
The Single-use Instrument Surveillance Programme
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Introduction

The Department of Health introduced single-use tonsillectomy instruments in January 2001. This was in response to serious concerns raised by the Spongiform Encephalopathy Advisory Committee (SEAC) regarding the theoretical risk of vCJD via prion transmission from patient to patient for certain procedures that were believed to be of high risk. Tonsillectomy was considered to be a high risk procedure especially as the majority of patients were children or young adults.

Following an initial assessment, the instruments were announced as being available in June 2001. However, after a short period of time in use the instruments were withdrawn in England as a result of serious concerns regarding their safety, although the advice relating to vCJD from SEAC remained unchanged.

The Welsh Assembly Government, at this stage, did not abandon the principle of single-use instruments as a solution to possible vCJD transmission during surgery but pursued their use and launched an independent investigation into single-use tonsillectomy instrumentation.

The mechanism to deliver safe surgery in Wales, free of risk from vCJD, arose from a collaborative effort between Welsh Assembly Government, ENT Surgeons and their respect NHS Trusts throughout Wales via the Welsh Otorhinolaryngology Association (WOURLA), the National Public Health Service for Wales (NPHS), Welsh Health Supplies and The Surgical Materials Testing Laboratory (SMTL). The result was The Single-use Instrument Surveillance Programme (SISP).

Aim

To determine if surgery with single-use instruments could be as safe as with their equivalent reusable instruments and provided reassurance and robust evidence of safe practice to both the Public and Health Care Professionals in an environment of much publicised fears over patient safety from vCJD and unsafe single-use instruments.

Methods

Potentially suitable single-use instruments were identified after a detailed laboratory and company analysis. These had never been used in a clinical setting and as public confidence in such instruments was extremely low, a national surveillance system was required to monitor their performance throughout all hospitals in Wales.

This would establish if their safety and suitability was equivalent to reusable instruments.

The Single-use Instrument Surveillance Programme (SISP) was designed to monitor all debris performed by ENT surgeons in Wales (Princes of Wales Health Service) with the specified single-use tonsillectomy and adenoidectomy instruments inside a carefully controlled environment.

Complication rates and individual instrument performance were closely monitored.

Results.

The details of over 10,000 procedures have been recorded to date with the use of close to 100,000 individual instruments.

The effect on complication rates of the initial introduction of poorly designed single-use instruments is shown in Fig 1. This was only corrected after the introduction of SISP and specified single-use instruments.

The introduction of these instruments was not without its problems but SISP was instrumental in the early identification and correction of problems, Fig 2.

Complication rates are now no different from when the procedure was performed with reusable instruments.

Conclusions

Patients in Wales that have been required to undergo tonsil surgery have continued to be protected from the theoretical risk of vCJD transmission during surgery with no apparent additional risk from the instruments used to perform the surgery.

The highest possible standards of care and safety have been demonstrated and continue to be achieved through the close cooperation of ENT Surgeons and Hospitals in Wales, the National Public Health Service for Wales and the Welsh Assembly Government.

Annex

The National Institute of Clinical Excellence (NICE) is presently conducting a detailed investigation into the risk of vCJD to patients from any surgical procedure. NICE conclude, through SISP, in the only sound and robust evidence based data on single-use surgical instruments to NICE.