

3rd March 2008

Dear Colleague,

DECONTAMINATION OF SURGICAL INSTRUMENTS: NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) GUIDANCE –“ PATIENT SAFETY AND REDUCTION OF RISK OF TRANSMISSION OF CREUTZFELDT-JAKOB DISEASE (CJD) VIA INTERVENTIONAL PROCEDURES”

My letter of 21st February 2007 reminded centres providing neurological and posterior eye surgery of the need to implement the above NICE guidance issued in November 2006 and set out our intention of providing additional advice on surgical instrument decontamination. Feedback from the first Engineering and Science Advisory Committee on instrument decontamination and prion removal (ESAC-Pr stakeholder event, held in April 2007, and preliminary findings from the National Decontamination Survey (NDS) details in Annex A) indicate that implementation has not progressed satisfactorily and some centres lack clear arrangements for the way forward.

Action is required to remedy this, especially in relation to the provision of separate instruments for use on children born after 1st January 1997 who have not been subject to previous high-risk tissue interventions. We are working on a number of initiatives to help you with implementation, which will include another ESAC-Pr stakeholder event on 3rd April 2008 and specific guidance in a Health Technical Memorandum (HTM) expected in April 2008.

Implementing the NICE guidance, especially in relation to preventing instrument migration between sets, is not proving straightforward. Additionally we are aware of growing interest in using new decontamination technologies to deactivate prions, an area in which the Department is actively commissioning research. These new technologies have not yet been fully validated within the established decontamination process. Accordingly, although these new technologies are in several cases promising, Departmental policy remains the promotion of risk reduction by implementation of the NICE guidance.



**From the
Chief Medical Officer**

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For action

- Chief Executives of NHS acute hospital Trusts and NHS Foundation Trusts for co-ordination of implementation activities, to ensure attendance at ESAC-Pr event and circulation to procurement managers.
- Medical Directors of NHS acute hospital Trusts and NHS Foundation Trusts for implementation in association with, Directors of Infection Prevention and Control, Infection Control Teams, Sterile Services Managers and consultants in neurosurgery, ophthalmology and paediatrics.

For information

- Chief Executives of PCTs
- Chief Executives of Strategic Health Authorities
- Nursing Directors of NHS acute hospital Trusts and NHS Foundation Trusts
- Regional Directors of Public Health

Authorised by the Department of Health: Gateway
no. 9504

A summary of the NICE guidance followed by an update on Departmental action is given below.

NICE Guidance and implementation

NICE produced the above guidance in November 2006 to further reduce any risk of iatrogenic spread of CJD via surgical instruments and neuroendoscopes. The recommendations relate to those instruments, which have or may have come into contact with high-risk tissues defined primarily as brain and the posterior eye. The guidance is available at <http://www.nice.org.uk/page.aspx?o=cjd>. The main recommendations are paraphrased below:

- Urgent steps should be taken to ensure that instruments in contact with high-risk tissues do not move from one instrument set to another. Supplementary instruments that come into contact with high-risk tissues remain with the set to which they have been introduced. (This in effect prohibits the temporary use of supplementaries with these sets as where such supplementaries are used they must become part of the instrument set)
- Rigid rather than flexible neuroendoscopes should be used wherever possible *as this permits steam sterilisation*.
- All accessories used through neuroendoscopes for interventions such as biopsies should be single-use.
- A special separate pool of reusable surgical instruments and new neuroendoscopes for high-risk procedures should be used for children born after 1st January 1997.

Our work with pilot centres on the NDS has shown a clear trend toward much greater use of rigid neuroendoscopes, with an increased use of single-use accessories, but has also identified the need for centres to procure new instruments for use only on children.

Single instrument tracking

Initial discussions with the NDS pilot sites indicate that significant instrument movement between sets occurs, particularly in the operating theatre. This reinforces the view that instrument tracking is a priority for neurosurgery and posterior eye work. The GS1 organisation, which is open to membership by NHS institutions has generated a unique identification system which DH recommends for use with devices in healthcare environments. Background information on this and other aspects of tracking is provided in *Coding for Success* at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandGuidance/DH_066082

Instrument migration

The NDS pilots have shown a marked trend in some Trusts towards the use of smaller and less specific instrument sets in neurosurgery and posterior eye procedures. This necessarily results in “ad hoc sets” of supplementary instruments or indeed the use of individual supplementary instruments, which cannot be adequately tracked. This is contrary to the NICE recommendation 1.1. and significantly increases the migration of surgical instruments from their original clinical step sets and would increase the number of patients infected if instruments are exposed to tissues from a carrier.

In light of the public health consequences, the use of full clinical / surgical step orientated sets containing all the instruments needed and avoid a routine need for supplementation is required. Some Trusts participating in the pilots have demonstrated significant reduction in instrument migration by expanding the sets beyond their original scope to more fully cover specific neurosurgery and posterior eye procedures

New technologies

As noted above there is considerable interest in the use of new decontamination technologies as these products may offer significant benefits. The major concern is that these products have not yet been shown to be effective as part of a validated decontamination programme and are not a substitute for the implementation of NICE guidance. ESAC-Pr has established a short-term working group to look at the various anti-prion technologies and a report is expected by Spring 2008. The research programme for new technologies will take approximately two to three years.

DH guidance

A revised package of guidance on the decontamination of all surgical instruments is reaching completion. This takes the form of highly detailed guidance in DH Health Technical Memorandum (HTM) 01-01 Parts A and B. This will cover the implementation of the NICE guidance and related technological solutions.

Part A, Management and Environment is available from www.dh.gov.uk through the Knowledge and Information Portal. Part B, Equipment, is currently in draft and will be available on the DH website from April 2008.

Stakeholder engagement

ESAC-Pr held a major stakeholder consultation exercise in April 2007. This was an opportunity for the Department to explain its approach to both the NICE guidance and to the broader control of prion related risk across surgery, as well as to hear from the NHS and supporting industry. Amongst views expressed was a strong preference for "universal precautions," that is applying the same procedures to all decontamination of surgical instruments. This was combined with interest in using the new anti-prion decontamination techniques to achieve risk reduction as an alternative to the tracking and set containment approach in the NICE guidance. However, although the stated aim is to reduce the possibility of instruments exposed to high-risk tissue not being subjected to the correct procedure, these new techniques have yet to be fully validated as explained above, and Trusts must continue to implement the NICE recommendations.

ESAC-Pr is organising a second stakeholder event on 3rd April 2008. This will focus on the practicalities of implementing the NICE recommendations especially in relation to instrument tracking and will feature feedback from NHS colleagues taking part in the NDS pilot study. and I would be grateful if Trusts would enable both theatre and decontamination staff to attend this event in London. Invitations will be sent out this week but if your Trust does not receive one please contact Rachael Whittaker (Rachael.whittaker@dh.gsi.gov.uk). Invitations to participate in the NDS will be issued at a similar time.

Summary

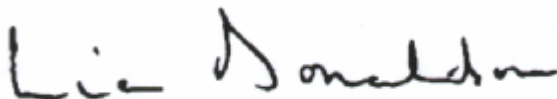
Trusts engaged in surgery involving the high-risk tissues need to urgently review their progress on implementation of the NICE guidance and take appropriate action to achieve compliance as soon as possible.

For those centres providing services to adults only, the key implementation steps relate to keeping instruments in their sets, largely by processes related to instrument tracking. The use of full clinical / surgical step orientated sets containing all the instruments needed in order to avoid routine use of supplementary instruments is required. In addition, the move towards rigid neuroendoscopes with more single-use accessories is important.

Where paediatric surgery is also performed, the generation of a separate pool of instruments for use with those born after January 1997 is required and again single instrument tracking will support the process of maintaining the integrity of these, often new, sets of instruments.

Adequate and appropriate representation at the ESAC-Pr stakeholder event on 3rd April 2008 is required.

Yours sincerely



**SIR LIAM DONALDSON
CHIEF MEDICAL OFFICER**

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ANNEX A: THE NATIONAL DECONTAMINATION SURVEY (NDS)

The Department, with advice from ESAC-Pr, is carrying out a National Decontamination Survey of centres providing neuro and posterior eye surgery. The essential aims are to compare decontamination quality systems as now implemented with the standards achieved at the previous (2003) survey and to encourage rapid implementation of the NICE risk reduction strategy.

The survey is now underway in five pilot centres covering both adult and paediatric high-risk tissue surgery. The full survey, following-on from the pilots, will involve approximately 28 surgical centres and their decontamination service providers.

The survey will be completed in two phases. The first phase, is underway and is scheduled to be completed by early June 2008. This phase will review the quality management systems in use and standards achieved in the decontamination of neuro and posterior eye surgical instruments. This work draws heavily on experience from the 2003/4 National Survey the results from which were published as *The Decontamination of surgical instruments in the NHS in England update report: 'A step change'*. The report can be downloaded at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4113543.

The second phase of the survey will examine key aspects of implementation of the NICE 2006 guidance and will take place in autumn 2008, though work in the pilot centres will be much earlier. This phase will focus on NICE guidance implementation and will involve more fully both the relevant theatre teams and those providing instrument decontamination services. Leakage of instruments between sets and the separation of instruments used with young children will be key aspects.

Prevention of instrument migration is increasingly seen as requiring the introduction of single instrument tracking both in the operating theatre and the supporting decontamination unit. The technology to support this is new and we are working with the pilot sites on how this can be used.