NICE guidance

Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

In preparing this guidance the Advisory Committee received evidence that effective methods for removing CJD infectivity from instruments are likely to be available and widely introduced within 5 years. Therefore any recommendations in this guidance for changes in practice needed to be both

practical and achievable within a short time frame. The recommendations take into account many potential difficulties in implementation, such as current problems with availability and quality of single-use instruments and imperfections in instrument tracking systems, in addition to a major exercise in cost effectiveness modelling.

1.1 For high-risk surgical procedures (intradural operations on the brain and operations on the retina or optic nerve – 'high-risk tissues'):

- Steps should be taken urgently to ensure that instruments that come into contact with high-risk tissues do not move from one set to another. Practice should be audited and systems should be put in place to allow surgical instruments to be tracked, as required by Health Service Circular 2000/032: 'Decontamination of medical devices' and described in the NHS Decontamination Strategy[1].
- Supplementary instruments that come into contact with high-risk tissues should either be single use or should remain with the set to which they have been introduced. Hospitals should ensure without delay that an adequate supply of instruments is available to meet both regular and unexpected needs.

A full list of high-risk procedures is given in appendix C (see PDF of the full guidance).

1.2 For neuroendoscopy:

- Rigid neuroendoscopes should be used whenever possible. They should be of a kind that can be autoclaved and they should be thoroughly cleaned and autoclaved after each use.
- All accessories used through neuroendoscopes should be single use.

1.3 A separate pool of new neuroendoscopes and reusable surgical instruments for high-risk procedures should be used for children born since 1 January 1997 (who are unlikely to have been exposed to BSE in the food chain or CJD through a blood transfusion) and who have not previously undergone high-risk procedures. These instruments and neuroendoscopes should not be used for patients born before 1 January 1997 or those who underwent high-risk procedures before the implementation of this guidance.

1.4 For all procedures considered in this guidance, with the exception of those involving neuroendoscopy accessories, the evidence on cost effectiveness related to the risk of possible transmission of CJD does not support a change to

single-use instruments, based on current costs. This includes all other neurosurgery, eye surgery, tonsillectomy, laryngoscopy and endoscopy procedures.

1.5 Single-use instruments should be manufactured and procured to specifications equivalent to those used for reusable instruments and should be subject to high standards and consistent quality control. Single-use instruments which are not similar in quality to the reusable instruments which they replace have the potential to harm patients and should not be purchased or used.

1.6 This guidance has been developed on the assumption that new and more effective decontamination methods are likely to become available for routine use in the NHS within the next 5 years. Rigorous evaluation of the safety of these methods and of their efficacy against human prions is urgently required.

Until then, the current Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathies (ACDP TSE) guidelines on decontamination should be followed.

The Institute will review this guidance after 2 years or sooner if important new information becomes available, including evidence on:

- new decontamination methods, which are safe and effective against human prions
- the epidemiology of CJD, including data on the prevalence of vCJD infectivity in the UK population
- cases of transmission of CJD via surgery
- the availability and performance of single-use instruments in high-risk specialties.

[1] Strategy for modernising the provision of decontamination services; section 4.2.1, NHS Estates, May 2003

2 Background

2.1 Remit

The Chief Medical Officer for England asked the National Institute for Health and Clinical

Excellence (NICE or 'the Institute'), on behalf of all UK Chief Medical Officers, to develop and publish guidance for the NHS on how best to manage the risk of transmission of CJD and vCJD via interventional procedures.

2.2 Interventional procedures and patient population considered

This guidance covers management of all patients undergoing procedures involving instruments and endoscopes that might pose a risk of transmission of CJD. These procedures have been classified as follows based on the risk of transmission of CJD.

High-risk procedures: Procedures that involve handling of tissue considered to be at high risk of transmission of CJD. High-risk procedures are intradural neurosurgical operations on the brain (excluding operations on the spine and peripheral nerves), neuroendoscopy and posterior eye procedures that involve the retina or optic nerve (see appendix C of the full guidance).

- **Medium-risk procedures:** All procedures on tonsils, spleen, lymphoid tissue, spinal cord, anterior eye and peripheral nerves.
- **Low-risk procedures:** All procedures other than the high- and medium-risk procedures.

This guidance focuses on the general population. It does not consider the following groups of patients.

- Symptomatic patients with definite, probable or possible CJD.
- Symptomatic patients with neurological disease of unknown aetiology where the diagnosis of CJD is being actively considered.
- Asymptomatic patients at risk of having familial forms of CJD or who have had previous iatrogenic exposure.

For the excluded patient population above, the guidelines set out by the ACDP TSE Working Group and published on the Department of Health website should be followed (see appendix B).

2.3 Clinical and decontamination practice

The following areas of clinical and decontamination practice were considered in terms of clinical and cost effectiveness, patient safety and the extent to which they reduce the risk of CJD transmission.

- Use of reusable and single-use instruments in surgical procedures.
- Use of reusable and single-use endoscopes, laryngoscopes and related accessories.
- Arrangements for cleaning, sterilisation and tracking of reusable surgical instruments and endoscopes[2].

The following areas were **not** considered in this guidance.

- Transfusion of blood or blood products, including occupational exposure to blood or body fluids. Several organisations (including the Department of Health Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs for Transplantation, the Spongiform Encephalopathy Advisory Committee (SEAC), the ACDP TSE Working Group and the CJD Incidents Panel – see appendix B) already advise on measures to reduce the risks from blood transfusion, including exposure to blood in the workplace.
- Extracorporeal life-support machinery, including cardiopulmonary bypass, haemodialysis and ventilator equipment.
- The risk of CJD and vCJD transmission via drugs and other materials of human or bovine origin. This area is already subject to regulation by the Medicines and Healthcare products Regulatory Agency (MHRA).
- The safety of transplant grafts. This area is the responsibility of the Department of Health Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs for Transplantation.
- The decontamination and reuse of single-use instruments. The MHRA has issued guidance against the reuse of such items (MHRA Bulletin DB 2000[04]).
- General dentistry. The initial remit excluded dentistry, but the Committee nevertheless considered issues relating to dental procedures. After deliberation it was agreed that general dentistry should be excluded. Aspects of dentistry, such as decontamination practices and dental tissue infectivity, are currently being considered by the Department of Health and the Health Protection Agency. Maxillofacial surgery was included in the guidance under medium- or low-risk procedures.

2.4 Context

2.4.1 Types of CJD

CJD is a progressive, fatal neurological disease that belongs to a wider group of neurodegenerative disorders known as transmissible spongiform encephalopathies (TSEs) or prion diseases. TSEs affect humans and animals. Traditionally, there are three aetiological categories of CJD.

- Sporadic CJD (85–90% of cases) is of unknown aetiology. Sporadic CJD has a worldwide distribution, with a relatively uniform annual incidence of about 1 in 1 million people.
- Inherited CJD (10–15% of cases) is associated with coding mutations, insertions or deletions in the prion protein gene.
- Iatrogenic CJD (less than 1% of cases) arises from accidental exposure to human prions through surgical or medical procedures.

CJD patients typically present with rapidly progressive dementia, usually accompanied by myoclonus and cerebellar ataxia. Most patients die within 4 months of disease onset, in a mute and immobile state.

2.4.2 Variant CJD

A novel form of human prion disease, vCJD, was first recognised in the UK in 1996 and is believed to result from consumption of food derived from cattle infected with BSE. Like BSE, vCJD is a fatal neurodegenerative disease that causes sponge-like changes in the brain. vCJD is characterised by extensive lymphoreticular tissue involvement and a young age at onset of disease (the mean age at death is 28 years, compared with 66 years for sporadic CJD). The clinical course of vCJD is also distinct from that of sporadic CJD. Patients with vCJD frequently present with sensory and psychiatric symptoms that are uncommon in patients with sporadic CJD. They then develop progressive neurological signs, such as gait disturbance, ataxia and tremor. The median duration of illness is longer than that for sporadic CJD (14 months compared with 4 months). Death in an immobile and mute state is a typical outcome.

By the beginning of September 2006, 156 people in the UK had died from definite or probable vCJD, and a further six were alive with the diagnosis.

> Note that throughout this guidance the abbreviation CJD is used to refer to both sporadic and vCJD (see the glossary, appendix F) unless otherwise specified.

2.4.3 Prions

The prion protein is a normal cellular protein that is widely expressed in almost all human tissues, with the highest levels seen in nerve cells. Prions are infectious particles composed of abnormally folded forms of the prion protein that are thought to cause TSEs, including CJD. They resist complete inactivation by conventional hospital decontamination techniques. Individuals undergoing surgery may therefore be infected by prion-contaminated instruments previously used on patients with CJD.

2.4.4 Iatrogenictransmission

There have been seven cases of iatrogenic transmission of (presumed sporadic) CJD via contaminated neurosurgical instruments or intracerebral electrodes. Five cases resulted from neurosurgical instruments: four in the UK and one in France. All of the UK cases occurred over 30 years ago. Neurosurgical instruments used on possible carriers of CJD are now handled in accordance with the ACDP TSE Working Group guidance. The other two cases were reported from Switzerland and resulted from the reuse of contaminated electrodes. All neuroelectrodes are now single-use.

There have been no reported cases of patient-to-patient transmission of vCJD via current techniques of surgery, laryngoscopy or endoscopy. The three documented UK cases of possible iatrogenic transmission of vCJD relate to blood transfusions, which are excluded from the remit of this guidance. Nevertheless, surgical transmission of vCJD cannot be ruled out as a risk to public health in the future. The potentially long incubation period makes it possible that patients may have become infected as a result of interventional procedures, even though no cases have been reported in recent years. Without the means to link between diagnosed cases, through instrument tracking, it is not possible to identify potential transmission events.

2.4.5 Advisory groups

A number of advisory committees, expert groups and academic units are actively involved in addressing a variety of issues relating to CJD (see appendix B). The issues range from developing the scientific basis of our understanding of the disease, to improving decontamination practices across the NHS, to minimising the risk of transmission. The Institute has made every effort to coordinate its activities with these groups and to ensure that this guidance takes account of, and builds on, their work. Many of the members of the Committee advising the Institute on CJD are also members of the other committees, working groups and academic units. In addition, the Institute has been represented on a number of these groups.

[2] Detailed consideration of costs was not possible for these areas.

3 Evidence and interpretation

3.1 Evidence on safety and cost effectiveness

3.1.1 Risk assessment and data sources

Assessing the risk of transmission of CJD via interventional procedures was the first step in the guidance development process. The risk assessment was informed by a number of evidence sources.

- A risk assessment by the Department of Health Economics, Statistics and Operational Research (ESOR) Division[3].
- A systematic review of issues such as the prevalence of CJD in the general population and efficacy of decontamination arrangements (see the Review Group's final report).
- A formal elicitation process using leading experts in CJD and decontamination and frontline practitioners (see the Review Group's final report).
- Empirical data from experimental studies coordinated by the Department of Health Research and Development Programme.
- Hospital Episodes Statistics (HES) were used to derive the number of operations per specialty per year and the rates of repeat operations.
- The NHS Purchasing and Supplies Agency (PASA) database provided information on costs of reusable instruments.
- Submissions by manufacturers on decontamination arrangements, tracking systems and costs of single-use instruments (see appendix E).
- Expert opinion.
- Additional information provided during the public consultation period.

Overall, there was a lack of data on many of the key parameters such as the prevalence of vCJD infectivity in the UK population and the effectiveness of current decontamination practices against human prions, resulting in a high degree of uncertainty (that is, wide reference ranges in the model outputs). Probabilistic sensitivity analysis was used to quantify the uncertainty surrounding these

key parameters. The risk assessment took account of the dynamics of CJD transmission via interventional procedures. Finally, the assessment also considered the costs and cost effectiveness of various methods of reducing the risk of transmission.

Three scenarios based on the inputs from the sources listed above were constructed: pessimistic, median and optimistic. The model outputs for each scenario were presented to the Committee for all medium- and high-risk operations as defined in the guidance remit (over 2 million operations per year in England and Wales). Initial model runs showed that, even when pessimistic assumptions about a high prevalence of CJD and a low effectiveness of decontamination were made, the number of cases of CJD resulting from medium-risk operations was still less than 25 cases from a total of approximately 2 million medium-risk operations undertaken in England each year. Therefore, the modelling suggested that medium- and low-risk interventions were unlikely to result in a self-sustaining epidemic and that changes in practice for these interventions would not be cost effective. As a result, further modelling focused on high-risk procedures only.

3.1.2 New decontamination methods

A number of potentially more effective decontamination methods are currently in development. These include decontamination solutions or changes in decontamination practice, such as keeping instruments wet immediately after use until they are cleaned. Preliminary commercial and academic in-confidence submissions on the efficacy of decontamination solutions and their likely costs were reviewed by the Committee and used to model their effects on transmission of CJD via interventional procedures. Based on the submissions considered, the modelling assumed that these new decontamination agents would be introduced universally throughout the NHS within the next 5 years. The model also assumed that these agents would reduce the average infectivity of all tissues by 5 log, which was at the lower end of the efficacy ranges submitted to the Institute. The safety and efficacy of these agents against human prions require rigorous evaluation. SEAC has described the principles which should govern this work.

3.1.3 Elimination of instrument migration between sets

Despite attempts to obtain data on instrument swapping and the use of supplementary instruments, very limited information about these practices exists. However, after considering the evidence available, the Committee assumed that the probability of at least one instrument, on average, being swapped during an operation or the subsequent decontamination process was 50%. Where a supplementary instrument was used, it was assumed that there was a 50% probability that it would become part of the main set with a similar instrument from the original set becoming the supplementary instrument (see the Review Group's final report).

For high-risk procedures, the model showed that keeping reusable instruments together within sets significantly reduced the number of cases of CJD transmission. Threshold analysis showed that, at an assumed willingness to pay £30,000 per quality-adjusted life year (QALY), it would be, on average, cost-effective for the average neurosurgical (brain surgery) unit to spend up to £5.9 million over a 5-year period in purchasing additional supplementary instruments and/or introducing instrument tracking methods, where appropriate, in order to eliminate instrument migration. For posterior eye surgery it would be cost effective to spend up to £10.9 million per surgical unit over a 5-year period (see the Review Group's final report).

For medium-risk procedures, there was no evidence that keeping reusable instruments together in sets reduced CJD transmission because of the lower levels of infectivity. However, the Committee considered that keeping sets together in medium- and low-risk procedures was desirable for other reasons (see 3.2.6).

3.1.4 Performance of single-use instruments

Systematic review of the literature identified a number of studies on the complication rates associated with single-use compared with reusable instruments in surgery, but these were related almost entirely to adenotonsillar surgery. The studies took the form of three prospective audits, six retrospective audits and a survey (see the Review Group's final report for details). Among these studies, the Welsh National Tonsillectomy Audit was considered to provide the highest quality evidence. It was therefore considered inappropriate to weaken the findings of this audit by combining these data with data from other studies in a meta-analysis.

The Welsh National Tonsillectomy Audit indicated that, compared with reusable instruments, single-use instruments were initially associated with a more than 100% increase in complication rates. Primary haemorrhage resulting in return to theatre doubled from a baseline rate of 0.6% with reusable instruments to 1.2% when single-use instruments were introduced. The rates returned to baseline levels (that is, equivalent to reusable instrument complication rates) when appropriate procurement and surveillance mechanisms were introduced, which ensured that single-use instruments met detailed specifications. The investigators also conducted two separate and detailed audits of suppliers of single-use tonsillectomy instruments in the UK, which showed considerable variation in the quality and consistency of the single-use instruments available. Careful specification and quality control of instruments were therefore emphasised as key requirements to ensure patient safety.

Scenarios were presented which assumed higher complication rates for single-use instruments in high-risk specialties (see the Review Group's final report).

3.1.5 QALYs lost

The model suggested that for every case of transmission of CJD via an interventional procedure, the average number of QALYs lost, based on the age distribution of the patients undergoing a procedure, was in the order of 17 for neurosurgery and 11 for posterior eye surgery.

3.1.6 Costs

The direct cost to the NHS of treating patients with CJD (approximately £40,000 per patient) is based on estimates provided by the Department of Health (see the Review Group's final report). Many other costs are borne by the public sector, individuals and society in general, but these have not been included in the cost-effectiveness modelling, in accordance with the NICE reference case (see the glossary, appendix F).

Modelling was performed using the assumption that single-use instruments would cost the same as their reusable counterparts. This assumption was made because there are almost no single-use instruments on the market for high-risk operations, meaning that, in most cases, reusable instruments would need to be used and disposed of after first use. In practice, the costs of single-use instruments may be lower than this.

Lists of the instruments used in all relevant procedures were prepared with the help of healthcare professionals and Committee members. For high-risk procedures, specific lists were compiled of those instruments that normally come into contact with high-risk tissues – these are the instruments that would need to be replaced with single-use alternatives. However, for many such instruments single-use versions are not currently available.

The costs associated with procurement and surveillance protocols for single-use instruments were also accounted for. These were based on the Welsh experience with single-use instruments for tonsillectomy. The costs of disposing of single-use instruments were assumed to be similar to the costs of autoclaving reusable instruments.

3.1.7 Cost effectiveness of preventing transmission of CJD through high-risk procedures using single-use instruments

The results of the model strongly suggested that preventing instrument migration for high-risk procedures was both effective and cost effective in reducing the risk of CJD transmission. Modelling of further measures to minimise the risk of CJD transmission was therefore performed assuming that reusable instruments stay together within sets.

Specifically, modelling was carried out to assess the effectiveness and cost-effectiveness of introducing single-use instruments for patients who have had previous high-risk procedures. Patients who have undergone high-risk procedures may have an increased risk of having contracted CJD and could potentially transmit the disease via subsequent high-risk procedures. Using single-use instruments on these patients would prevent onward transmission and reduce the overall number of infections via interventional procedures.

The estimated average mean incremental cost per QALY of introducing single-use instruments for patients who have previously undergone high-risk surgery was approximately £100,000 for intradural brain surgery and £45,000 for surgery on the retina and optic nerve. For surgery on the spine, the average cost per QALY was around £400,000. The estimated average incremental cost per QALY of introducing single-use instruments for all patients undergoing high-risk operations was in excess of £50,000.

For neuroendoscopy, the average incremental cost per QALY of introducing single-use accessories was around £16,000 for rigid and £22,000 for flexible neuroendoscopes. The average incremental cost per QALY of introducing single-use neuroendoscopes was £126,000 for rigid and over £1 million for flexible neuroendoscopes. These figures assume that rigid reusable neuroendoscopes are autoclaved. For the above calculations, the full price of reusable surgical instruments, neuroendoscopes and accessories was used, as there are no single-use equivalents currently available, with the exception of single-use rigid neuroendoscopes (see the Review Group's final report).

The confidence intervals around these means were very wide, with median cost-effectiveness values being generally higher than the means, as the distributions were highly skewed. Cost-effectiveness acceptability curves were used to depict the uncertainty around the mean (see the Review Group's final report).

3.2 Consideration of the evidence

3.2.1 The Committee reviewed the available evidence on the risk of transmission of CJD via interventional procedures and on the safety and clinical effectiveness of a range of interventions aimed at reducing this risk. Prevention of a self-sustaining epidemic was considered particularly important. The work of the Committee was hindered by a lack of firm evidence and considerable uncertainty surrounding many key aspects of CJD, such as the prevalence of vCJD infectivity in the UK population and the efficacy of current decontamination practices against human prions. These uncertainties caused

considerable problems for the Committee in its attempt to identify appropriate risk-reducing and cost-effective interventions which could be rapidly introduced in the NHS.

3.2.2 In its deliberations, the Committee was mindful of the need to ensure that its advice took account of the efficient use of NHS resources. At the same time, it was particularly concerned about the need to avoid even a low risk of a self-sustaining CJD epidemic occurring through surgical transmission. The Committee considered three main measures as possible means of reducing the risk of transmission of CJD.

- The introduction of more effective decontamination practices.
- The prevention of instrument migration between sets.
- The introduction of single-use instruments.

The Committee took account of evidence relating to the safety, efficacy, costs and practicalities of implementing these different interventions for various types of procedures and patient groups, with a view to reducing the risk of transmission of CJD via interventional procedures.

3.2.3 The Committee considered in-confidence information about agents that are being developed to decontaminate instruments from human prions. The manufacturers' submissions, together with information provided by research groups and the Department of Health Research and Development Programme, satisfied the Committee that effective and practical decontamination methods are likely to be available in the NHS within the next 5 years, and that, once available, they could prevent surgical transmission of CJD via most types of instruments. The Committee therefore decided to limit the time horizon for modelling to 5 years. However, the data were considered insufficient to support any recommendations about the use of these decontaminants. Further assessments of efficacy against human prions, safety, and costs of these decontaminants were regarded by the Committee as urgently needed to support future recommendations to the NHS.

3.2.4 Initial outputs from the model showed that it is not cost effective to change to single-use instruments for medium-risk procedures, and, by implication, for low-risk procedures. Medium-risk procedures include tonsillectomy, for which single-use instruments are readily available, in contrast to many other

procedures. These instruments are relatively inexpensive and have been the subject of a number of studies. More detailed modelling indicated that for tonsillectomy, the mean cost of changing to single-use instruments was over £500,000 per QALY using median scenarios, and over £50,000 per QALY for pessimistic scenarios.

Model outputs indicated that continuing with reusable instruments for medium-risk procedures (including tonsillectomy) would not confer a risk of a self-sustaining CJD epidemic. In view of these results, it was decided that the model should concentrate on high-risk procedures only, namely intradural neurosurgery, neuroendoscopy and posterior eye surgery (see appendix C for a full list of high-risk procedures). Further modelling demonstrated that any change in practice for surgery on the spine, which is considered to be 100 times less infectious than the brain and posterior eye, would not be cost-effective. Therefore, the Committee focused on intradural brain surgery, neuroendoscopy and posterior eye surgery.

Approximately 56,000 high-risk and 2 million medium-risk procedures are performed each year in England and Wales.

3.2.5 The Committee was particularly concerned about the possible risks associated with instruments migrating from one set to another and the use of supplementary instruments. Modelling showed that migration of instruments between sets increased the risk of transmission of CJD in high-risk procedures and that preventing instrument migration through tracking and abolishing the use of supplementary instruments was cost effective in these procedures. The Committee considered it most important that systems are put in place to ensure no instruments are swapped between sets in high-risk procedures and that the effectiveness of these systems is demonstrated through regular audit. The Committee noted that this practice is line with the guidance set out in Health Service Circular 2000/032.

3.2.6 For medium- and low-risk procedures, instrument swapping had no significant effect on the overall risk of onward transmission of CJD. However, the Committee noted that there may be other reasons for keeping instruments together in sets in these procedures, as suggested in Health Service Circular 2000/032, such as to allow identification of patients who may have been exposed to the risk of any infectious disease at the time of an interventional procedure.

3.2.7 The Committee was aware of advice by professional organisations, such as the British Society for Gastroenterology, recommending replacement of reusable endoscope accessories with single-use items. Although this is not a cost-effective measure to prevent transmission of CJD (except in the case of accessories for neuroendoscopy), single-use instruments (including accessories) currently represent the only means of eliminating all risk of transferring infectious diseases from one patient to another. This provides justification for continuing the carefully monitored development and introduction of single-use instruments.

3.2.8 The Committee considered neuroendoscopy and decided that reusable rigid neuroendoscopes that can be autoclaved should be used whenever possible and should be thoroughly cleaned and autoclaved after each use. Only when the use of rigid neuroendoscopes is impractical should reusable flexible neuroendoscopes be used.

3.2.9 The Committee considered children born since 1 January 1997, who are unlikely to have been exposed to BSE or CJD via diet or blood transfusion, respectively. Therefore, the prevalence of CJD in this population is close to zero. The Committee decided that new reusable surgical instruments for high-risk procedures and new neuroendoscopes should be purchased and used solely on those children born after 1 January 1997 who have not previously undergone high-risk procedures. These instruments and neuroendoscopes should not be used on children who have been identified as being at risk of any form of CJD, including inherited CJD.

3.2.10 The Committee discussed the performance of single-use compared with reusable instruments, with a focus on patient safety. There were repeated concerns that complication rates might be increased if single-use instruments were of inadequate quality. The published literature, and in particular the Welsh National Tonsillectomy Audit, demonstrated that this could occur, but also showed that single-use instruments can be of equivalent quality to reusable instruments, provided that appropriate quality-control mechanisms are in place. The Committee therefore accepted the premise that the quality and performance of single-use instruments could be equivalent to those of reusable instruments, provided appropriate procurement, quality control and audit mechanisms are in place. The modelling was undertaken assuming equivalent performance and taking account of the costs of an adequate quality-control

system.

3.2.11 The Committee noted that single-use instruments are used regularly in some high-risk procedures, but that no single-use instruments exist to replace the reusable ones for other high-risk procedures. Based on the Welsh experience with tonsillectomy instruments, there would be a significant time lag (18 to 24 months) before single-use instruments could be introduced with mechanisms to guarantee appropriate levels of consistency and quality.

The Committee considered the scenario of introducing single-use instruments for high-risk procedures, either for all patients or only for those who have had previous high-risk surgery. However, this was not cost effective, except in the case of single-use accessories for neuroendoscopy for all patients. Taking account of both costs and the practical challenges of introducing single-use instruments, the Committee decided against recommending their use, with the exception of single-use accessories for neuroendoscopy.

3.2.12 Throughout its deliberations the Committee was mindful of the potential implications of a self-sustaining CJD epidemic. This was particularly important given the episodic nature of the possible transmission of CJD via high-risk operations. The model demonstrated that, unless instruments are kept with their sets, a single high-risk procedure in an infectious patient could result in a large number of cases of onward transmission. For example, the model suggested that if instrument swapping and use of supplementary instruments continued at assumed current levels, there was a 10% chance that approximately 700 new fatal CJD infections could occur as a result of transmission by interventional procedures every year in England and Wales. This could result in an epidemic occurring within the 5-year timeframe considered by the Committee. The likelihood of an epidemic would be significantly reduced if instruments were kept with their sets. Therefore, the Committee felt it was essential that instrument swapping should not occur and that the effectiveness of any measures taken to ensure instruments are kept together is clearly demonstrated through audit.

[3] Assessing the risk of vCJD transmission via surgery: an interim review (June 2005).

4 Implementation and audit

NICE has developed tools to help organisations implement this guidance (listed below). These are

available on our website.

- Costing report and costing template to estimate the savings and costs associated with implementation.

4.1 Implementation

4.1.1 There may be a number of ways of ensuring that instruments stay together within sets. The Committee did not review any data on the effectiveness of specific systems. It is the responsibility of individual Trusts to ensure that effective systems are in place.

4.1.2 Consideration should be given to packaging those instruments that normally come into contact with high-risk tissues (brain, retina, optic nerve) in separate sets to those that do not (for example, instruments used only for approach and closure).

4.1.3 Enough instruments should be purchased to ensure that the practice of using supplementary instruments is abolished and that all instruments stay within their sets. This will involve a one-off cost of purchasing sufficient instruments to incorporate into sets, so that those frequently required as supplementary are routinely available. Additional instruments will also need to be purchased to allow for immediate availability of replacements if instruments in sets are found to be defective or if they become unsterile during procedures. If high-quality, single-use instruments become available, these may be introduced as alternatives.

4.1.4 The Committee was not aware of the availability of single-use accessories for neuroendoscopy. Until such instruments become available, reusable accessories should be used only once and disposed of.

4.1.5 Neurosurgical units should purchase sufficient rigid neuroendoscopes suitable for autoclaving to allow these to be used in preference to flexible neuroendoscopes whenever possible. The neuroendoscopes should be suitable for autoclaving, and they should be thoroughly cleaned and autoclaved after each use.

4.1.6 Neurosurgical units should purchase or allocate new instruments and neuroendoscopes for exclusive use on children born after 1 January 1997, as

described in section 3.2.9. Ophthalmic surgery units should similarly set aside new instruments for children born after 1 January 1997 who have posterior eye operations.

4.2 Audit

4.2.1 Evidence on the effectiveness of preventing instrument swapping should be collected and assessed in a systematic way. The Institute will review this evidence when it reviews the guidance.

4.2.2 Any problems relating to the performance of single-use instruments should be documented and transmitted to the Medicines and Healthcare products Regulatory Agency and the National Patient Safety Agency, as appropriate.

5 Recommendations for further research

5.1 Research is urgently needed to establish the prevalence of vCJD infectivity in the UK population.

5.2 New decontamination methods should be evaluated urgently as they become available to validate their safety and efficacy against human prions and to assess the feasibility of their introduction into widespread use in the NHS. Their cost effectiveness should also be considered.

5.3 Research is needed into the practice of keeping instruments wet during and after use, as a potential means of enhancing the efficacy of the decontamination process. Further research is also required into the effectiveness of the full decontamination cycle (washing and autoclaving) in reducing prion infectivity.

5.4 Further research to help establish the risk of infection via neuroendoscopy is required. Experimental data are needed on the degree of contamination of neuroendoscopes and the efficacy of current decontamination methods in reducing CJD infectivity.

6 Review of the guidance

Because of the substantial uncertainties in many of the assumptions used for this guidance, the Committee has recommended continuous review of data relevant to the model. The Institute will

consider this guidance for review in November 2008 or earlier if new relevant evidence becomes available. This may include data on:

- the availability of appropriately validated decontamination methods for routine use in the NHS
- the epidemiology of CJD, including data on prevalence of vCJD infectivity in the UK population
- cases of transmission of CJD via surgery
- the availability and performance of single-use instruments for high-risk procedures.

7 Further information

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

8 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

19 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Contact NICE

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.