic maculopapular rash?**
  - Yes
  - **One or more of the following clinical signs?**
    - Cough
    - Conjunctivitis
    - Coryza
    - Koplik’s Spots
  - Yes
  - **One or more of the following risk factors?**
    - *Recent contact with a confirmed case*
    - *Recent travel abroad or to outbreak areas in the UK*
    - Part of an unvaccinated community (e.g. Travellers)
  - Yes
  - **PROBABLE CASE**
    - ≤10 days since onset
    - >10 days since onset
    - **Urgent PCR**
      - Throat swab
    - **Urgent IgM**
      - Clotted blood sample

If the case meets the criteria above, and it is within 10 days of the onset of illness, then a throat swab should be sent urgently to the WoSSVC for measles, parvovirus B19 and enterovirus PCR tests (parvovirus B19 and enterovirus can resemble measles clinically). The PHPU will liaise with the lab to arrange for the test to be done urgently. Throat swabs should be sent in Viral PCR Sample Solution (VPSS) or in viral transport medium. If unavailable, then a normal swab re-sheathed in its plastic tube should be used. Charcoal swabs should not be used.

If more than 10 days have passed since the onset of symptoms then a clotted blood sample should be sent for urgent IgM testing for measles, parvovirus B19 and enterovirus. NB. If parvovirus B19 is the most likely diagnosis then blood is the sample of choice.

If the case has the clinical features described above but no risk factors then it is classed as a ‘possible’ case and does not require urgent laboratory investigations. Instead, a routine salivary-testing kit will be sent out by the PHPU (saliva sample can be taken 1-6 weeks after onset of illness).

*The PHPU will advise on time-scales associated with these risk factors.

**TB in NHSGG&C and Scotland**

In Scotland, over the past decade, overall TB case numbers have remained stable, in the range of 350 to 400 a year with half of these (~200) within NHSGG&C. However, provisional figures for 2008 indicate approximately 450 cases in Scotland and approximately 213 in NHSGG&C. If these figures are confirmed, they might signal that the plateau of TB incidence has ended and that Scotland may now be experiencing a sustained rise in the incidence of TB. The epidemiology of TB in Scotland has been changing and appears to be moving closer to the situation seen in England, where the majority of TB cases occur in non UK-born persons.

World TB day (24th March) saw the publication by the Health Protection Network of new guidelines for tuberculosis, *Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland*. Adapted for use in Scotland from NICE guidelines, the guideline offers best practice advice on the care of people with, or at risk of contracting, TB.


In addition, the Scottish Government marked World TB day by initiating work on an Action Plan for tuberculosis. A working group bringing together experts in the field, including specialist TB doctors and nurses and representatives from Health Protection Scotland and the UK-wide Health Protection Agency, will be preparing a draft plan for publication by the end of 2009.

**Hep B immunisation - eligibility**

The PHPU continues to receive enquiries about NHS eligibility for *single antigen* Hep B immunisation. Risk groups for which Hep B immunisation is recommended are clearly listed in the DoH’s *Immunisation against Infectious Disease* (Green Book) p.168-175. Hep B vaccination is funded through the GMS global sum for all risk groups listed except the following:-

- **occupational** - patients should be referred to their employer’s occupational health service. A GP practice can enter into a contractual arrangement with an employer to provide this service and then charge the employer but not the patient (NHIS (GMS Contracts) (Scotland) Regulations 2004 Schedule 4 Regulation 24, 1(b)).
- **GPs who opt to use stock vaccine or provide an NHS prescription cannot charge the patient or employer a fee for administering the vaccine.**
- **travellers** – GPs can privately prescribe *single antigen* HBV for patients travelling to high-risk countries whether registered or not. Fees can be charged for the private prescription and administration of the vaccine. In fact, the only occasion when a doctor may charge a registered patient for a private prescription is in relation to travel overseas. (NHIS (GMS Contracts) (Scotland) Regulations 2004 Schedule 4 Regulation 24 1(g)).

GPs who opt to use stock vaccine or provide an NHS prescription cannot charge the patient a fee for administering the vaccine.

If you would like to comment on any aspect of this newsletter please contact Marie Laurie on 201 4933 or at marie.laurie@ggc.scot.nhs.uk