DRAFT

PS/Secretary of State

From: Liam Donaldson
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VARIANT CJD AND SURGICAL INSTRUMENTS

Issue/recommendation

1. We need to establish and announce a clear clinical policy further to reduce risk of transmission of vCJD via surgical instruments for high and medium-risk surgical procedures, and particularly tonsillectomy and appendectomy, in the NHS in England.

2. This submission considers:
   - recent progress on decontamination and an updated analysis of the risk of transmission of vCJD. The risk analysis shows that applying current decontamination techniques does not give sufficient assurance on minimising risks of transmission.
   - progress in improving the safety, reliability and cost-effectiveness of single use surgical instruments and whether we are in a position to recommend their use to surgeons.
   - training issues and the acceptability of single use instruments to surgeons.

3. The submission recommends:

[either that we move towards a clear statement of preference for single use instruments for procedures involving high and medium-risk tissues, pointing out the range of options becoming available in the next few months, and in effect giving notice of withdrawal of the option for reusable instruments

or that, because of practical issues concerning the availability of single use instruments we should at this stage simply re-inforce existing advice that single use instruments should be considered wherever practical, and supplement this by:
(a) working with the surgical profession to educate its members on risks and benefits and
(b) providing more information to surgeons on options for single-use instruments

Timing

4. Urgent. The Department's policy on single use instruments continues to attract comment. We need to have a policy in place which is credible and coherent. The issue will be brought into sharper focus with the publication of two reports in the New Year:
   - a retrospective study of appendices which will show that three positive prion samples have been discovered. This points to there being some tens of thousands of people possibly infected with the vCJD agent, and potentially infective

- a laboratory study in Wales which compared single use instruments with reusables which found problems with a wide range of single use instruments that could adversely impact on patient safety.

The effect of these publications will suggest both that the risk of transmission is greater than previously thought and that one of the main policy options, introduction of single use instruments appears unreliable.

Background

5. Current policy, established in December 2001, is for the use of re-usable surgical devices, including reusable diathermy devices, for tonsil and adenoid surgery. This reversed guidance issued in January 2001, which had introduced single use instruments for tonsil surgery. The decision to revert to re-usables was made in reaction to problems with the supply and reliability of the single use instruments then available and lack of training for surgeons with the new instruments.

6. The process leading to the original policy decision in favour of single use instruments in January 2001 and the change in policy in December 2001 are described in Annex A.

7. Background information on variant CJD and risks of transmission is at Annex B. The initial risk assessment carried out by EOR in 2000 and subsequent advice from SEAC are at Annex C and a summary of policy in Scotland Wales and Northern Ireland is at Annex D.

Recent developments and need for new policy decisions

8. There have been developments in several of the factors which influenced the decisions made in 2001. Taken together, these suggest a need to reconsider whether our prime objective of minimising the risk of transmission is best served by continuing to rely on improved decontamination of re-useable instruments or if we should now revert to recommending single use instruments.

<u>Progress on decontamination</u>

9. Surgical instrument decontamination practice in NHS hospitals was found to be highly variable, when initially surveyed in 2000. A recent operational review, carried out by NHS Estates, has shown a marked improvement in decontamination standards. The review showed that in those centres which had been resurveyed, decontamination practice had undergone considerable improvement.

10. While decontamination standards are generally improving, this does not appear to be enough to remove the CJD transmission risk. The CJD agent differs from conventional bacteria viruses and has a high affinity for steel surfaces. It also appears that in some hospitals, instruments are allowed to dry out before being cleaned and sterilised. Research indicates that dried-on material may be much harder to remove.

11. Protein residue has recently been sampled on instruments that have been cleaned and are ready for re-use in theatre. High variability has been found on instruments from within the same hospital, with a significant minority of instruments showing gross contamination. This may indicate that decontamination standards, although clearly improving, may have been worse than initially thought.

12. The national decontamination strategy will result in the greater centralisation of services leading to higher standards. However, this process will take some years. As well as improving the application of existing technologies, new decontamination techniques such as the use of hot alkali or enzymes are being developed aimed at effective removal of inactive prion. Early laboratory results are encouraging, but it will take some time to develop these techniques for widespread use.

Risk assessment

13. The Department's Economics and Operational research Division (EOR) were commissioned at the end of July to carry out a revised risk assessment on the risks associated with different surgical procedures on secondary transmission of vCJD. The preliminary assessment of the NHS Estates review of instrument decontamination was incorporated into EOR's interim review of the risk assessment.

14. The EOR report shows that the effectiveness of decontamination is improving, but also points to new scientific evidence which is emerging on protein residues which remain after cleaning. **The main finding of the EOR risk assessment is that the greatest scope for risk reduction lies in making further progress on decontamination followed by the use of single use for high risk and medium risk procedures.**

15. Further improvement of decontamination practice and standards are necessary to reduce infection risk from all types of CJD. But it appears doubtful that risk can be reduced to acceptable levels using current technologies sufficiently quickly. Priority should be given to the development of the experimental techniques currently under investigation, but in the interim, other approaches such as the use of single use instruments are needed.

16. All lymhoreticular tissue potentially poses some risk of vCJD transmission. A generic approach is therefore required to encouraging single use for surgery that comes into contact with these tissues rather than addressing specific procedures such as tonsillectomy or appendectomy. The highest risk remains with the brain and the back of the eye.

Instrument quality and reliability

17. In view of the problems encountered with single use instruments in 2001 we will need the strongest assurance on the availability, safety and cost of these

instruments before these can be recommended for high and medium risk operations including tonsillectomy.

18. The study in Wales referred to above was initiated in 2002 to compare single-use instruments with reusables, to try to identify specific problems. All instruments evaluated were CE marked, and all suppliers accredited to the Medical Device Directive. When assessed against a number of criteria (design being fit for purpose, variability between multiple samples of the same instrument, ease of use), the study team found that 93% of the reusable instruments tested were judged ideal, and 0% unacceptable, whilst between 19% and 50% of single-use instruments from six different manufacturers were judged unacceptable.

19. The Welsh study (which is still confidential) concludes that: "it is highly likely that poorly designed and inconsistently manufactured instruments led to the collapse of disposable tonsil surgery throughout the UK".

20. The Welsh study notwithstanding, there have been several strands of activity since 2001 to improve reliability and safety. A number of promising options for single use equipment are now emerging.

21. Some single use neuro-surgical and ophthalmic instruments are currently available. Some surgeons have embraced their use, but many have not. PASA have reported that manufacturers are unwilling to commit significant funding to the development of single use instruments unless the Department issues guidance along those lines. A statement of our intention to recommend single use instruments whenever practical, should encourage manufacturers to invest in the further development of these products and encourage competition and put downward pressure on prices.

22. A stringent technical specification is required to ensure single use instruments of appropriate quality. The NHS in Wales have made considerable progress on this and have been pursuing a tender for their purchase. Disposable instruments from various manufacturers have been evaluated with input from surgeons and one manufacturer chosen. These instruments will now be used for all tonsillectomies in Wales.

23. We are now aware of three types of instruments for tonsillectomies that are either single-use or have single-use detachable parts. These are:
    - the harmonic scalpel, (Ethicon Endosurgery)
    - the coblation wand (ArthroCare) and
    - single use surgical instruments SUSI developed by BBraun.

24. The safety, cost and availability of each of these are summarised in Annex E.

Professional engagement

25. It will be essential for any change in policy to have support from the leaders of the surgical profession. Most surgeons will never have been involved in a procedure involving a known CJD infection risk. The withdrawal of single use instruments in

December 2001 was disputed by some surgeons who had found single use instruments satisfactory.

26. The key group is the British Association of Otorhinolaryngology Head and Neck Surgeons (BOA-HNS). I have spoken to David Proops, President of BOA-HNS. Mr Proops agreed that a statement to clarify DH stance on the issue would be desirable. He was concerned about central instructions to surgeons to set aside their own clinical judgement.

27. I pointed out that the risk of vCJD being transmissible through reuseable instruments was unknown. He thought risks in this area would be clarified by current work including the tonsil archive which will collect anonymised tonsil tissue and the study of tonsil tissue at the National Prion Unit at St Mary's London.

28. Mr Proops made clear that ENT surgeons would be unwilling to return to disposable instruments because of concerns about the imprecision of such instruments and the risks to of children of complications in using them (eg haemorrhage). He thought experience in Wales should help to clarify risks of complications with single use instruments. He also agreed that the harmonic scalpel and other alternatives appeared promising, but that further work would be needed to determine their efficacy and safety.

29. Training will be a key issue. The manufacturers of the products referred to above are addressing this issue. PASA through the IPP has already asked the BOA - HNS to produce training standards for the coblation wand. The manufacturers of the harmonic scalpel (Ethicon) have stated that training in its use is included in the purchase price and have suggested that training could take place in teaching hospitals in the NHS, and the trained surgeons could then train their colleagues in the technique.

Argument

30. Progress is clearly being made on improving decontamination standards with substantial investment being put in place. However, in relation to vCJD transmission risk, we need to accelerate the development and introduction of improved decontamination technologies, especially for highest risk surgery (brain, spinal cord and back of the eye).

31. However, even if we continue to make progress on decontamination including the development of new techniques in the longer term, this is not a sufficient policy at this stage to demonstrate that we are taking timely action to address the risk of tranmission.

32. I believe that the evidence which is becoming available shows that the use of single use instruments or attachments is currently the only way to completely remove the infection risk. However, this will need to be balanced by individual surgeons against other risks that use of such instruments may incur.

33. While new information continues to become available on decontamination and on developments in single use instruments. I do not think we can continue to wait to collect further information and that we need to make a policy statement.

34. The new options in the harmonic scalpel, coblation wand and single use surgical instruments (SUSI) are not immediately available in sufficient numbers to support a recommendation that these should be introduced for medium, and high risk procedures. We would need to select a manufacturer through a European tendering process. This would take several months after which the chosen manufacturer would need a further lead time of weeks running into months. It would also take time to organise training. We have explored the possibility that the NHS in England might join the Welsh tender, but under European Union procurement requirements England would have had to be mentioned in the first OJEU reference.

35. There are also considerations of cost. To require single use instruments for all high and medium surgical procedures would be prohibitively expensive. The estimates for the single use instruments required for 5,000 tonsillectomies a month range between £5m and £10m pa, with some additional start up costs of between £1in the first year.

36. We are likely to need to follow a phased approach and current evidence suggests that our priority should be to address instruments such as clamps, retractors and suction heads which are in prolonged contact with the highest risk tissue.

37. *[There are two options open to us*
- *[either* that we move towards a clear statement of preference for single use instruments for procedures involving high and medium-risk tissues, pointing out the range of options becoming available in the next few months, and in effect giving notice of withdrawal of the option for reusable instruments

or that, because of practical issues concerning the availability of single use instruments and costs we should at this stage simply re-inforce existing advice that single use instruments should be considered wherever practical, and supplement this by:
    - working with the surgical profession to educate its members on risks and benefits and
    - providing more information to surgeons on options for single use instruments

38. I recommend that at this stage we should follow the second option but move forward as quickly as possible on the procurement, training and costing issues.

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