Medical Device Alert

Action

Ref: MDA/2009/080 Issued: 09 December 2009 at 15:30

Device

Ultrasound transducer probes with an internal lumen used for taking transrectal prostate biopsies.

All manufacturers.

Problem

Potential onward transmission of abnormal prion protein, the putative infective agent in variant Creutzfeldt Jakob disease (vCJD), when ultrasound transducer probes with an internal lumen are used for taking transrectal prostate biopsies on men at risk of vCJD.

The needle that passes through the internal lumen of a reusable ultrasound probe could transfer the abnormal prion protein from rectal lymphoid tissue, via the outside surface of the biopsy needle, onto the internal lumen of the ultrasound probe. Any attempt at subsequent decontamination of the internal lumen would not be successful due to the inability of any current decontamination process to reliably eliminate or destroy abnormal prion protein.

Action by

All staff who carry out prostate biopsies.

CAS deadlines

Action underway: 31 December 2009
Action complete: 26 February 2010

Action

Review the advice given in the Advisory Committee on Dangerous Pathogens (ACDP) TSE Working Group's alert to urological surgeons 'Transrectal prostatic biopsy in men at risk of variant CJD', published on the Department of Health's website.

The ACDP TSE Working Group and CJD Incidents Panel advise the following:
'Patients at risk of vCJD requiring transrectal prostatic biopsy should have the procedure performed by means of single use equipment that runs alongside (rather than through) the ultrasound probe. Where a unit does not have such equipment and intends to carry out a biopsy procedure on a patient at risk of vCJD, their options are as follows:

- To refer the patient to a unit offering an alternative technique that does not pose a risk of contaminating the internal channels with traces of biopsy tissue
- To borrow the alternative equipment from another unit
- To undertake the procedure with equipment that has internal biopsy channels, and then quarantine the reusable components of that equipment after decontamination. It must be accepted that this equipment would be unlikely to return to general use, except for dedicated re-use in the same patient.'

Device

All ultrasound transducer probes which require the passing of a biopsy needle through the internal lumen.

Action

From the ACDP TSE Working Group's alert to urological surgeons:

'The following patient groups have been notified of their increased risk of subclinical vCJD infection:

- people who have received blood from someone who went on to develop vCJD
- people who have given blood to someone who went on to develop vCJD
- people who have received blood from someone who has also given blood to a patient who went on to develop vCJD
- people who have had surgery using instruments that had been used on someone who developed vCJD
- people who have had a neurosurgical procedure, or an operation for a tumour or cyst of the spine, before August 1992
- people who have received an organ or tissue from a donor infected with vCJD or at increased risk of vCJD
- people who have been treated with certain UK sourced plasma products between 1980 and 2001.

It is important to note that new patient groups may be notified in the future of their increased risk of vCJD.'

The advice in the ACDP's alert does not apply in procedures on men who are not at risk of vCJD nor to the use of probes that are covered by latex in their entirety while guided prostatic biopsy is being performed via a separate single use external biopsy sheath.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Day surgery units
- Decontamination leads
- Directors of infection prevention and control
- Directors of nursing
- General surgeons
- General surgical units, directors of
- Health and safety managers
- Infection control departments
- Infection control nurses
- Medical directors
- Medical physics departments
- Microbiologists
- Oncologists

- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Purchasing managers
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Adult placement
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Health Protection Agency to:

Directors for onward distribution to:

- Consultants in communicable disease control
- Health protection nurses
- Regional epidemiologists
- Regional microbiologists

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Directors of infection prevention and control

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/080 or 2009/010/030/291/001**

TSEs and decontamination issues
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Health Protection Scotland (HPS) advises that the advice given in the Advisory Committee on Dangerous Pathogens (ACDP) TSE Working Group's Alert titled 'Transrectal prostatic biopsy in men at risk of variant CJD' is applicable in Scotland.

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

E-mail: nss.iric@nhs.net
http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

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