Possible contamination of Viaspan organ transport fluid  
Information for clinicians

Dear All

MHRA:
This document has been produced to keep you updated regarding the potential contamination of Viaspan organ preservation fluid with *Bacillus cereus* and has been brought together by NHSBT, HPA and MHRA. This product is used in the transfer of solid organs for transplant (liver, kidney, bowel and pancreas) and in pancreatic islet transplant. In some cases where alternatives are not available, the potentially contaminated product may continue to be used in order to allow transplants to go forward. This may affect product issued since mid 2011.

You will be aware that the MHRA was notified of the potential contamination on 23rd March 2012 and the manufacturer subsequently issued a precautionary recall of the product (where alternatives exist) on 29th March 2012.

- The contamination was found in the fluid used to test the integrity of the production process but not in the Viaspan itself.
- An investigation is ongoing to delineate the root cause and further quantify the potential risks to patients. Interim results are due around April 10th and any significant results will be communicated via NHSBT when available.

HPA:
The potential contaminating organism is *Bacillus cereus*. Although *B cereus* is common cause of toxin-mediated food poisoning, it may also cause invasive disease including bacteraemia, septicemia, endocarditis, osteomyelitis, pneumonia, brain abscess, and meningitis in severely immunocompromised patients such as those with haematological malignancy, and in patients with indwelling vascular catheters. The antimicrobial susceptibility of the contaminating organism(s) is currently unknown, however *B. cereus* in vitro is likely to be sensitive to vancomycin, ciprofloxacin, chloramphenicol, linezolid, and daptomycin.\(^1\) *B. cereus* produces \(\beta\)-lactamases and is commonly, though variably, resistant to penicillins, including beta-lactamase inhibitor combinations, carbapenems and cephalosporins.

Solid organ transplant recipients are routinely given prophylactic antimicrobials peri-operatively. Practice varies between units and according to the organ being transplanted. In some cases the antimicrobials will not include agents active against *B. cereus*. We advise physicians to seek advice from their local microbiologist and conduct an individual risk assessment of the patient to decide whether a change in prophylactic antimicrobials is required. Health Protection Agency regional microbiologists may be contacted for additional advice.

Patients who have received potentially contaminated product and who develop post operative infection should be empirically treated with antimicrobial therapy mindful of the antibiotic sensitivity

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\(^1\) Bottone EJ. *Bacillus cereus,* a volatile human pathogen. Clin Microbiol Rev. 2010 Apr;23(2):382-98. Accessible at: http://cmr.asm.org/content/23/2/382.abstract. This is a useful review article for those wishing further information.
Thursday 5th April 15:00

of *B. cereus* (see above). Therapy should be chosen after discussion with a local or HPA microbiologist and adjusted with culture results. Culture of organ transport fluid after use is already performed in some units and is recommended whilst the affected product is in circulation.

**Please notify NHS Blood and Transplant of any suspected *Bacillus spp* infections in solid organ transplant recipients and forward the *Bacillus* isolate to Dr Kathie Grant, Laboratory of Gastrointestinal Pathogens, Health Protection Agency Colindale.**

The Health Protection Agency will update this guidance when further information is available. An advice letter issued from the manufacturer and NHSBT will be available at the following address:  
http://www.mhra.gov.uk/NewsCentre/CON146896

**NHSBT:**

It is likely that the interruption to the supply of Viaspan will be ongoing for some time because of the recall by the manufacturer. Alternative solutions are available to use.

- Each retrieval team should ensure all unaffected stocks of Viaspan are used BEFORE using contaminated batches.
- If contaminated stocks are used, please ensure samples are taken from each batch and sent for microbiological culture. The results should then be communicated with the recipient centre.
- If any positive cultures are identified please inform NHSBT’s Duty Office on 0117 9753 7580 and forward any *Bacillus* spp isolated to Dr Kathie Grant, Laboratory of Gastrointestinal Pathogens, Health Protection Agency, Colindale.
- Transplant centres should ensure they let the NHSBT Duty Office know of any recipient who appears to be suffering from an infection post transplantation.

**Reporting**

Clinicians should remain vigilant for any signs of infection in organ recipient and should initially seek advice from their local hospital microbiologist. Serious post-transplant events should be reported to the ODT duty office (01179 757575).

The Health Protection Agency and NHS Blood and Transplant will continue to work together to review any cases of *Bacillus cereus* infection related to organ transplantation and provide expert advice as required.