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An Roinn
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www.dhsspsni.gov.uk

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To: Chief Executive of Trusts for distribution to:
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Dear Colleague

DECONTAMINATION OF SURGICAL INSTRUMENTS IN LIGHT OF 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

Introduction

The purpose of this letter is to bring to your attention important guidance on *patient safety and reduction of risk of transmission of CJD via interventional procedures.* This guidance (interventional procedure guidance 196) was issued by NICE in November 2006. DHSSPS advises that this guidance is as valid for Northern Ireland as for England and Wales and endorses its implementation. Trusts providing neurological and eye surgery should be developing arrangements to implement the above NICE guidance which is available at http://www.nice.org.uk/IPG196

Background

The four Chief Medical Officers in the UK asked NICE in 2004 to consider the choice of surgical instruments used in procedures involving tissues which are classified as high or medium risk for variant CJD and CJD. NICE produced the above guidance to further reduce any risk of iatrogenic spread of CJD via surgical instruments and endoscopes. 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.

NICE GUIDANCE

The Institute's main recommendations are as follows:

- Steps should be taken urgently 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.
- Rigid rather than flexible neuroendoscopes should be used wherever possible.
- All accessories used through neuroendoscopes for interventions such as for 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.
- Apart from neuroendoscope accessories, the guidance does not advocate a wholesale move to single use instruments and specifically advises that single use instruments should only be used if they are of equivalent quality to reusable instruments.

The guidance makes reference to requirements set out in Health Service Circular 2000/C32 and in the "NHS Decontamination Strategy". The Northern Ireland equivalents of these documents are HSS(MD) 4/01 and HSS(SC) 3/04.

IMPLEMENTATION

HSC Trusts can start implementation of the NICE guidance by reviewing current practice and protocols as well the purchase of additional equipment. It seems appropriate to prioritise the purchase of separate endoscopes for use on children born after 1997.

However, other issues are more complex. For example, the extent of instrument migration between different sets is not known, and it is not clear if tracking by tray level [in accordance with HSS(MD) 4/01] is adequate to monitor supplementary instruments added to instrument sets or instruments removed following damage or for maintenance. The Department of Health in England (DH) will be issuing further advice on decontamination based on the following work areas:

- An investigation of the extent of instrument migration between high risk sets will form part of the planned National Decontamination Survey 2007 in England.
- The DH Engineering and Science Advisory Committee – Prion Removal (ESAC-Pr) carried out a stakeholder consultation on 18 April 2007 on the practical aspects of implementing this NICE guidance. For example, should high risk instrument sets be quarantined while instruments are repaired or should damaged instruments be discarded and replaced with another instrument from an unallocated pool of new instruments?
- An investigation into the feasibility and desirability of single instrument tracking for these high risk sets will be conducted in association with colleagues from Connecting for Health and elsewhere.
- Design quality of single use instruments is not a well-researched area, and as part of DH's consideration of the NICE guidance they will be contacting professional bodies and others to assess the need for detailed guidance or further action on single use instrument quality and testing.

We will review the DH Guidance once published and consider its applicability in Northern Ireland before issuing further advice here.

TWIN-STREAMING OF SURGICAL INSTRUMENTS

The issue of "twin streaming" of reusable surgical instruments through the whole cycle of their use and decontamination has been raised by ESAC-Pr. This would require any instruments exposed to high-risk tissues to be separated into a discrete stream and kept contained from any direct contact with instruments used for other tissues. The implication being that the instruments in the high-risk stream should be subject to additional vigilance and measures to retain them within their sets. The use of marked baskets and the use of clear physical separation from other instruments streams could be required. This would further reduce any risk of contamination of other reusable surgical instruments, but perhaps more importantly would facilitate the introduction of new technologies that are effective at removing prions from instruments. Further work is being undertaken on the feasibility and desirability of this approach. The ESAC-Pr 2006 report is available on the DH's website at http://www.dh.gov.uk//PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4142318&chk-MU5nKS

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Yours sincerely

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