Date: **19 June 2002**

Venue: **Committee Room 2, National Assembly for Wales**

Title: **Use of Disposable instruments in Tonsillectomy and Adenoidectomy Operations in NHS Wales**

Purpose

1. To provide a written summary and inform Committee Members of the current situation and recent developments associated with single use instruments for tonsillectomy and adenoidectomy operations in NHS Wales.

Summary

2. Following advice from the Spongiform Enchephalopath Advisory Committee, 2001 saw the introduction of single use instruments for tonsillectomy and adenoidectomy operations in England and Wales. In Dec 2001 the DoH issued guidance reverting to the use of re-usable instruments in response to a number of issues and adverse incidents arising from the use of disposable instruments. The CMO considered this guidance and in the absence of robust evidence related to complications arising and in the light of extant guidance from SEAC decided not to revert to re-usable instruments in Wales.

3. The Chief Medical Officer further wished to explore clinical evidence and reliable data prior to issuing definitive guidance for adoption in NHS Wales. In the interim, guidance is for those surgeons who are confident in their use should continue to use the current single use instruments. Those who are unhappy with the current sets to use new –re-usable instruments once **only.**

Background

4. The Spongiform Enchephalopath Advisory Committee (SEAC) have identified a theoretical risk of transmission of variant Creutzfeld-Jacob Disease (vCJD) prion proteins, which may not be removed from the instruments during decontamination procedures and not inactivated during sterilization procedures. In February 2001, following a meeting between the Department of Health and the British Association of Otorhinolaryngologists, Head and Neck Surgeons (BAOHNS) advice was issued stating

that single use instruments should be used for all non-urgent operations on tonsils, adenoids and lingual tonsils. This advice was followed in Wales.

5. In April 2001 Jane Hutt, Minister for Health and Social Services announced funding of £1 million for single use instruments. NHS Trusts were notified of their allocation with the monies directed via Welsh Health Supplies who were tasked with buying and distributing the instruments on behalf of the Welsh Assembly Government. The first batch of instruments arrived in Wales in July and was distributed forthwith. Initially there were some problems with demand exceeding supply but these were quickly overcome and operations started taking place across Wales.

6. By October a number of problems were identified in England:

- Complaints were received about the quality of the instruments.
- There were reports from NHS trusts, of a higher than expected incidence of secondary haemorrhaging (in 72 cases: 11%).

7. In Wales:

- Some trusts complained about the poor quality of the instruments.
- Some reported increased incidence of secondary haemorrhage rate

8. The Medical Devices Agency (MDA) started to audit equipment sterilisation sites, visiting those who had reported a problem to see if there was a pattern. The Purchasing and Supply Agency (PASA) had already started to assess the possibility of problems with the devices being used. In September a questionnaire had been sent to all ENT surgeons in England and Wales to assess the complications resulting from the introduction of disposable instruments. Unfortunately little information could be gathered because of the poor response.

9. Initially, it was suggested by the MDA that the secondary haemorrhaging may be attributable to two possible causes, associated with one particular piece of equipment

- that the diathermy forceps being used are not specifically designed for ENT work and/or
- too much power is being used during the operative procedure

10. Following their investigations the MDA issued a Hazard Notice (MDA HN2001 (04)) setting out preliminary advice. The same Notice was also issued in Wales (NAfW SN No (01)) in which the MDA advised all units performing tonsil or adenoid surgery to immediately review their post operative haemorrhage rates and compare these with the rates prior to the change to single use instruments. All adverse events were to be reported to the MDA. Electrosurgical forceps should be chosen with the smallest electrode area compatible with achieving the required clinical result and when using bipolar electrosurgery surgeons were advised to start with a low setting, especially when using a new electrode.

11. After the above Hazard Notice was issued the number of adverse incidents associated with tonsillectomy and adenoidectomy operations fell. Even so reports were still being received by the MDA and following the report of a death in Northern England associated with the use of diathermy equipment a Device Alert was issued (MDA DA2001 (08)) advising that with immediate effect disposable diathermy forceps were not to be used. This Alert was also issued in Wales (NAfW DA No (2001) 08).

12. Following the issuing of the Alert, concerns continued to be raised across England and Wales about the quality of the instruments and the continuing incidence of secondary haemorrhage and some surgeons in Wales ceased operating. In response to this the Department of Health, on 14 December 2001, announced a re-introduction of re-usable surgical instruments for tonsillectomy and adenoidectomy operations. Such instruments were to be sterilized in the usual way. It was the opinion of the Department of Health that following a large injection of funds; their decontamination units were now of a high enough standard to be in a position to sterilise and decontaminate instruments used in such operations. However SEAC advice was still extant.

13. At the time, in Wales, the Chief Medical Officer and her professional advisors considered England's position. They felt that before such a decision could be made objectively in Wales about the balance of risk and the use of single use instruments, more information was needed from the trusts and surgeons on the number of adverse incidents and their view on the quality of the instruments. Also on 14 December, Dr Hall issued guidance (Annex 1) which stated that whilst this data is gathered surgeons who were confident in their use of the disposable instruments should continue to use them. Others should continue to wait until the outcome of the review. Reusable instruments should not be used. NHS Scotland and Northern Ireland are reported to have taken a similar stance.

14. On 20 December 2001 the MDA issued a second Device Alert, this one advising surgeons not to use single use instruments for tonsillectomy and adenoidectomy operations. In light of the earlier guidance issued by Dr Hall, this Alert was not issued in Wales. In order to reinforce the position Dr Hall wrote to all ENT surgeons in Wales reiterating the current guidance and the way forward.

15. A meeting between Dr Hall, her professional advisors, Welsh Assembly Officials, representatives from Welsh Health Supplies and the Surgical Materials Testing Laboratory and a representative number of ENT surgeons from Wales took place in March 2002. The purpose of that meeting was to review the current policy in Wales. A number of issues were discussed at the meeting including:

- the evidential basis for the introduction of single use instruments to combat the possibility of associated vCJD contamination,
- The relevance of the extant SEAC guidance
- Clinical risks associated with the use of single use instruments.
- The pertinent and accuracy of the audit date

16. It was agreed that the risk of vCJD contamination existed and that earlier guidance from SEAC remained in force. At the time of the meeting operations were being performed regularly at the

- Royal Gwent Hospital, Newport
- Singleton Hospital, Swansea
- West Wales General Hospital, Carmarthen
- Ysbyty Gwynedd, Bangor,
- Wrexham Maelor Hospital, Wrexham.

Four hospitals had ceased operations, namely the

- Royal Glamorgan Hospital, Llantrisant
- Princess of Wales Hospital, Bridgend
- Glan Clwyd Hospital, Bodelwyddan
- University Hospital of Wales, Cardiff

17. The meeting also considered several suggestions from the Clinicians involving improvements in the design and construction of the disposable instrument sets and increased flexibility for surgeons in selecting the disposable instruments. It was agreed that there was a need for a further and more comprehensive audit. In the interim it was agreed with the ENT surgeons that the current guidance should remain unchanged whilst further analysis of available date was undertaken.

18. During April 2002 a full and independent evaluation of the available data was undertaken, based on tonsillectomies performed between 1995 and 2002 was considered, this demonstrated a significant initial rise in complications rates following the introduction of disposable instruments

19. At the most recent meeting, between ENT surgeons and Officials held on 16 May, the following options were considered in detail:

- To return to re-usable instruments and accept the theoretical risk of vCJD transmission
- To use centrally provided and nationally agreed sets of single use instruments.
- Use re-usable instruments once only
- A hybrid based on a merger of options 2 and 3 – to use re-usable instruments once until such time that sufficient supplies of a nationally agreed set are in place
- To allow each Trust to choose its own single use instruments

Preferred Option

20. This would be Option 4; to work towards nationally agreed sets of single use instruments. Until these are in place for surgeons to use re-usable instruments once only.

Outcome and Current Situation

21. The Department of Health states that the majority of Trusts in England are in a position to

adequately sterilise and decontaminate the re-usable instruments. This has been based on the results of an audit conducted last year where trusts were awarded ‘green’, ‘amber’ or ‘red’ status – green being the highest, though it does not necessarily follow that a ‘green’ trust would also be compliant with the Medical Devices Directive (MDD).

22. Proposed guidance from the CMO is for those surgeons confident in their use to continue to use the current single use instruments. Those who are not to use new re-usable instruments only once. After use the re-usable instruments are to be decontaminated and stored. It is anticipated that this guidance will stand until a universal set of single use instruments have been developed and successfully piloted in Wales.

Waiting List Statistics

23. A special collection of details of numbers of patients waiting for surgery on tonsils, adenoids or lingual tonsils was launched with the issue of WHC (2001) 14 in March 2001 to facilitate monitoring of the situation. Between the end of April 2001 and 2002m the total number reported as waiting for the specified procedures increased from 3,483 to 4,257, an increase of 774 (22%). The total actually waiting first peaked at 4,165 at the end of September 2001 and then fell to 3,775 by the end of November but has risen each month since then.

24. The increases in the numbers of patients waiting long times for treatment are much larger in percentage terms. For example, numbers waiting over 18 months increased from 94 at end April 2001 to 791 a year later, an increase of 741%. The composition of the all-specialties waiting list is now vastly different as a result. Whereas people waiting in the Ear, Nose and Throat specialty represented 6% of all Welsh residents waiting over 18 months for in-patient or day case treatment at the end of April 2001, by a year later they represented 29% of that group.

25. Headline waiting time figures are now presented excluding tonsillectomies, although the previous series including tonsillectomies is still maintained.

Action for the Committee

26. The Health and Social Services Committee are asked to note the above. An update will be provided when final agreement is reached on the preferred option.

Jane Hutt
Minister for Health & Social Services

Annex 1

PUBLIC HEALTH LINK

To: Directors of Public Health

CC Consultants in Communicable Disease Control

From: Dr Ruth Hall, Chief Medical Officer

National Assembly for Wales

Date: 14 December 2001

Reference: CEM/CMO/2001/18

Category: **URGENT CASCADE**

TONSILLECTOMIES AND SINGLE USE INSTRUMENTS

Please forward the attached message urgently to the following:

- Chief Executives of Trusts
- Medical Directors
- ENT Surgeons
- Chief Executives, Health Authorities

In response to a request for advice from Chief Executives in Wales, guidance is as follows. We are also aware of the change of policy in England.

In Wales, evidence of increased rates of complications has been patchy, both before and after the introduction of single use instruments in July. One Welsh Trust which has conducted an audit found that after a small rise in complication rates, these reduced after a short period to original expected levels. This is likely to have been related to surgeons becoming more practised with the new instruments. In the light of this, I am proposing to review experience across Wales to inform decisions. In the meantime, surgeons who are confident in their use of the new instruments should continue to use them. Others will wish to continue to wait until the outcome of the review. Reusable instruments should not be used.

Tonsillectomies are only undertaken after careful consideration of the benefits to patients. I am satisfied that this policy represents an acceptable balance of risk, recognising that the aim of introducing single use instruments was to reduce risk of vCJD transmission. (end message).

RUTH HALL
Chief Medical Officer