



The Royal College of Surgeons of England

National Prospective Tonsillectomy Audit

FINAL REPORT of an audit carried out in England and Northern Ireland between July 2003 and September 2004

MAY 2005

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and Northern Ireland between July 2003 and
September 2004

On behalf of the British Association of Otorhinolaryngologists –
Head and Neck Surgeons Comparative Audit Group
and the
Clinical Effectiveness Unit, The Royal College of Surgeons of England

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Foreword

In the Spring of 2003, the ENT community in England and Northern Ireland was invited to participate in a national audit of tonsillectomies. The Audit provided a unique opportunity to review our practice and the response has been impressive. It was only with the support of all professionals and hospitals involved that the National Prospective Tonsillectomy Audit could investigate the occurrence of postoperative haemorrhage and other complications in more than 40,000 tonsillectomies. This investigation into the safety of tonsillectomy is unique because of its data quality, statistical power, and generalisability.

The Audit has already influenced the practice of tonsillectomy and made tonsillectomy safer for patients. As you can read in this report, the ENT community in England and Northern Ireland responded immediately to the guidance that was jointly issued by NICE and the BAO-HNS in March 2004. Following this guidance, there was an immediate shift towards lower risk surgical techniques and a drop in the postoperative complication rate. I hope that the results presented in this final report will contribute to reducing complication rates even further.

The Audit was a response to various issues raised by ENT surgeons. These included concerns about the quality of the single-use instruments introduced in 2001 to combat the transmission of variant Creutzfeldt-Jakob disease, observations that haemorrhage rates varied between hospitals, and evidence of an increase in haemorrhage rates over a number of years. A survey carried out by the BAO-HNS Comparative Audit Group provided an invaluable picture of tonsillectomy practice at that time. In turn, the Department of Health (England) and the Department of Health, Social Services and Public Safety (Northern Ireland) decided to provide the necessary funds.

The Audit was conducted by the BAO-HNS Comparative Audit Group and the Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine. Their combined efforts guaranteed a sound clinical and methodological framework. But the success of the Audit depended on many factors. First and foremost, the staff of the participating NHS Trusts and independent hospitals diligently recruited patients, asked for their consent and entered the data. Second, the Audit benefited from the experience and expertise of the Scottish Otolaryngology Society and the Welsh safety audit. Third, the interactive web-based data entry system developed by the Web Team of the College proved secure and easy to use, and minimised the burden of data collection.

I'd like to thank everyone for their contribution.

Professor Richard Ramsden,

Chairman of the Steering Group of the National Prospective Tonsillectomy Audit
President-elect British Association of Otorhinolaryngologists
– Head and Neck Surgeons

May 2005

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The Audit was conducted by the Comparative Audit Group of the British Association of Otorhinolaryngologists – Head and Neck Surgeons and the Clinical Effectiveness Unit of The Royal College of Surgeons of England – London School of Hygiene and Tropical Medicine. The Department of Health (England) and the Department of Health, Social Services and Public Safety (Northern Ireland) provided funding.

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Peter Brown, Rowena Ryan and Matthew Yung initiated the Audit; Jan van der Meulen, John Browne, Peter Brown, Rowena Ryan, Matthew Yung and Brian Bingham developed the protocol for the Audit and supervised its execution; David Lowe coordinated the data collection supported by Lynn Copley and Jackie Horrocks; Alex Luton and Mark Cuthbertson developed the web-based data entry system; James Lewsey and Lynn Copley analysed the data, supported by David Cromwell, David Lowe and Jan van der Meulen; David Cromwell, David Lowe and Jan van der Meulen wrote the report with contributions from all project team members.

Executive Summary

The National Prospective Tonsillectomy Audit (NPTA) collected information on tonsillectomies performed in England and Northern Ireland from July 2003 until September 2004. The aim of the Audit was to investigate the occurrence of haemorrhage and other complications in the first 28 days after tonsillectomy, the risk factors for these complications, and whether these risk factors explain variation in outcome between hospitals.

The NPTA received data from 145 NHS hospitals and 132 independent hospitals on a total of 40,514 patients. Of these patients, 3,582 (9%) were treated in Northern Ireland. Consent to participate in the Audit was given by 33,921 patients. A consent rate of at least 80% was achieved by 70% of the NHS hospitals, and by 59% of the independent hospitals. 95% of consenting patients recovered uneventfully, while 0.9% required a return trip to theatre. The remainder suffered less severe complications such as mild bleeding, pain or vomiting.

Risk of haemorrhage was found to increase with age, and to be higher for males. Patients with pharyngeal obstruction had the lowest risk.

Overall risk of haemorrhage was related to surgical technique. A 'hot' surgical technique for both dissection and haemostasis (diathermy or coblation) had a risk of haemorrhage that was around three times larger than cold steel tonsillectomy without the use of any 'hot' technique. The risk for operations using cold steel for dissection and bipolar diathermy for haemostasis was around 1.5 times higher than cold steel operations using only ties/packs for haemostasis. There was, however, no strong statistical evidence for variations in the risk of return to theatre among most techniques. Only coblation had an elevated risk that was statistically significant.

The risk of haemorrhage for single-use instruments was around four times the risk for reusable instruments in operations using cold steel and ties/packs but this was based on a sample of only 81 single-use instruments compared to over 4,000 reusable instruments. The risk of haemorrhage was around 1.5 times larger for single-use instruments in operations using cold steel and bipolar diathermy for haemostasis. There was no association between complication rates and grade of operating surgeon in the final analysis.

Most hospitals had a haemorrhage rate that fell within the range expected due to sampling error alone, and adjusting the crude rates for patient characteristics resulted in fewer hospitals being identified as outliers. However, the NHS Trusts identified as 'high' and 'low' outliers using Audit data only partially matched the Trusts identified as outliers using HES data. This was because the Audit captured fewer operations and complications than reported in HES, and highlights the caution needed when using the data of the Audit to assess hospital performance nationally.

Interim guidance on tonsillectomy was issued by NICE/BAO-HNS during the Audit. Both the Audit and HES data suggest that the absolute level of risk fell subsequently. There was also a shift towards the use of surgical techniques with a lower risk of haemorrhage.

Recommendations

- When a patient is counselled for surgery, the risk of tonsillectomy complications, and in particular postoperative haemorrhage, should be carefully explained to the patients/parents.
- This risk should be quantified, preferably using the surgeon's own (or department's) figures. National figures can be used but this should be made clear to patient.
- All 'hot' techniques should be used with caution especially if they are used as a dissection tool.
- Surgeons using monopolar diathermy should consider using an alternative technique. There are no advantages to using this instrument over other methods.
- All trainee surgeons should become competent in cold steel dissection and haemostasis using ties before learning other techniques in tonsillectomy.
- Emphasis must be placed on teaching the correct use of, and the potential hazards of, diathermy and other 'hot' techniques. Checks should be made of the power settings before starting the operation.
- Inexperienced trainees must be supervised by a more senior surgeon until competency has been achieved. This recommendation is in agreement with the College's Standards on Good Surgical Practice issued in 2002.
- Irrespective of seniority and experience, surgeons who wish to start using new techniques such as coblation should undergo appropriate training.
- All ENT departments should have regular Morbidity & Mortality meetings to monitor adverse incidents affecting patient outcome. For tonsillectomy, data should be presented by surgeon, technique used for dissection and haemostasis and power settings if applicable, type of instrument used, and any difficulties encountered. It is the responsibility of the surgeon, and if appropriate his trainer, to follow up any identified problems appropriately.
- Use of single-use instruments should also be recorded, especially for cold steel dissection.
- There is an urgent need for new standards for diathermy machines so that the amount of power used is obvious to the user. Manufacturers of diathermy machines should be encouraged to produce machines with information on the total amount of energy delivered to patients.
- Hospitals should encourage the use of machines that provide clear information on power settings.
- Manufacturers of single-use instruments should be encouraged to improve the quality of the instruments.
- There is a need for further laboratory and clinical research to investigate the influence of diathermy and other 'hot' techniques on an open wound such as the tonsillar bed. In particular, there is a need to investigate the dose-response relationship between power used and complications.

1 Introduction

1.1 Background to Audit

Tonsillectomy is one of the most frequently performed surgical operations. In 2003/04, 50,531 patients underwent tonsillectomy within English NHS Trusts, of which 49,765 (98%) were elective admissions.¹ Just over half of the operations were performed on children under the age of fifteen.

Tonsillectomy is a low risk operation with few complications, the majority of which are not serious. Complications can include difficulty swallowing, vomiting, fever and excessive pain. Postoperative bleeding may also occur, either soon after the operation while the patient is in hospital (primary haemorrhage) or after the initial recovery, typically following the discharge of the patient (secondary haemorrhage).

In January 2001, the UK Department of Health (DH) recommended that single-use instruments be used for all adenotonsillectomy surgery following advice from the Spongiform Encephalopathy Advisory Committee (SEAC). This formed part of a larger investment aimed at reducing the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) via standard reusable tonsillectomy instruments.²

Over the course of 2001, there were reports of higher levels of complications, particularly haemorrhage rates, with some of the single-use instruments, most notably bipolar diathermy forceps.³ Discussions between DH, the British Association of Otorhinolaryngologists – Head and Neck Surgeons (BAO-HNS) and the Medical Devices Agency about the best way to balance the actual risk of complication with the theoretical risk of transmitting vCJD resulted in revised guidance to surgeons. Surgeons were advised to return to using reusable surgical instruments⁴ and suspend the use of single-use diathermy instruments except when bleeding cannot be controlled by other means.⁵

The concerns over postoperative haemorrhage rates led to several studies. The Scottish Otolaryngology Society undertook a retrospective audit of tonsillectomy operations in Scotland. The proportion of patients experiencing no

complications fell slightly from 95% to 94% but it was concluded that there was no significant increase in secondary haemorrhage following the introduction of single-use instruments.⁶ A retrospective survey of tonsillectomy operations in England and Wales in 2002 found overall haemorrhage rates similar to those in Scotland but noted that rates had increased at some hospitals and decreased at others.⁷ It also found considerable variation in tonsillectomy complication rates between hospitals and it was unclear how this variation was related to differences in the characteristics of the patients treated at the hospitals and characteristics of the treatment (such as use of single-use instruments, surgical technique, grade or experience of surgeons). In addition, haemorrhage rates were found to increase each financial year by an exploratory study using Hospital Episode Statistics (HES) data. The study found that haemorrhage rates in English NHS Trusts rose from 3.8% in 1995/96 to 6.9% in 2000/01.⁸

Taken together, the studies suggested that there were a range of issues related to risk of postoperative complications after tonsillectomy. Consequently, a national prospective audit was established to investigate the occurrence of haemorrhage and other complications of tonsillectomy, as well as risk factors for these complications, and the extent to which these risk factors explained differences in outcomes between hospitals.

1.2 Overview of tonsillectomy

Tonsillectomy is commonly performed as treatment for severe recurrent tonsillitis. Guidelines on the indications for tonsillectomy from the Scottish Intercollegiate Guidelines Network recommend that patients should meet all of the following criteria:

- **sore throats are due to tonsillitis**
- **five or more episodes of sore throat per year**
- **symptoms for at least a year**
- **the episodes of sore throat are disabling and prevent normal functioning⁹**

Other indications for tonsillectomy may include chronic tonsillitis, peritonsillar abscess (quinsy) and obstructive sleep apnoea.

The traditional technique of 'cold' dissection was introduced about one hundred years ago.¹⁰ In this technique, the tonsils are dissected with metal instruments by blunt dissection. Any subsequent bleeding may be controlled by packing the tonsillar fossae with gauze dressings or ligating bleeding vessels.

Many different advances in this surgical technique have developed with the aim of reducing intra-operative bleeding, and subsequent postoperative morbidity. About 40 years ago, diathermy techniques were first introduced. In the last two decades, use of these 'hot' techniques has increased dramatically in routine practice¹¹ and diathermy is now the most frequently used method. The ability to dissect and control intra-operative bleeding with the same instrument was probably the most important factor contributing towards their popularity, despite early suggestions that the rates of secondary haemorrhage were increased.¹² Diathermy allows blood loss during tonsillectomy to be minimised, which is a particularly important consideration in young children. The technique tends to be favoured by trainee surgeons because it is quicker to learn and requires less dexterity than cold steel dissection with the ligation of vessels.

Recently, coblation tonsillectomy has been introduced. This technique is a variation of 'electro-surgery' but dissects at lower tissue temperatures than diathermy (60–70°C compared to 400–600°C) with the aim of minimising thermal damage to the tissues adjacent to the tonsils.¹³ Like diathermy, coblation usually causes less peri-operative blood loss. The coagulation mode, however, does work by generating heat which could cause damage to surrounding tissues.

Many other tonsillectomy techniques have been adopted and can include use of various types of LASER for the surgery, bipolar diathermy scissors or various monopolar diathermy instruments. Importantly, while diathermy is often used for both tonsillar dissection and haemostasis, its use may be reserved for haemostasis after a traditional cold steel dissection.

Adenoidectomy (surgical removal of adenoid tissue) may be performed in conjunction with tonsillectomy. Adenoidectomy is usually performed in children when there is evidence of enlarged adenoids causing symptoms such as

blocked nose, mouth breathing or obstructive sleep apnoea. The traditional technique for removal of the adenoids is with a specially designed metal curette. The main alternative is with a suction diathermy technique. Haemostasis is generally achieved by packing of the surgical field with swabs after the procedure for a few minutes.

Whatever technique is used, tonsillectomy is performed under general anaesthesia in the UK. Patients generally spend an initial period of recovery as an inpatient in hospital, although tonsillectomy may be planned as a day case procedure, particularly for children. Discharge home is usually dependent upon the patient's resumption of drinking as well as the absence of vomiting, uncontrolled pain, bleeding or fever. Pain is generally expected following tonsillectomy and analgesia is usually required during the recovery period. Complete recovery may take two weeks or even longer from the time of surgery.

1.3 Aims of the National Prospective Tonsillectomy Audit

The National Prospective Tonsillectomy Audit (NPTA) was initiated in England and Northern Ireland in 2003. The overall aim was to investigate the occurrence of haemorrhage and other complications after tonsillectomy, the risk factors for these complications, and whether these risk factors explained variation in outcomes between hospitals.

The specific objectives of the Audit were:

- **To establish a minimum data set for tonsillectomy including case mix, peri-operative data, and outcome data**
- **To collect these data prospectively for all tonsillectomies carried out in NHS and independent hospitals within England and Northern Ireland over a period of 12 months**
- **To determine to what extent the occurrence of haemorrhage and other complications were associated with type of instruments used (single-use or reusable), surgical technique, and surgical experience**
- **To compare the prospective Audit data with data from Hospital Episode Statistics to assess the completeness of patient inclusion and detection of complications in both databases**
- **To derive a risk model for complications after tonsillectomy that can be used for risk adjustment in future audits**

Box. 1.1: Letter sent to all BAO-HNS members in March 2004 summarising the interim results

Important message from Professor Richard Ramsden, President-elect BAO-HNS, Chairman of Steering Group of the National Prospective Tonsillectomy Audit.

The National Prospective Tonsillectomy Audit began collecting data in July 2003. The great majority of hospitals in England and Northern Ireland, both in the NHS and private sector, have signed up to the Audit. This high level of participation is a credit to the specialty and gives the Audit great statistical power. We have collected data on nearly 15,000 operations. We aim to collect data for a further 7 months and we expect to obtain details about around 30,000 operations in total.

We have analysed the data on all tonsillectomies carried out prior to 23 February 2004 submitted to the Audit's database. We are now in a position to share with you the patterns that are emerging about tonsillectomy technique as a risk factor for postoperative bleeding. We do this because the evidence is so strong that it would be wrong not to inform you at this time. The following is a summary of results that will be published in full in the very near future.

Tonsillectomy technique

The results for five popular tonsillectomy techniques can be summarised as follows:

1. **Cold steel tonsillectomy** using ties and /or packs was the technique with by far the lowest risk of postoperative haemorrhage (1.3%) and return to theatre (1.0%).
2. **Cold steel dissection with (bipolar or monopolar) diathermy haemostasis** had a haemorrhage rate of 2.9%, and 1.7% of the patients returned to theatre.
3. **Bipolar (forceps or scissors) diathermy** for dissection and haemostasis had a haemorrhage rate of 3.9%, and 2.4% of the patients returned to theatre.
4. **Monopolar diathermy** for dissection and haemostasis had a haemorrhage rate of 6.1%, and 4.0% of the patients returned to theatre.
5. **Coblation** for dissection and haemostasis had a haemorrhage rate of 4.4%, and 3.1% of the patients returned to theatre.

These results demonstrate that the haemorrhage rates with 'hot' techniques are at least double the rate with

traditional cold steel using only ties and/or pack for haemostasis. All these results are statistically significant (P value always < 0.01).

Disposable instruments

Another important observation is that haemorrhage rates are significantly higher with disposable than with reuseable instruments (5.2% compared to 3.2%; P = 0.002).

Grade of surgeon

Patients operated on by trainees are more likely to suffer from postoperative haemorrhage than those operated on by consultants and non-training grades (4.6% compared to 2.7%; P < 0.0001).

Conclusions

1. 'Hot' techniques should not be stopped on the basis of the current evidence. However, the Audit found particularly high postoperative haemorrhage rate with monopolar diathermy, and the use of this technique should be carefully considered.
2. The extent to which diathermy is used in a patient seems to be linked to the amount of thermal damage to surrounding tissues. This indicates that diathermy should always be used with caution, and the power setting, frequency and duration of diathermy use should be carefully controlled.
3. The training in ENT may need to be more stringent than in the past. We should emphasise that excessive use of diathermy whilst readily controlling bleeding during surgery may lead to increased postoperative haemorrhage. The technique of tying blood vessels should be taught to all trainees.
4. Coblation may be a particularly difficult technique to learn, and that must be reflected in the way this technique is taught.

We are very grateful for your participation so far and strongly value your continued involvement in this important Audit. We need to get a better understanding of the mechanisms underlying these increased postoperative haemorrhage rates with diathermy and coblation.

Richard Ramsden

1.4 Interim results from the NPTA

The Audit began on 7 July 2003. Interim results, based on the first half year of data collection, were produced in March 2004. By that time, data had been collected on approximately 15,000 tonsillectomies. The interim analysis compared the rates of postoperative haemorrhage for seven tonsillectomy techniques that were frequently observed in the Audit. It was shown that the use of a 'hot' technique (diathermy or coblation) throughout an operation had a postoperative haemorrhage rate that was at least three times as high as cold steel tonsillectomy without the use of a 'hot' technique.¹⁴

Given these results, the National Institute for Clinical Excellence provided interim guidance on the use of hot techniques in tonsillectomy on 24 March 2004.¹⁵ This guidance was accompanied by a letter from the Chairman of the Audit, Professor Richard Ramsden, summarising the interim results and providing recommendations on how the risk of postoperative haemorrhage can be reduced (Box 1.1).

2 Audit method

2.1 Audit organisation and design

The Audit was designed and conducted as a comprehensive national audit with prospective data collection. The Audit was a collaboration between the British Association of Otorhinolaryngologists – Head and Neck Surgeons (BAO-HNS) and the Clinical Effectiveness Unit (CEU) of The Royal College of Surgeons of England. The Department of Health (England) and the Department of Health, Social Services and Public Safety (Northern Ireland) provided funding. It was administered centrally from the CEU, and was overseen by a Steering Group which included representatives from:

- **British Association of Otorhinolaryngologists – Head and Neck Surgeons, also known as ENT-UK**
- **Department of Health**
- **Hospital Episode Statistics**
- **Medicines and Healthcare products Regulatory Agency, formerly known as Medical Devices Agency**
- **The Royal College of Surgeons of England (Clinical Effectiveness Unit)**
- **the Scottish and Welsh Tonsillectomy Audits**
- **the academic community**

The Audit was designed to capture the activity during one year within the NHS and independent sector in England and Northern Ireland. Over 40,000 tonsillectomies were expected to be performed in hospitals that were eligible to participate. An audit of this size was considered of sufficient power to produce clinically meaningful results. A sample of approximately 25,000 patients would have a power of 95% to detect at a significance level of 5% an increase in the haemorrhage or complication rates from 6.0% to 8.0% associated with a risk factor present in 10% of the patients.

2.2 Audit period

The recruitment of patients began on 7 July 2003 and ended on 30 September 2004. The Audit was originally planned to last 12 months. However, it was decided to extend the recruitment period in order to increase the ability of the

Audit to capture the effects of the interim guidance issued by NICE /BAO-HNS on tonsillectomy practice and outcomes.

2.3 Patient selection and recruitment

All patients, children and adults, undergoing a tonsillectomy in an NHS or independent hospital in England and Northern Ireland were eligible for inclusion. Patients were excluded if they underwent:

- **a unilateral tonsillectomy**
- **a tonsillar biopsy**
- **a tonsillectomy for known cancer**
- **a tonsillectomy in conjunction with palatal surgery**
- **any second or revision tonsil operation (revision or remnant tonsillectomy)**

The inclusion of patients in the Audit was subject to having obtained full written consent. When requesting consent from the patient (or parent/legal guardian of the patient), the patient or relative was provided with all necessary documentation, including a patient information sheet for both children and adults. It was stressed that recruitment to the Audit would at no time alter or affect the patient's care or surgical procedure in any way.

The Audit was approved by the Northern and Yorkshire multi-centre research ethics committee prior to commencement. Local research ethics committees were informed about the Audit directly and asked to send all enquiries to the CEU. Approval was also granted by the Department of Health's Review of Central Returns (ROCR) Steering Committee. The Committee noted that the Audit was 'developed in consultation with the Department of Health, who consider the data collection to be useful and reasonable.'

2.4 Data items and definition of complication outcomes

The Audit collected data on patient characteristics, type of hospital, and information about the initial operation including duration of operation, surgical technique, instruments used, and grade of surgeon. Details of subsequent complications, either during the initial admission or leading to a readmission, were also collected. The outcome data that hospitals were requested to record on complications related to whether a patient:

- returned to the operating theatre
- received a blood transfusion
- remained in hospital for longer than planned pre-operatively (delayed discharge)
- was readmitted because of an haemorrhage or other complication in the first 28 days after the tonsillectomy

A copy of the data collection sheets can be found in Appendix 2.

The Audit differentiated between primary and secondary postoperative haemorrhages. A primary haemorrhage was defined as any bleeding that led to delayed hospital discharge, blood transfusion or return to theatre during the initial stay. A secondary haemorrhage was defined as any bleeding that led to readmission to hospital within 28 days of surgery.

These definitions were chosen because such complications were sufficiently severe to require significant levels of extra care (eg extended stay, or readmission to hospital). It was recognised that minor primary complications may not have been captured. The NPTA data collection forms were based on those used by the Scottish Otolaryngology Society.

Box. 2.1: The Audit process

The Clinical Effectiveness Unit of the Royal College of Surgeons of England developed and maintained a 'contact database' of all hospitals ENT consultants involved in tonsil surgery in England and Northern Ireland. 'Link' ENT consultants and administrative contacts were identified for every participating hospital.

Patient packs had to be placed in the medical records of each tonsillectomy patient.

The patient pack contained:

- Patient information sheet (to be given to the patient)
- Consent form (to be kept in patient's medical record)
- Adhesive sticker (to be stuck on front cover of medical record)
- Operation sheet and postoperative complication sheet

Before surgery (either at the pre-admission clinic or around the time of surgery):

- Patient information sheet had to be given to the patient
- Consent form had to be signed by the patient
- Adhesive sticker had to be stuck on front cover of medical record if the patient has agreed to take part

Immediately after surgery:

- Operation details had to be filled in on operation sheet (this replaced the regular operation record)

At discharge:

- Outcome during the initial stay had to be filled in at the bottom of the operation sheet
- A postoperative complication sheet had to be completed in the event of a complication that is defined as:
 - clinically delayed discharge (according to your usual practice)
 - return to theatre
 - blood transfusion

In case of a readmission within 28 days of the initial surgery:

- The postoperative complication sheet had to be completed

Data entry:

- Local administrative contact submitted data in central database via secure web-based data entry system

Web-based feedback to ENT departments was available.

2.5 Data collection

Data collection procedures were designed to minimise the burden on staff time (Box 2.1). An operation sheet was used to collect data on the initial operation, being designed to act as the main operation note filed in each patient's medical records. A complication sheet had to be completed when a patient experienced a complication. Both forms were included in the patient packs sent to all participating hospitals. Both forms also incorporated carbon copy paper so that one copy of the form could remain in the medical record while the other could be used by the person responsible for submitting data to the Audit. Complication sheets were kept within each patient's medical record, but further complication sheets were distributed to casualty departments and ENT wards.

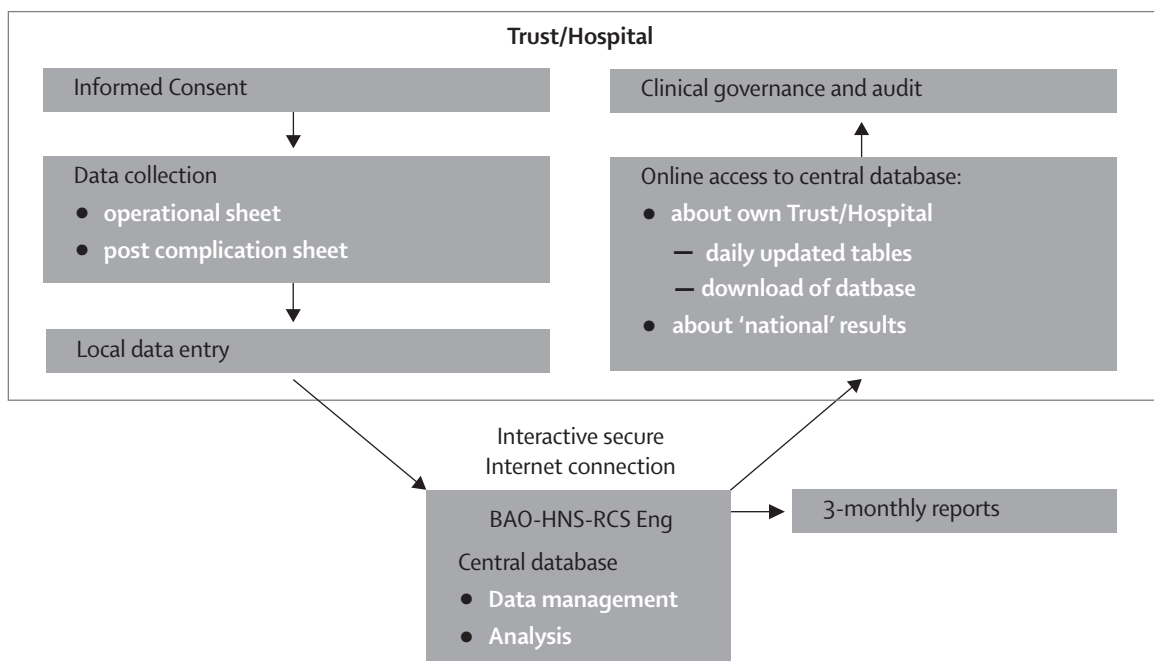
The submission of data from both the operation and complication sheets was entirely web-based (Figure 2.1). Data entry was performed locally at each hospital, with data being submitted via the NPTA website (www.tonsil-audit.org). Data were electronically transferred from participating hospitals to a secure central database within The Royal College of Surgeons of England. All information coming in and out of the website server was protected by 128-bit encryption, and the server was protected by the

College's firewall. Participants of the Audit gained access to the restricted areas of the NPTA website through a password-protected user account.

The NPTA website also provided immediate online feedback to the hospitals about their own practice and outcomes. Hospitals were able to compare the characteristics of the data they had submitted with the characteristics of the complete Audit database. A table gave information on patient demographics, indication for surgery, surgical techniques used, and number of complications. The information shown on the website was updated on a daily basis. From December 2003, hospitals were also able to download a copy of their submitted data as a Microsoft™ Excel file.

A pilot study in 10 hospitals was undertaken to assess the acceptability and feasibility of all aspects of the Audit. These hospitals trialled the patient packs (patient information sheet, the consent form, the operation sheet, and the complication sheet). The hospitals also tested the web-based data entry system. Feedback from the pilot hospitals on how improvements could be made was incorporated in the main Audit.

Figure 2.1: Basic description of information flows between the Audit and hospitals



2.6 Management of data submission and quality

After hospitals had registered, levels of data submission were monitored and hospitals were contacted if data were slow to be submitted. The quality of submitted data was monitored as the Audit progressed. The process of data validation combined online checks at the time of submission of an individual record (implemented on the website) with a regular offline review of data quality in the entire database by the CEU data manager. Checks were made for missing data, duplicate records, and the proportion of patients who had given consent. The submission of complication sheets was also reviewed on an on-going basis to ensure records could be linked to initial operations.

Hospitals could link a complication to the corresponding index operation only if the latter was performed at the same hospital. A complication record could also be entered unlinked, which allowed the Audit to capture complications for patients who had had their index operation elsewhere. In these cases, the link was made offline by the Audit's data manager by matching the patient identifiers (ie NHS number, date of birth, postcode, and sex). For the analysis, complications were always assigned to the hospital where the index operation was performed. For example, readmissions to NHS hospitals following an index operation in the independent sector were assigned to the appropriate independent hospital.

A newsletter was sent to hospitals in November 2003 which contained information of the data submitted on a monthly basis. Another newsletter was circulated in April 2004.

This contained the number of tonsillectomies that a hospital had submitted to the Audit. For English NHS hospitals, the April newsletter also reported the number of tonsillectomies recorded in HES for the same period in the previous year.

2.7 Statistical analysis

Complication rates were expressed as percentages. Relative risks for tonsillectomy technique were calculated as ratios of the complication rates. Multilevel multiple logistic regression was used to adjust for potential confounding factors (such as sex, age, and grade of operating surgeon) and to account for the clustering of patients within hospitals.¹⁶ All P values are 2-sided, and P values lower than 0.05 were considered to indicate a statistically significant result. Stata software (Release 8) was used for all statistical calculations (www.stata.com) except for the multilevel analysis, which was performed using MLwiN (www.ioe.ac.uk/mlwin).

3 Description of patients, treatment and surgical technique

3.1 Participating hospitals

The NPTA received data from 277 hospitals in England and Northern Ireland, and described the activity of 577 consultant surgeons. Information was received from 145 NHS hospitals and 132 independent organisations (Table 3.1).

There were 40,514 operation records submitted to the Audit. Over 50% of hospitals submitted 75 or more records, though most activity was undertaken in the public sector. NHS hospitals submitted 35,223 (87%) operations compared to the 5,291 (13%) operations from the independent sector. The 32,134 operations submitted by English NHS hospitals correspond to 76% of the 42,465 operations recorded in HES the period over which these hospitals were registered with the Audit.

The different level of activity in the two sectors is reflected in the number of operations received from each hospital. While 116 NHS hospitals submitted at least 100 operations to the Audit, 125 of the independent hospitals submitted

less than 100 records. Sixty-nine independent hospitals submitted fewer than 25 records.

3.2 Levels of patient consent

Consent to participate in the Audit was given by 33,921 (84%) of the 40,514 patients. Overall, levels of consent were considered to be very good (Table 3.2). A consent rate of at least 80% was achieved by 70% of the NHS hospitals, and by 59% of the independent hospitals. Without patient consent, personal data could not be collected, which made it impossible to link the index tonsillectomy with postoperative complications.

While overall levels of consent were high, 13 hospitals achieved a consent rate of less than 40% and four had a consent rate of 0%. However, each of these four hospitals submitted less than five patients to the Audit, and hospitals with lower consent rates tended to have fewer patients within the Audit database. There was a small difference in age and sex among those patients who did and did not

Table 3.1: Characteristics of participating hospitals participating in the Audit

	In England		In Northern Ireland	
	Public	Independent	Public	Independent
Number of hospitals	135	130	10	2
Number of NHS Trusts	122	n/a	8	n/a
Number of operations submitted	32,134	4,798	3,089	493

Table 3.2: Levels of consent obtained by hospitals

	0%	1-19%	20-39%	40-59%	60-79%	80%-99%	100%
Number of hospitals	4	2	7	29	55	131	49
% of total	1%	1%	3%	10%	20%	47%	18%

Table 3.3: Completeness of key variables used to link complication records in consenting patients

	Number of patients	Number of patients with missing information	% of total
NHS number (NHS patients only)	29,628	14,577	49.2%
Postcode	33,921	699	2.1%
Date of birth	33,921	37	0.1%

consent. This difference was not considered to be a potential source of bias.

Although a high proportion of records were missing NHS numbers, it was possible to investigate whether or not a complication had occurred in nearly 98% of consenting patients on the basis of postcode and date of birth (Table 3.3).

A total of 2,006 complication records were submitted to the database. It was possible to link 1,862 (93%) complications to operations submitted to the Audit, of which 1,767 related to operations on patients consenting to participate. The unlinked complication records were excluded from the analysis.

Linking readmissions to operations performed in independent hospitals was a more complex process than linking readmissions to operations performed in the NHS. This was because a patient undergoing tonsillectomy in an independent hospital was less likely to be readmitted to the same hospital if a complication arose. The Audit captured 45 readmissions that arose from an index operation in an independent hospital and 36 of these were to an NHS hospital. 144 complications could not be linked. By contacting the hospitals that had submitted unlinked complications, a further 50 complications appeared to have occurred in NHS hospitals and 22 in independent hospitals. If these 72 complications had been included in the analysis,

it would have added 0.2% to the overall complication rate for NHS hospitals and 0.5% for independent hospitals.

3.3 Patient characteristics

Of the 33,683 consenting patients whose age and sex were known, 21,063 (63%) were children aged less than 16 years and 5,130 (15%) aged less than 5 years (Table 3.4). There were more boys than girls in the youngest age group whereas the reverse was the case in the older age groups. There were 14 patients aged less than 18 months, three of these being under 1 year old. There were 22 patients aged over 65 years, the oldest being 83 years old.

The percentage of male and female patients did not differ between NHS and independent hospitals. However, patients treated in independent hospitals tended to be older. The proportion of patients aged 16 years and over treated at NHS and independent hospitals was 36% and 49%, respectively. Each sector treated similar proportions of patients under five.

The indications for surgery were similar among patients in NHS and independent hospitals. Recurrent acute tonsillitis was the indication for surgery in 76% of patients (Table 3.5). 7.5% of patients had chronic tonsillitis. This indication was more frequent in older patients. Nearly 10% of patients had pharyngeal obstruction. This indication was the second most frequent indication in patients under 5 years old.

Table 3.4: Age-sex distribution of consenting patients¹, column percentages

Age group	Female	% of total	Male	% of total
Under 5 years	2,059	10%	3,071	23%
5 to 16 years	9,318	46%	6,615	49%
16 years or over	8,783	43%	3,837	28%
Total	20,160		13,523	

¹ Age or sex unknown for 238 patients

Table 3.5: Indications for surgery, split by age-group¹, column percentages

Indication	Under 5 years	% of total	5 to 16 years	% of total	16 years and over	% of total
Recurrent acute tonsillitis	3,037	61%	12,760	82%	9,894	81%
Chronic tonsillitis	229	5%	1,038	7%	1,285	11%
Previous quinsy	5	0%	84	1%	588	5%
Pharyngeal obstruction	1,631	33%	1,384	9%	202	2%
Other indication	101	2%	225	1%	268	2%
Total	5,003		15,491		12,237	

¹ Indication or age unknown for 1,190 patients

3.4 Treatment characteristics

The characteristics of the different aspects of care received by patients is summarised in Table 3.6. Tonsillectomy was combined with an adenoidectomy in 27% of patients, and

the proportion of operations that were adenotonsillectomies was about equal in the two sectors. An adenotonsillectomy was performed on 84% of patients with a pharyngeal obstruction.

Table 3.6: Characteristics of treatment received by patients within the Audit

	Number of patients	% of total
All consenting patients	33,921	
Type of operation		
Tonsillectomy	24,220	71%
Tonsillectomy & adenoidectomy	9,174	27%
Not specified	527	2%
Type of hospital		
NHS	29,628	87%
Independent	4,293	13%
Planned admission		
Day case	4,207	12%
Overnight stay	28,411	84%
Not specified	1,303	4%
Grade of operating surgeon (NHS only)		
Consultant	8,649	29%
Non-training staff grade/ associate specialist	9,699	33%
Specialist registrar	6,753	23%
Senior house officer	4,435	15%
Not specified	92	0%
Dissection instrument used		
Reusable	29,508	87%
Single-use	2,862	8%
Not specified	1,551	5%

Only a minority of patients had their surgery planned as a day case. The proportion of operations planned as day cases was slightly higher in NHS hospitals than in independent hospitals (13% v 8%, respectively). Of the 28,411 patients with a planned overnight stay, 24,281 (85%) patients were discharged the day after they were admitted, though 683 (2%) of these patients were discharged on the day of admission.

All operations within the independent sector were performed by consultant surgeons and consultant anaesthetists. Within the NHS, just over 60% of operations were performed by a senior surgeon (consultant or non-training staff grade/associate specialist). Consultant anaesthetists were involved in around 65% of operations.

3.5 Surgical techniques

The different techniques used for tonsillectomy were grouped into seven categories (Table 3.7). The most common surgical techniques were cold steel for dissection and bipolar diathermy for haemostasis (35%) and bipolar diathermy forceps throughout (30%). The category containing operations using cold steel and ties/packs was restricted to operations that did not use any 'hot' technique. In this group, ties were used for haemostasis in 3,936 (92%) operations. If an operation had used cold steel dissection and a combination of ties and diathermy, the operation was allocated to the appropriate cold steel and diathermy group. Ties were used with diathermy in 5,508 (46%) cases in the cold steel and bipolar diathermy group and in 649 (37%) cases in the cold steel and monopolar diathermy group.

There were some differences between surgical technique and type of planned admission. Very few patients undergoing an operation with bipolar diathermy scissors were admitted as day cases (5% in NHS hospitals, 1% in independent hospitals). However, a higher proportion of patients had admissions planned as day cases when the surgical technique involved bipolar diathermy forceps (19% and 10% in NHS and independent hospitals, respectively) and for operations involving coblation (40% and 24% in NHS and independent hospitals, respectively).

In general, the surgical techniques used by the grades of operating surgeon followed a similar pattern to that seen overall. The most notable differences were the following. First, senior surgeons performed a slightly higher proportion of cold steel operations. Second, around 75% of the operations undertaken by specialist registrars and senior house officers involved either cold steel for dissection and bipolar diathermy for haemostasis or bipolar diathermy forceps throughout. Third, consultants performed the highest proportion of coblation operations.

Table 3.7: Surgical techniques used for tonsillectomy

	Number of patients	% of total
Surgical technique (n=33,921)		
Cold steel dissection & ties/packs for haemostasis	4,285	13%
Cold steel dissection & Monopolar diathermy haemostasis	1,772	5%
Cold steel dissection & Bipolar diathermy haemostasis	11,956	35%
Monopolar diathermy forceps	452	1%
Bipolar diathermy forceps	10,240	30%
Bipolar diathermy scissors	2,322	7%
Coblation	1,565	5%
Other	1,329	4%

4 Postoperative complications

4.1 Primary and secondary complications

In this chapter, we report on the rates of postoperative complications in the first 28 days after tonsillectomy. The Audit was principally interested in complications caused by postoperative tonsillar haemorrhage and this chapter describes how these differ for various subgroups of patients. A formal statistical analysis is contained in chapter 5.

Patients were flagged as having a primary complication if, during their initial stay, their discharge was delayed, they were returned to theatre, or they had a blood transfusion (or any combination of these). Patients were flagged as having a secondary complication if they were readmitted to hospital within 28 days of the initial surgery. Secondary complications were also characterised by whether a readmitted patient was returned to theatre and/or required a blood transfusion.

Among the 33,921 consenting patients in the Audit, there were 454 (1.3%) primary complications and 1,309 (3.9%) secondary complications. There were 71 patients who had

both primary and secondary events. The Audit was also notified of one postoperative death during the data collection period.

Among the patients with a primary complication, 150 (33%) patients were returned to theatre, although this only delayed the discharge of 26 patients. Eight patients received a blood transfusion, and six of these also returned to theatre. Discharge was delayed for 328 (73%) patients, the reasons for which are summarised in Table 4.1. The causes of the delay were fairly evenly spread across the different reasons. There were 87 patients with multiple reasons.

Among the patients with a secondary complication, the majority were readmitted with tonsillar bleeding (Table 4.2). Among the 1,309 readmissions, 176 (13%) patients returned to theatre, while 54 (4%) patients had a blood transfusion. There were 42 patients who had a blood transfusion and returned to theatre.

Table 4.1: Reasons for a delayed discharge during the initial hospital stay

Delayed discharges	Pain	Tonsillar haemorrhage	Vomiting	Fever	Other	Unknown
328	117	73	55	65	100	9
% of total	36%	22%	17%	20%	30%	3%

Table 4.2: Reasons for readmission to hospital after tonsillectomy

All secondary Complications	Pain	Tonsillar haemorrhage	Vomiting	Fever	Other	Unknown
1,309	295	1,014	59	58	94	59
% of total	23%	77%	5%	4%	7%	5%

4.2 Tonsillar haemorrhage rates

Among the 33,921 consenting patients in the Audit, there were 1,197 (3.5%) complications involving either a primary or secondary tonsillar haemorrhage. There were 188 (0.6%) patients who had a primary haemorrhage and 1,033 (3%) patients who had a secondary haemorrhage (24 individuals had both). 318 (0.9%) patients were returned to theatre within 28 days of their initial operation. Of these, 150 (0.4%) patients were returned to theatre during their initial hospital stay, while 176 (0.5%) patients were returned to theatre during a readmission (8 individuals had both events).

Table 4.3 describes how the postoperative haemorrhage and return to theatre rates were related to patient characteristics. Adults had higher haemorrhage rates than children. Patients with quinsy had the highest haemorrhage rates among the various indications. Patients with pharyngeal obstruction had a lower rate of haemorrhage than patients with recurrent acute tonsillitis (the most common indication for surgery).

Outcomes are also related to treatment characteristics (Table 4.4). Haemorrhage rates were slightly higher in patients operated upon by junior grades (senior house officer and specialist registrar) compared to those operated upon by senior surgeons. Risks also appear higher for operations that involved single-use instruments. Risks were lower for

patients undergoing an adenotonsillectomy. Different complication rates can also be seen between NHS and independent hospitals. Patients did not experience any complication at 90 independent hospitals and at 23 NHS hospitals. This is broadly in line with expectations given the low numbers of operations submitted by these hospitals; 82 of the 90 independent hospitals and 7 of the 23 hospitals submitted fewer than 50 operations. However, we would caution against drawing inferences about outcome and treatment from these simple analyses. The unadjusted rates are likely to reflect the influence of various factors and a fuller analysis is contained in subsequent chapters.

The overall haemorrhage and return to theatre rates for the different surgical techniques are shown in Table 4.5. The return to theatre rates are lower than the rate published in the interim results.^{14,15} This was because a detailed analysis of data quality demonstrated that some hospitals had misinterpreted the way the completion sheet should be completed. Consequently, the coding of the complication sheets was revised for the final analysis.

The lowest haemorrhage rate was observed with cold steel and ties/packs. Operations that used a 'hot' technique for both dissection and haemostasis had higher levels of haemorrhage. The highest rate was observed with

Table 4.3: Patient characteristics and postoperative haemorrhage and return to theatre rates

	Tonsillar haemorrhage rate (%)	Return to theatre rate (%)
Sex (n=33,921)		
Male	3.7%	1.2%
Female	3.4%	0.8%
Not specified	3.7%	0.5%
Age group (n=33,921)		
Under 5 years	1.9%	0.8%
5 to 15 years	3.0%	0.8%
16 years or over	4.9%	1.2%
Not specified	0.0%	0.0%
Indication (n=33,921)		
Recurrent acute tonsillitis	3.7%	1.0%
Chronic tonsillitis	4.1%	1.1%
Previous quinsy	5.4%	1.2%
Pharyngeal obstruction/OSA	1.4%	0.6%
Other	2.4%	1.2%
Not specified	2.9%	0.9%

	Tonsillar haemorrhage rate (%)	Return to theatre rate (%)
Type of operation (n=33,921)		
Tonsillectomy	4.1%	1.0%
Tonsillectomy & adenoidectomy	2.0%	0.7%
Not specified	2.7%	1.1%
Type of hospital (n=33,921)		
NHS	3.8%	1.0%
Independent	1.5%	0.7%
Planned admission (n=33,921)		
Day case	3.1%	0.7%
Overnight stay	3.6%	1.0%
Not specified	3.7%	0.9%
Grade of operating surgeon (NHS only, n=29,628)		
Consultant	3.9%	1.1%
Non-training/associate specialist	3.4%	0.9%
Specialist registrar	4.0%	0.9%
Senior house officer	4.3%	1.0%
Not specified	5.4%	4.3%
Dissection instrument used (n=33,921)		
Reusable	3.5%	0.9%
Single-use	4.1%	1.2%
Not specified	3.1%	1.0%

monopolar diathermy. For operations involving cold steel for dissection and diathermy for haemostasis, the haemorrhage rate was between the levels observed for the other groups. Coblation had the highest return to theatre rate.

In section 3.5, it was noted that the cold steel and bipolar diathermy group contained operations during which both ties and diathermy were used for haemostasis as well as operations involving only diathermy. It could be argued that

	Tonsillar haemorrhage rate (%)	Return to theatre rate (%)
Surgical technique (n=33,921)		
Cold Steel & ties/packs	1.7%	0.8%
Cold Steel & Monopolar diathermy	2.9%	0.8%
Cold Steel & Bipolar diathermy	2.7%	0.7%
Monopolar diathermy forceps	6.6%	1.6%
Bipolar diathermy forceps	4.6%	1.0%
Bipolar diathermy scissors	5.1%	1.3%
Coblation	4.6%	1.8%
Other	4.1%	1.4%

the use of diathermy with ties was in response to excessive intra-operative bleeding after ties had been used, and as such, reflects patients who were at higher risk of haemorrhage. This does not seem likely. Among the 11,956 patients in this group, the 5,508 patients for whom ties as well as diathermy was reported for haemostasis had a haemorrhage rate of 2.3%. The 6,448 patients for whom only diathermy was reported had a haemorrhage rate of 3.0%. The return to theatre rates for these two subgroups were 0.5% and 0.8%, respectively.

Secondary haemorrhages accounted for 86% of the observed haemorrhages (1,033/1,197). Thus, the differences between the techniques in the overall haemorrhage rates mostly reflected differences in the secondary haemorrhage rates (Table 4.6). A different pattern of risk for the surgical techniques was observed for primary haemorrhages. There seems to be a slightly lower risk of primary

haemorrhage if diathermy is used throughout or for haemostasis only.

The primary and secondary return to theatre rates across the various surgical techniques are shown in Table 4.7. The pattern of risk among the surgical techniques for a secondary return to theatre is similar to the pattern among techniques for a secondary haemorrhage. Cold steel and ties/packs again had the lowest rate, whereas operations in which a 'hot' technique is used throughout all have slightly higher rates. There are also similarities in the pattern of risk for a primary return to theatre and a primary haemorrhage. As before, there appears to be a lower risk of primary return to theatre if diathermy is used throughout or for haemostasis only.

Table 4.6: Surgical techniques and primary and secondary postoperative haemorrhage rates

	Primary tonsillar haemorrhage rate (%)	Secondary tonsillar haemorrhage rate (%)
Surgical technique (n=33,921)		
Cold Steel & ties/packs	0.8%	1.0%
Cold Steel & Monopolar diathermy	0.5%	2.4%
Cold Steel & Bipolar diathermy	0.5%	2.3%
Monopolar diathermy forceps	1.1%	5.5%
Bipolar diathermy forceps	0.4%	4.3%
Bipolar diathermy scissors	0.6%	4.6%
Coblation	1.0%	3.6%
Other	0.7%	3.6%

Table 4.7: Surgical techniques and primary and secondary return to theatre rates

	Primary return to theatre rate (%)	Secondary return to theatre rate (%)
Surgical technique (n=33,921)		
Cold Steel & ties/packs	0.7%	0.2%
Cold Steel & Monopolar diathermy	0.6%	0.3%
Cold Steel & Bipolar diathermy	0.3%	0.4%
Monopolar diathermy forceps	0.9%	0.7%
Bipolar diathermy forceps	0.3%	0.7%
Bipolar diathermy scissors	0.4%	1.0%
Coblation	1.1%	0.7%
Other	0.5%	1.0%

4.3 Changes in surgical technique and risk of tonsillar haemorrhage after the NICE/BAO-HNS guidance

The period over which the Audit collected data was extended to 30 September 2004 because of the publication of the NICE/BAO-HNS guidance. The final database contained details on 18,856 operations carried out in consenting patients before the guidance was published, and 14,999 thereafter.[†]

After the interim guidance on tonsillectomy techniques was published, there was a clear change in the pattern of surgical techniques being used (Figure 4.1). In particular, there was a decreased use of diathermy throughout an operation, an increase in the use of cold steel and ties/packs, and a reduction in the use of monopolar diathermy. All three changes are consistent with the issued guidance.

The number of complications submitted to the Audit also fell after the guidance was published. The overall rate of tonsillar haemorrhage (primary and secondary) was 4.1% in the

Figure 4.1: Proportions of operations by surgical technique recorded by the Audit before and after the NICE/BAO-HNS guidance was published

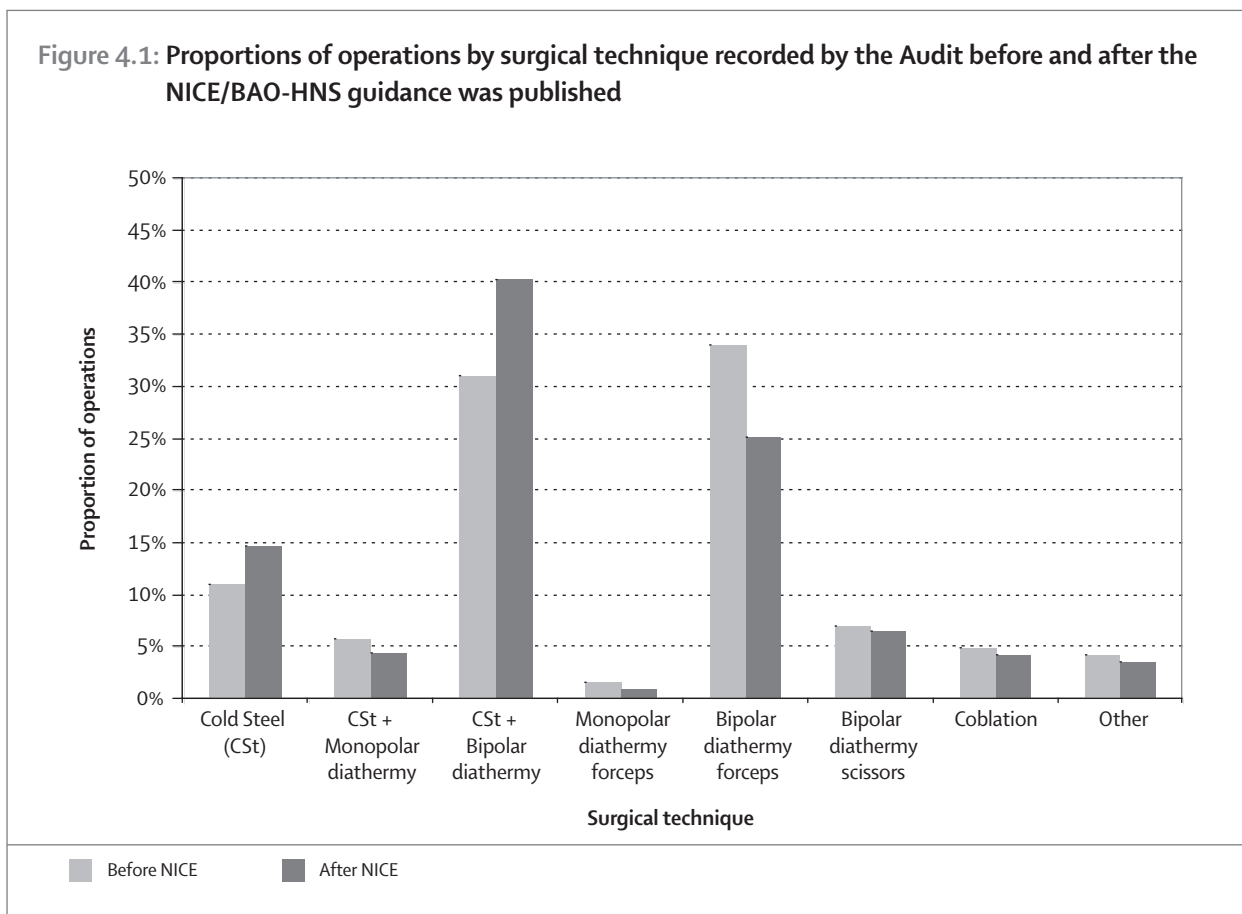


Table 4.8: Haemorrhage rates before and after NICE/BAO-HNS issued its guidance

	Before guidance	After guidance	P value*	Standardised 'before guidance'
Primary haemorrhage	0.6%	0.5%	0.46	0.6%
Secondary haemorrhage	3.5%	2.4%	<0.001	3.3%
Overall haemorrhage rate	4.1%	2.9%	<0.001	3.8%

*X² test

[†] Date of operation was missing for 66 patients

period before the guidance and 2.9% in the period thereafter. The drop was most pronounced among secondary haemorrhages, falling from an overall rate of 3.6% to 2.4% after the guidance was issued. The primary haemorrhage rate was largely unchanged. The falls in the overall and secondary rate were both statistically significant (Table 4.8).

Part of the change in overall haemorrhage rates will have been due to the change in the distribution of surgical techniques being used. To allow a more direct comparison of overall haemorrhage rates, the rates observed before the guidance were standardised using the distribution of surgical techniques observed afterwards. The standardised 'before guidance' haemorrhage rates become closer to rates observed in the following period but a sizable difference remained for both the secondary and overall haemorrhage rates (Table 4.8). This suggests that the underlying risk of haemorrhage also decreased, possibly because surgeons used the techniques more cautiously. There were no substantial changes in the distributions of patient characteristics (age, sex, or indication). The distribution of operations performed by grade of surgeon also did not change greatly; the proportion undertaken by junior doctors changed from 36% to 40%.

The return to theatre rates after the NICE/BAO-HNS guidance was published did not change greatly from the rates observed in the previous period (Table 4.9). Large changes were not expected given the infrequent occurrence of this complication and none of the changes in rates in the before and after periods were statistically significant. A standardised 'before guidance' figure was calculated as described above, and this tended to reduce the differences in rates between the two periods.

In summary, the publication of the NICE/BAO-HNS guidance had a number of effects. The most obvious change was in

the use of different surgical techniques. It also appears that the overall risk of complication reduced, particularly in relation to haemorrhage rates.

4.5 NICE/BAO-HNS guidance and quality of data submitted to Audit

Changes in clinical practice after the publication of the NICE/BAO-HNS guidance may have lowered the complication rates observed by the Audit. Another plausible explanation is that the guidance caused hospitals to change how they collected data. For example, a hospital might be less or more enthusiastic about submitting details of tonsillectomies and the number of complications. To examine this further, Hospital Episodes Statistics (HES) data were used to assess the degree to which data submissions might have changed for the 122 English NHS Trusts that had participated in the Audit. HES data were extracted for each participating hospital for the period over which they were registered with the Audit.

Table 4.10 presents the number of patients treated in the two periods as recorded by the Audit and HES. Prior to the guidance, the English NHS Trusts submitted information on 16,593 patients, approximately 70% of the 23,574 patients identified in the HES data. In the period after the guidance was issued, the Audit received information on about 66% of the patients in HES. It was considered unlikely that a fall of only 4% would have a large effect on the pattern of patient characteristics or types of treatment observed.

There was a fall in both Audit and HES derived complication rates in the period after the guidance was published. The fall in the HES-derived complication rates provides evidence that at least some of the change was due to a change in clinical practice. However, the ratio of the Audit to HES rates of secondary haemorrhage and secondary return to theatre also fell from one period to the next. Both figures were above

Table 4.9: Return to theatre rates before and after NICE/BAO-HNS issued its guidance

	Before guidance	After guidance	P value*	Standardised 'before guidance'
Primary return to theatre	0.4%	0.5%	0.36	0.5%
Secondary return to theatre	0.6%	0.4%	0.07	0.5%
Overall return to theatre	1.0%	0.9%	0.50	1.0%
* χ^2 test				

Table 4.10: Levels of case-ascertainment and rates of complication before and after the NICE/BAO-HNS guidance was published in participating English NHS Trusts

	Before NICE/BAO-HNS guidance			After NICE/BAO-HNS guidance		
	Number of records	Secondary haemorrhage rate	Secondary return to theatre rate	Number of records	Secondary haemorrhage rate	Secondary return to theatre rate
Audit	16,593	3.4%	0.6%	12,483	2.1%	0.4%
HES	23,574	5.4%	0.8%	18,891	4.5%	0.8%
Ratio	70%	62%	69%	66%	46%	48%

60% prior to the guidance, but were just below 50% thereafter. It is not clear whether this decrease in data quality affected the relationship between rate of haemorrhage and risk factors such as surgical technique. The extent to which the effect of a risk factor changed after the guidance was issued is investigated in the next chapter.

5 Risk model for tonsillectomy complications

5.1 Method of risk adjustment

The descriptive statistics in chapter 4 demonstrate that outcomes depend upon both patient characteristics and treatment related factors. These multiple influences mean that the unadjusted complication rates may not accurately reflect the relationship between outcome and any single factor. They are likely to be biased because of one or more confounding factors. To overcome this, a risk model was developed using multilevel multiple logistic regression. The multilevel approach takes account of the fact that differences in outcomes among patients treated at the same hospital are likely to vary less than outcomes among patients treated at different hospitals.

The risk model was developed on the basis of data from NHS hospitals only. Initial analyses included data from both NHS and independent hospitals. However, the model assumption that hospital-level variation is normally distributed was only met satisfactorily when the analysis was based solely on data from the NHS hospitals. This was related to the high proportion of independent hospitals reporting no complications (see Section 4.2).

5.2 Risk model for tonsillar haemorrhage

Table 5.1 shows the odds ratios of age, sex, indication for surgery, grade of operating surgeon, surgical technique and stage of the Audit (before and after NICE/BAO-HNS guidance) for tonsillar haemorrhage. Age was treated as a continuous variable. The rate was not adjusted for type of operation (tonsillectomy/adenotonsillectomy) or type of instrument (reusable or single-use) because an imbalance in the distribution of the values across the other risk factors would have made the estimates less robust.

Among the patient factors, the risk model suggests that the risk of haemorrhage increases with age and the risk is lower in females compared to males. Patients with pharyngeal

obstruction also had lower haemorrhage rates than patients with recurrent acute tonsillitis.

The adjusted postoperative haemorrhage rates when a 'hot' technique was used for both dissection and haemostasis (diathermy or coblation) were all between 2.4 and 3.2 times higher than in the cold steel group. The postoperative haemorrhage rates when diathermy was used only for haemostasis were around 1.5 times larger. There was no statistically significant relationship between the risk of haemorrhage and the grade of surgeon.

As noted in section 4.4, there appeared to be a reduction in the risk of haemorrhage in the period after the publication of the NICE/BAO-HNS guidance. The analysis confirms that there was a small but real drop in the observed haemorrhage rates, independent of changes in the other risk factors.

Finally, the multilevel risk model estimated the variance between hospitals to be significantly different from zero. There are numerous potential sources of this hospital level variation including unmeasured risk factors, differences in the quality of data submitted by hospitals, and real differences in performance. The existence of this hospital-level effect will be considered in chapter 8 when differences in hospital performance are examined.

The effect of the NICE/BAO-HNS guidance was explored further by estimating the odds ratios for the risk factors in the period before and after publication in separate models. There was no statistical evidence to suggest that the relative risks across the surgical techniques changed from one period to the other. There was evidence that the risks associated with grade of surgeon might have changed between the two periods. Consequently, terms for this interaction were included in a model that used data from both periods. The results suggested that the risk of haemorrhage for senior house officers fell after the guidance was issued.

Table 5.1: Risk model for tonsillar haemorrhage

Risk factor		Adjusted odds ratio (95% CI)	P value
Surgical technique	Cold steel & ties/packs	1	
	Cold steel & Monopolar diathermy	1.62 (1.03–2.54)	0.03
	Cold steel & Bipolar diathermy	1.57 (1.16–2.13)	0.004
	Monopolar diathermy forceps	2.71 (1.63–4.49)	0.0001
	Bipolar diathermy forceps	2.47 (1.81–3.36)	<0.0001
	Bipolar diathermy scissors	3.20 (2.09–4.90)	<0.0001
	Coblation	3.07 (2.03–4.65)	<0.0001
	Other	2.48 (1.62–3.79)	<0.0001
Age, change in risk per year		1.02 (1.02–1.03)	<0.0001
Sex	Male	1	
	Female	0.82 (0.73–0.93)	0.002
Indication for surgery	Rec acute tonsillitis	1	
	Chronic tonsillitis	1.05 (0.84–1.31)	0.7
	Previous quinsy	1.06 (0.74–1.53)	0.8
	Phar. obstruction	0.46 (0.33–0.63)	<0.0001
	Other indication	0.46 (0.26–0.81)	0.007
Grade of operating surgeon	Consultant	1	
	NTG/SAS	0.96 (0.80–1.14)	0.6
	Specialist registrar	1.04 (0.86–1.24)	0.7
	Senior house officer	1.17 (0.95–1.43)	0.1
Stage of Audit	Before guidance	1	
	After guidance	0.70 (0.62–0.80)	<0.0001

Variance (SE) between hospitals in log-odds of tonsillar haemorrhage = 0.42 (0.08)

5.3 Risk model for return to theatre

An equivalent multilevel multiple logistic model was used to estimate odds ratios for return to theatre (Table 5.2). As before, the risk of returning to theatre was associated with several patient characteristics, increasing with age and being lower for females compared to males. The risk was also lower for patients with a pharyngeal obstruction.

Coblation is the only surgical technique that has an elevated risk compared to the cold steel reference group. There was no statistically significant relationship between the risk of return to theatre and the grade of surgeon, nor was there any statistically significant effect associated with the NICE/BAO-HNS guidance. However, the variance between hospitals was again estimated to be significantly different from zero and provides evidence of hospital-level effects that could not be explained by the patient and treatment factors included in the model.

5.4 Sensitivity of the adjusted estimates to data quality

Poor levels of case-ascertainment for both the initial operations and the complications have the potential to bias the study results. Consequently, we repeated the development of the risk models in patients treated by 61 English NHS hospitals (55 Trusts) that were judged to have good data quality. To be included in this repeat analysis, an NHS hospital was required to have similar numbers of initial operations and readmissions observed in the Audit and HES data.

The size of the odds ratios in the haemorrhage risk model varied but the pattern across the various techniques remained the same. For example, the postoperative haemorrhage rates for operations in which a 'hot' technique was used for both dissection and haemostasis (diathermy or coblation) were between 2.3 and 2.7 times higher than in the cold steel group. The postoperative haemorrhage rate

Table 5.2: Risk model for return to theatre

Risk factor		Adjusted odds ratio (95% CI)	P value
Surgical technique	Cold steel & ties/packs	1	
	Cold steel & Monopolar diathermy	1.26 (0.63–2.53)	0.5
	Cold steel & Bipolar diathermy	0.88 (0.55–1.40)	0.6
	Monopolar diathermy forceps	1.70 (0.70–4.14)	0.2
	Bipolar diathermy forceps	1.38 (0.87–2.19)	0.2
	Bipolar diathermy scissors	1.90 (0.99–3.64)	0.05
	Coblation	2.84 (1.56–5.17)	0.0006
	Other	1.89 (0.97–3.71)	0.06
Age, change in risk per year		1.02 (1.01–1.03)	0.003
Sex	Male	1	
	Female	0.60 (0.47–0.76)	<0.0001
Indication for surgery	Rec acute tonsillitis	1	
	Chronic tonsillitis	1.12 (0.72–1.72)	0.6
	Previous quinsy	0.93 (0.43–2.02)	0.8
	Phar. obstruction	0.69 (0.42–1.14)	0.1
	Other indication	1.12 (0.52–2.42)	0.8
Grade of operating surgeon	Consultant	1	
	NTG/SAS	0.89 (0.65–1.24)	0.5
	Specialist registrar	0.85 (0.60–1.21)	0.4
	Senior house officer	1.21 (0.83–1.77)	0.3
Stage of Audit	Before guidance	1	
	After guidance	0.94 (0.73–1.20)	0.6

Variance (SE) between hospitals in log-odds of tonsillar haemorrhage = 0.27 (0.10)

for the cold steel & bipolar diathermy group remained around 1.5 times larger.

The results of the model for the risk of return to theatre were similarly stable. For example, the odds ratio for coblation reduced from 2.8 to 2.3 but was still statistically significant (P=0.02).

A second set of alternative risk models were developed using ordinary logistic regression. Ignoring the multilevel nature of the data allowed the effect of the patient and treatment variables to be estimated using all the available data (ie from both NHS and independent hospitals). The risk models included the same set of patient and treatment variables as used previously, plus a variable indicating the status (NHS or independent) of the hospital.

The odds ratios of the surgical techniques in the haemorrhage risk model were all larger than the equivalent estimates in the standard multilevel model but the pattern across the techniques remained the same. The same patient factors were also statistically significant as was the effect of the NICE/BAO-HNS guidance. The results of the model for the risk of returning to theatre were also similar to the results of the multilevel model. Therefore, the basic conclusions were considered to be robust.

6 Single-use instruments as a risk factor for tonsillar haemorrhage

As noted in Section 1.1, concerns were raised within the UK about a possible link between complication rates and the introduction of single-use tonsillectomy instruments, an initiative aimed at reducing the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD). Consequently, an aim of the Audit was to assess whether the risk of haemorrhage differed between operations that involved reusable and single-use instruments. This issue only applied to the cold steel and diathermy groups. However, the risks were not assessed for the two monopolar diathermy groups because there were too few of these operations involving single-use instruments for an analysis to be performed. The observed rates of complication for the other surgical techniques are summarised in Tables 6.1 and 6.2.

The Audit collected the type of instrument used for dissection. Only a small proportion of the operations reported to the Audit involved single-use instruments. Their use was reported

in 10% of operations using bipolar diathermy throughout, in 6% of operations using cold steel and diathermy and 2% of operations using cold steel and ties/packs.

When diathermy forceps or scissors were used for dissection and haemostasis, there was no evidence that the risk of tonsillar haemorrhage differed between reusable and single-use instruments. There was, however, a higher risk of haemorrhage associated with single-use instruments (4.1, 95% CI 1.7 to 9.9) when dissection was performed by cold steel and haemostasis used ties/packs. The difference in risk was reduced when bipolar diathermy was used for haemostasis with cold steel dissection. A similar pattern was observed for the risk of returning to theatre although the low level of complication meant that the relative risks were not statistically significant (Table 6.2).

Table 6.1: Relative risk of haemorrhage associated with reusable and single-use dissection instruments by surgical technique

Tonsillar haemorrhages	Cold Steel & ties/packs	Cold Steel & Bipolar diathermy	Bipolar diathermy forceps	Bipolar diathermy scissors
<i>Reusable instruments</i>				
No. of operations	4,033	10,682	8,878	1,957
No. of haemorrhages	61	286	409	105
Haemorrhage rate (%)	1.5%	2.7%	4.6%	5.4%
<i>Single-use instruments</i>				
No. of operations	81	675	946	300
No. of haemorrhages	5	27	46	13
Haemorrhage rate (%)	6.2%	4.0%	4.9%	4.3%
Relative risk	4.1	1.5	1.1	0.8
(95% CI)	(1.7 to 9.9)	(1.0 to 2.2)	(0.8 to 1.4)	(0.5 to 1.4)
P value (χ^2 test)	<0.001	0.04	0.7	0.5

Table 6.2: Relative risk of return to theatre associated with reusable and single-use instruments by surgical technique

Returns to theatre	Cold Steel & ties/packs	Cold Steel & Bipolar diathermy	Bipolar diathermy forceps	Bipolar diathermy scissors
<i>Reusable instruments</i>				
No. of operations	4,033	10,682	8,878	1,957
Returns to theatre	32	74	86	26
Return to theatre rate (%)	0.8%	0.7%	1.0%	1.3%
<i>Single-use instruments</i>				
No. of operations	81	675	946	300
Returns to theatre	2	5	12	4
Return to theatre rate (%)	2.5%	0.7%	1.3%	1.3%
Relative risk	3.1	1.1	1.3	1.0
(95% CI)	(0.8 to 12.8)	(0.4 to 2.6)	(0.7 to 2.4)	(0.4 to 2.9)
P value (χ^2 test)	0.1	0.8	0.4	1.0

A few comments need to be made about the interpretation of these figures. First, information on single-use instruments was reported only for dissection. This means that the two groups may not have been as distinct as intended which could have resulted in the calculated risks being underestimated.

Second, the Audit began after the Department of Health had directed that reusable instruments should be used for tonsillectomy operations whenever possible.⁴ It is therefore not surprising that the Audit recorded so few operations involving single-use instruments. This limited the statistical power of the analysis, especially in the case of the cold steel & ties group. Only 81 such operations involved single-use instruments, and the confidence intervals around the estimated relative risks were wide.

Third, the Audit did not collect the make of the instruments being used. It is possible that the complication rate depends on the quality of the single-use instrument, and is sensitive to the particular collection of instruments used during the Audit. The Audit also did not ask for the reason why a single-use instrument was used and it is possible that the appropriateness of the instruments were being assessed. Alternatively, their use may reflect surgeon or patient judgements on the risk of transmission of vCJD. The frequency of operations involving single-use instruments was the same in NHS and independent hospitals.

Finally, these figures relate only to hospitals in England and Northern Ireland. It is therefore plausible that the risk associated with single-use instruments may be different in Scotland and Wales. Definitive figures for Wales or Scotland have yet to be published.

7 Power setting for diathermy and tonsillar haemorrhage

Hospitals were asked to provide the Audit with the power settings for diathermy and coblator instruments when these were used for dissection and/or haemostasis. Overall levels of completion were generally good (Table 7.1). The unit of power (watts, joules, other) rather than the level of power used was the most commonly missing data element.

When bipolar forceps or scissors were used for dissection, power was reported in watts in 97% of operations (10,456/10,787). Among these operations, though, it proved difficult to interpret the distribution of values. There were some unrealistically extreme values. 502 (1%) operations had values above 40 watts and 529 (5%) values of less than 5 watts. In addition, values tended to be grouped at particular values (8, 10, 12, 15 and 20 watts). This raised questions about the meaning of the values reported and further investigation suggested that some diathermy instruments provided only a rudimentary power scale.

A similar picture was found for the power settings when bipolar diathermy instruments were used for haemostasis only. Power was reported in watts in 97% of these operations (9,107/9,347). There were 80 (2%) operations had values above 40 watts and 381 (4%) had values of less than 5 watts.

Multilevel multiple logistic regression was used to estimate the increase in risk of haemorrhage associated with an increase in power. The analysis was limited to those operations with a power setting in watts. The analysis was also limited to operations performed in NHS hospitals. Adjustments were also made for patient age, sex, indication, grade of operating surgeon and the effect of the NICE/BAO-HNS guidance.

Table 7.1: Completeness of power settings before and after the publication of the NICE/BAO-HNS guidance*

Surgical technique	Before guidance	%	After guidance	%
<i>Dissection settings</i>				
Monopolar diathermy	223	69%	94	74%
Bipolar diathermy forceps	5,310	83%	3,271	86%
Bipolar diathermy scissors	1,247	93%	938	95%
Coblation	262	28%	270	42%
<i>Haemostasis settings</i>				
Cold steel & Mono polar diathermy	772	70%	509	76%
Cold steel & Bipolar diathermy	4,619	79%	4,714	78%
Monopolar diathermy	215	67%	94	74%
Bipolar diathermy forceps	4,914	76%	3,060	81%
Bipolar diathermy scissors	1,144	86%	838	85%
Coblation	247	27%	260	40%

*excludes records that were missing date of operation

When bipolar diathermy was used for both dissection and haemostasis, no association was found between haemorrhage rate and dissection power setting (adjusted odds ratio=1.01 per increase of 1 watt, 95% CI 0.99 to 1.03, P value=0.3). When bipolar diathermy was used for haemostasis only, the overall risk of haemorrhage was estimated to increase by around 2% for every additional watt in power used for haemostasis (adjusted odds ratio=1.02, 95% CI 1.0 to 1.04, P value=0.04). This means, for example, that the risk associated with a power setting of 20 watts is roughly 30% higher than with a setting of 8 watts.

In summary, there appears to be a modest increase in risk of haemorrhage with diathermy power setting if diathermy is used for haemostasis only. The results need to be interpreted with caution because of the unusual values in the distribution of power settings. The different types of power markings on diathermy instruments also suggest that the power delivered from one machine at a setting of (say) '10' may not be equivalent to the power delivered on another machine set at the same value. Thus, the analysis is compromised by the quality of the data but the nature of the possible errors means that our results probably underestimated the increase in risk with the diathermy power setting.

Finally, there was some evidence that surgeons had reviewed the power settings used in their practice after the NICE/BAO-HNS guidance was issued. There were fewer operations with power settings above 20 watts reported after the guidance for both operations using diathermy throughout and operations using diathermy for haemostasis only. There was a small but statistically significant shift in the overall distribution of power settings to lower values for both types of surgical technique. Finally, the overall completeness of the information collected by the Audit rose from 78% to 83% for dissection power settings and from 75% to 77% for haemostasis (see Table 7.1 for more detail).

8 Performance of hospitals

An objective of the Audit was to examine whether there were systematic differences in haemorrhage rates among hospitals, and to what degree these might be explained by differences in risk factors like patient age, sex and indication. Differences in outcomes are first described using data submitted to the Audit. An equivalent analysis is then described using HES data. Comparing the results of the two analyses provided a way of verifying the results but this comparison could only be made for English NHS hospitals, aggregated by Trust.

There were 63 tonsillar haemorrhages in independent hospitals and 1,134 in NHS hospitals, which corresponded to average haemorrhage rates of 1.5% and 3.8%, respectively. This might reflect differences in the performance of hospitals but it may also be due to various other reasons. The completeness of the reporting of haemorrhages in patients treated in the independent sector is likely to be lower than in the NHS. This suggests that data quality is a factor in the apparently low haemorrhage rate for independent hospitals. Reasons to suspect the lower rate is linked to data quality include the lower levels of consent and the more complex process required to identify and link complications (see Section 3.2).

It was decided not to present the haemorrhage rates of individual independent hospitals because, in addition to the potential bias described above, the low number of operations submitted by each hospital meant the rates were unreliable. The highest value among independent hospitals with more than 50 operations in the Audit was 5.2%.

The postoperative haemorrhage rate in the 130 NHS Trusts as derived from unadjusted Audit data is shown in Figure 8.1. In this figure, the Trusts are ranked by the number of consenting patients they submitted to the Audit. Each rate is shown with a 99% confidence interval. The overall haemorrhage rate among these NHS Trusts is shown as a continuous horizontal line. If the 99% confidence interval does not overlap the overall NHS rate, the Trust can be considered an outlier. If the variation in the haemorrhage rates were due purely to random variation between patients, we would expect only 1% of the Trusts to have confidence intervals that do not overlap the overall NHS rate.

The unadjusted haemorrhage rates ranged from 0 to 12%. The majority of Trusts had rates similar to the overall average (116 Trusts had a rate under 7%) but there were 24 Trusts whose unadjusted haemorrhage rate differed from the overall rate by an amount greater than expected. Fourteen of these outliers had unadjusted rates above the overall rate, while ten had rates below it. However, this variation should not be automatically seen as evidence of good/poor performance at these Trusts. Haemorrhage rates were shown to be influenced by various factors such as patient age and sex as well as surgical technique. Consequently, an adjusted value was produced for each Trust with a multilevel risk model that took account of patient factors (age, sex, indication) and the clustering of patients within hospitals.

Figure 8.1: Tonsillar haemorrhage rates in 130 NHS Trusts calculated from Audit data. Vertical lines indicate 99% confidence intervals. The continuous horizontal line represents the overall haemorrhage rate of 3.8%

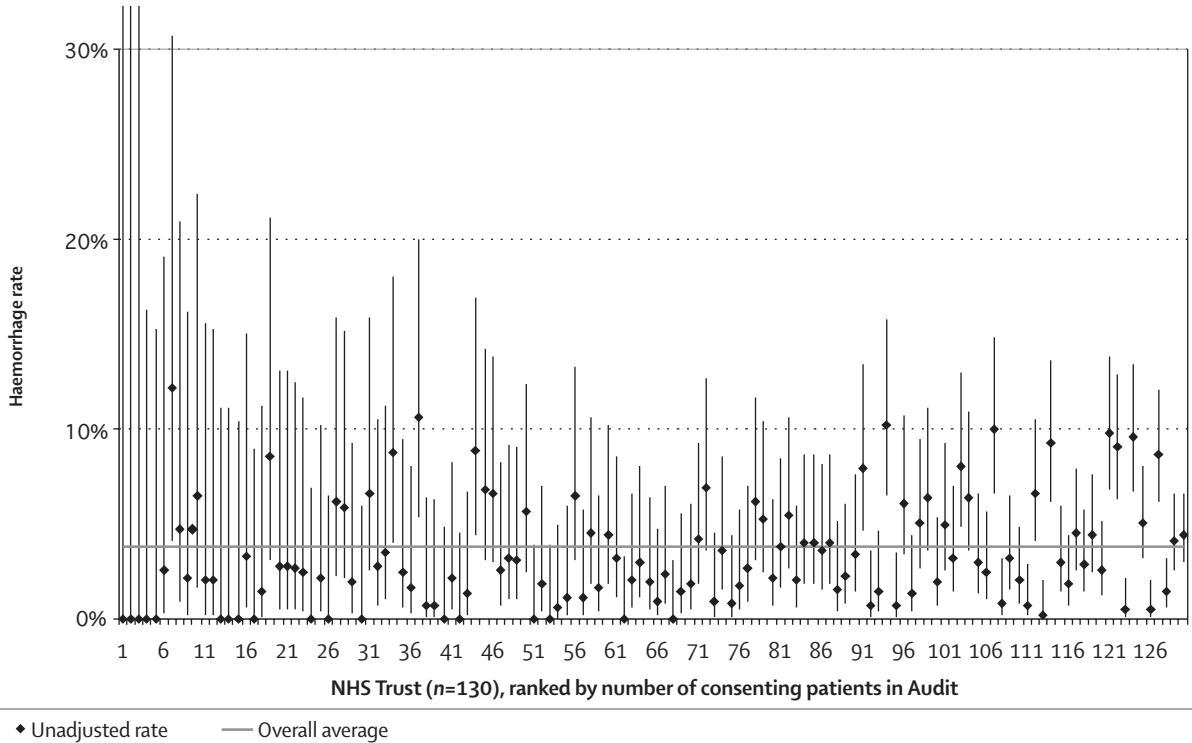


Figure 8.2: Ratio of observed odds of postoperative haemorrhage over the expected odds on the basis of age, sex and indication in 130 NHS Trusts (O/E; with 99% confidence intervals).

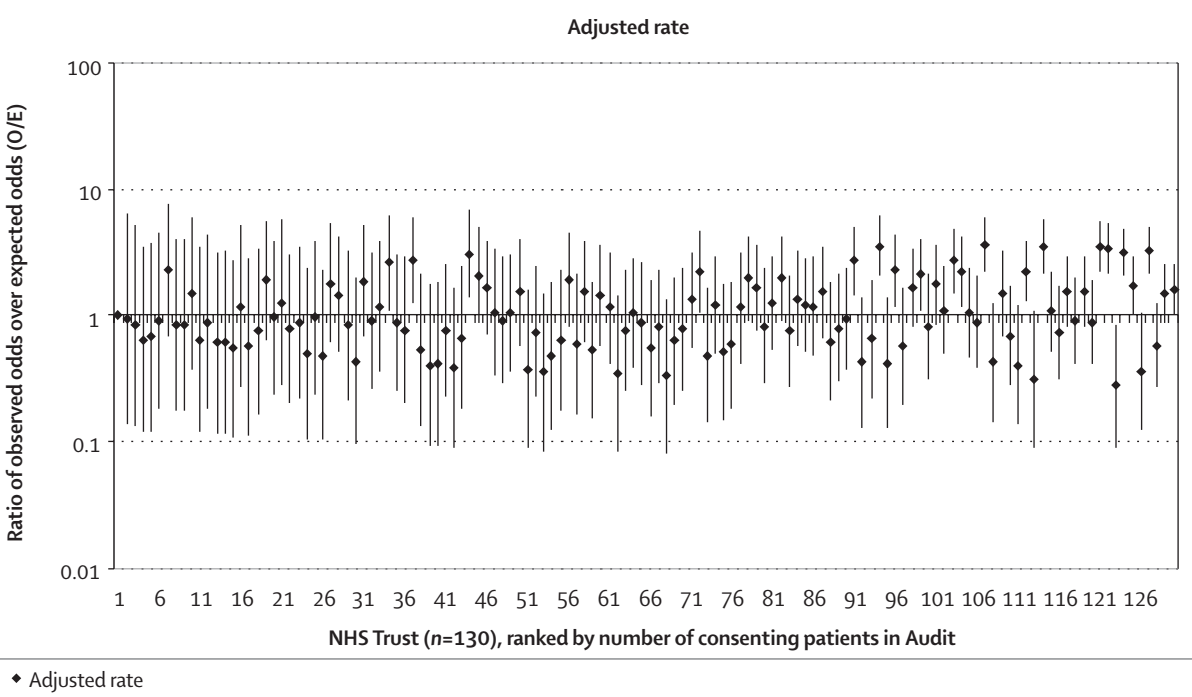


Figure 8.2 shows the adjusted haemorrhage rates, expressed as the ratio of the observed odds of tonsillar haemorrhage over the expected odds based on the age, sex, indication (O/E). Each estimate is presented with its 99% confidence interval, shown as a solid vertical line. If the 99% confidence interval does not include the value of 1, it can be considered an outlier.

Adjusting the haemorrhage rates reduced the overall number of outliers to 20 NHS Trusts. Thirteen Trusts whose unadjusted value was a high-value outlier remained as outliers. Only one Trust whose unadjusted rate was a low-value outlier remained as such. The other ten original outliers all had an adjusted rate that did not differ from the overall average by more than would be expected through chance alone. Finally, the risk adjustment identified six additional Trusts as outliers.

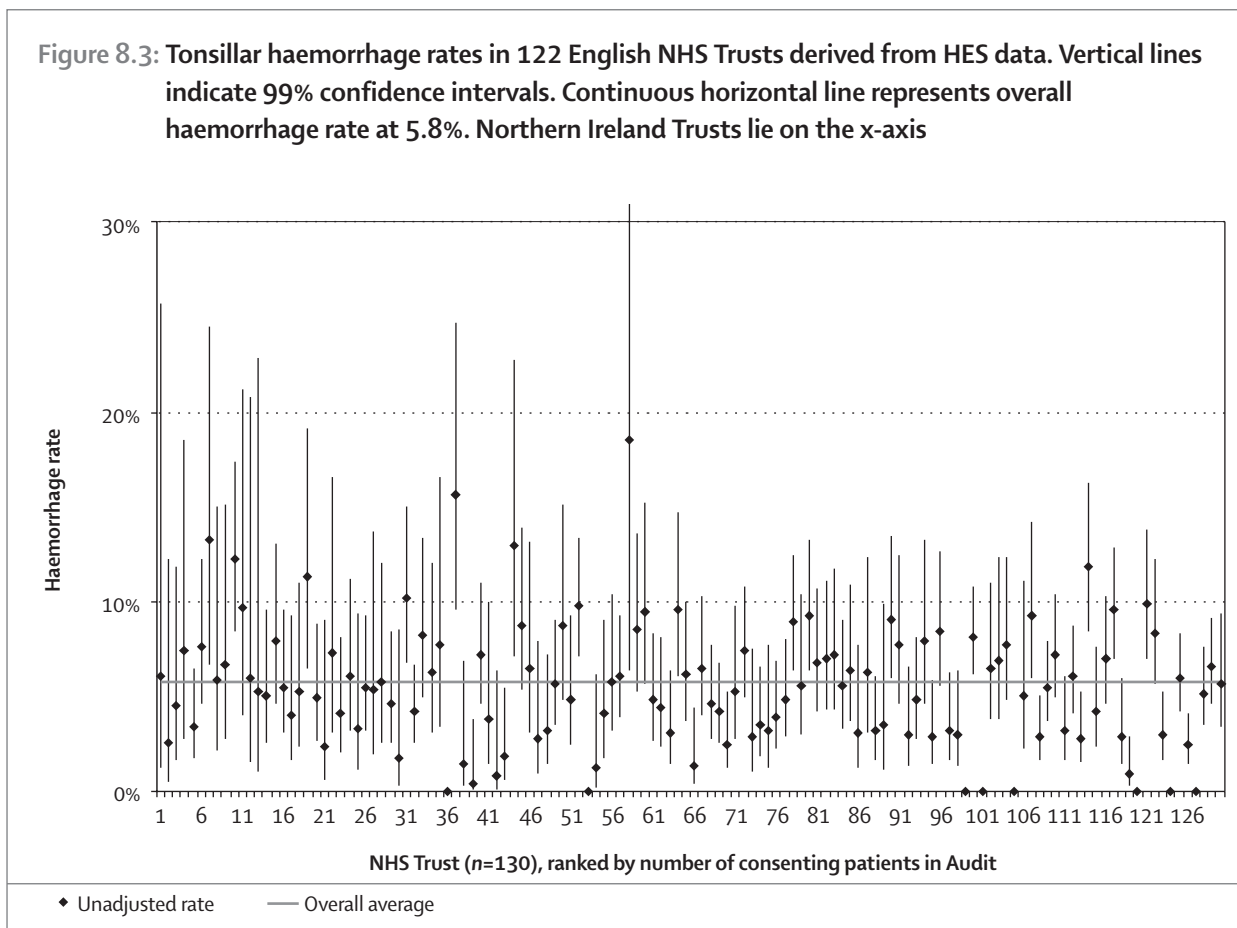
A second adjusted value was produced for each Trust with a multilevel risk model that took account of patient and treatment factors (age, sex, indication, surgical technique and grade of operating surgeon) and the clustering of patients within hospitals. Adding the treatment factors to

the risk-model changed the adjusted rates of individual hospitals by a small amount. Differences in treatment factors did not appear to be the reason why some Trusts were outliers. 17 of the 19 Trusts remained as high-value outliers.

Trust-level haemorrhage rates were calculated from HES data to assess the level of agreement between the haemorrhage rates produced from the Audit and HES data. Figure 8.3 presents the unadjusted haemorrhage rates derived from the HES data. For comparison with earlier graphs, the same set of 130 NHS Trusts is shown along the x-axis although values could only be derived for the 122 English Trusts. The Northern Ireland Trusts are shown as markers on the x-axis. As before, values are shown with 99% confidence intervals and the overall HES average.

The overall spread of HES-derived rates is larger than the Audit-derived rates, but in most cases, the amount by which a Trust differed from the overall average was within the range expected by chance alone. There were 26 Trusts whose unadjusted rates identified them as outliers but there was poor agreement with the set of outliers identified from the Audit data. Of the 17 English NHS Trusts identified as being

Figure 8.3: Tonsillar haemorrhage rates in 122 English NHS Trusts derived from HES data. Vertical lines indicate 99% confidence intervals. Continuous horizontal line represents overall haemorrhage rate at 5.8%. Northern Ireland Trusts lie on the x-axis



high-value outliers using HES data, only six were identified as outliers using both sets of data. Nine Trusts were identified as low-value outliers according to their HES-derived rates but only four were so classified according to their Audit-derived rates.

The poor agreement in the outliers identified by the two data sources suggests that the differences in haemorrhage rates between NHS Trusts need to be interpreted with caution. Although the variation may be due to differences in the performance of Trusts, it may also be caused by sampling variation, differences in patient characteristics, differences in hospital policy (such as readmission policies) and in data quality. The overall rate of haemorrhage for tonsillectomy is low and most Trusts have a rate that falls within the range expected due to sampling alone. Moreover, adjusting the crude rates for patient characteristics resulted in fewer hospitals being identified as outliers.

9 Conclusions and recommendations

9.1 Conclusions

The National Prospective Tonsillectomy Audit (NPTA) was established to investigate the occurrence of haemorrhage and other complications after tonsillectomy, the risk factors for these complications, and whether these risk factors explained variation in outcome between centres. During the Audit period, hospitals in England and Northern Ireland submitted the details of over 40,000 operations. We would like to thank all involved for their hard work and diligence.

The minimum dataset established for use in this Audit proved to be workable and practical. The burden of data collection was within acceptable limits and the web-based data collection system proved successful and secure. The final analysis of the Audit, based on over 33,000 tonsillectomies, indicated that 95% of patients recovered uneventfully, while 0.9% required a return trip to theatre. The remainder suffered less severe complications such as mild bleeding, pain or vomiting. Associations were found between complication rates and various risk factors. Differences in the distributions of these factors explained some of the variation in haemorrhage rates observed between hospitals. Nonetheless, haemorrhage rates for most hospitals varied within the range that would be expected from the play of chance alone. In addition, after the early findings relating to surgical technique and haemorrhage prompted the publication, mid-study, of interim guidance from NICE and BAO-HNS, haemorrhage rates following tonsillectomy fell.

Tonsillectomy technique

The results of the Audit indicated that overall risk of haemorrhage was related to surgical technique. The differences remained after adjusting for other risk factors. A 'hot' surgical technique for both dissection and haemostasis had a risk of haemorrhage that was around three times larger than cold steel tonsillectomy without the use of a 'hot' technique. The risk for operations using cold steel for dissection and bipolar diathermy for haemostasis

was around 1.5 times higher than cold steel operations using ties/packs. The results suggest a potential 'dose-response relationship' between haemorrhage rates and the use of bipolar diathermy. The Audit data also provide weak evidence for a dose-response relationship between haemorrhage rates and power settings when bipolar diathermy is used for haemostasis only. There was, however, no strong statistical evidence for differences in return to theatre rates between most techniques. Only coblation had an elevated risk that was statistically significant.

Surgical experience

There was no association between complication rates and grade of operating surgeon in the final analysis. This was unexpected as the rates observed for specialist registrars and senior house officers were higher than rates for senior surgeons in the interim analysis.¹⁴ The difference in results between the interim and final analysis is likely to reflect improvements in the performance of junior doctors after the NICE/BAO-HNS guidance was issued. The interim guidance made specific reference to training.

NHS and independent hospitals

The unadjusted risk of haemorrhage appeared to be lower for patients treated in independent hospitals. This may reflect a real difference in clinical care but the analysis also suggested that the difference may be due to data quality. Levels of consent attained at independent hospitals were lower than those attained at NHS hospitals and the process of linking complications was more complex because patients who underwent tonsillectomy in independent hospitals were often treated for complications in NHS hospitals.

Single-use instruments

The risk of haemorrhage with single-use instruments was around four times the risk for reusable instruments in operations using cold steel and ties/packs. However, this was based on a sample of only 81 single-use instruments

compared to over 4,000 reusable instruments. The risk of haemorrhage was around 1.5 times higher with single-use instruments in operations using cold steel and bipolar diathermy for haemostasis. Risks of haemorrhage did not differ with the type of instrument used for tonsillectomies performed with bipolar diathermy throughout.

The analysis of risk associated with single-use instruments was limited by the small proportion of operations involving these instruments submitted to the Audit. This reflects the advice published by DH recommending the use of reusable instruments. The Audit also does not have detailed data (such as model/manufacturer) on the single-use instruments. Problems with single-use instruments may relate to differences in the quality of the actual instruments used rather than to the concept of single-use itself.

Surgical technique and the risk of primary and secondary haemorrhage

Secondary haemorrhage accounted for 86% of all observed haemorrhages. The relationship between overall rates of haemorrhage and surgical techniques followed the rates associated with these secondary complications. The rates of primary haemorrhage showed a different relationship with surgical technique. Here, the 'hot' techniques did not show an elevated risk of bleeding. Indeed, the risk associated with bipolar diathermy techniques was roughly half the rate for cold steel tonsillectomy without any use of diathermy.

Impact of NICE/BAO-HNS guidance

There was a clear change in the choice of surgical technique after NICE/BAO-HNS issued interim guidance, with a shift away from the higher risk techniques. This contributed to a lower overall risk of haemorrhage after publication. But the fall in the overall haemorrhage rate from 4.1% to 2.9% could not be fully explained by this change. Both the Audit and HES data suggest that the absolute level of risk also fell, independent of surgical technique. For the Audit however, the publication of the guidance was a mixed blessing. While it allowed us to monitor its effect, the analysis was made more complex and it reduced the completeness of the data being submitted.

Hospital performance

Data quality was especially an issue in the analysis of hospital performance. The NHS Trusts identified as 'high' and 'low' outliers from using Audit data did not match the Trusts identified as outliers using HES data. This highlights the caution needed when using Audit data to monitor hospital

performance nationally. The analysis also demonstrated the unreliability of unadjusted complication rates. Figures should be adjusted for patient age and sex and indication. Feedback on performance was given to individual hospitals after the Audit.

Methodological issues and audit procedures

The NPTA invested in various procedures to improve levels of case ascertainment, reporting of complications, and patient consent. Overall, the web-based data collection proved a very successful and secure medium for data collection. It also allowed regular feedback to hospitals on their submitted data. However, it should be noted that there is still variation in access to the web among hospital staff, often because of different hospital policies rather than IT difficulties.

The operation sheet was designed to collect basic patient, hospital, and surgical information likely to influence outcome. It was not feasible to collect all potentially relevant information such as: intra-operative blood loss, prescribed postoperative antibiotics or analgesia, makes/models of diathermy generators or other equipment used. Both intra-operative blood loss and potential postoperative pain are important considerations affecting a surgeon's choice of tonsillectomy technique. For example, minimising intra-operative blood loss, an advantage of diathermy, may be a particular consideration in young or anaemic patients. However, the adopted dataset was considered to be a reasonable compromise between the need to measure risk and to minimise the burden of data collection.

Being an observational study, the results of the National Prospective Tonsillectomy Audit are susceptible to a number of biases. First, the Audit captured only a sample (albeit a large sample) of the patients who underwent tonsillectomy in England and Northern Ireland during the study period. The incomplete inclusion could have distorted the differences in haemorrhage rates if the probability of a patient being excluded from the Audit was related to the various risk factors.

Second, the results of the Audit may depend upon the adopted definition of a primary and secondary complication. Different definitions may change the relative incidence of the two types of event and so change the overall rates of complication observed. A different definition of a primary haemorrhage may also change the relative risks associated with specific factors. For example, the current definition of a primary complication measures events of sufficient severity to delay discharge, require return to theatre, or blood transfusion. A definition that captured less severe haemorrhages could change the

relative risks of the various surgical techniques as minor bleeds are more common after cold steel dissection. However, the adopted definitions for primary and secondary complications were considered practical and feasible because both are linked to important changes in the routine care of patients.

Third, the type of tonsillectomy technique used may be related to patient and treatment characteristics that are risk factors for haemorrhage. However, after adjustment for these risk factors, the increased risk associated with 'hot' techniques remained.

Fourth, our results are based on outcomes reported by the participating departments. It seems likely that haemorrhages were underreported given the lower overall rates of complication found by the Audit when compared to HES data. This is a reason not to automatically interpret differences in outcomes across the Trusts as indicating good/poor performance. Sensitivity analysis suggests that it had a minimal effect on the estimates of risk associated with the different patient and treatment factors.

Finally, selective underreporting of outcomes might have influenced the relative differences between the tonsillectomy technique groups. For instance, our results might be explained by underreporting of haemorrhage in patients who had a cold steel tonsillectomy. However, the observed haemorrhage rate in the cold steel group would have to be at least twice as high to negate the difference in risk between this and the bipolar diathermy forceps group. Consequently, selective underreporting is unlikely to explain away this finding.

9.2 Recommendations

Counselling patients for tonsillectomy:

- **When a patient is counselled for surgery, the risk of tonsillectomy complications, and in particular postoperative haemorrhage, should be carefully explained to the patients/parents.**
- **This risk should be quantified, preferably using the surgeon's own (or department's) figures. National figures can be used but this should be made clear to patient.**

Surgical techniques:

- **All 'hot' techniques should be used with caution especially if they are used as a dissection tool.**
- **Surgeons using monopolar diathermy should consider using an alternative technique. There are no advantages to using this instrument over other methods.**

Training:

- **All trainee surgeons should become competent in cold steel dissection and haemostasis using ties before learning other techniques in tonsillectomy.**
- **Emphasis must be placed on teaching the correct use of, and the potential hazards of, diathermy and other 'hot' techniques. Checks should be made of the power settings before starting the operation.**
- **Inexperienced trainees must be supervised by a more senior surgeon until competency has been achieved. This recommendation is in agreement with the College's Standards on Good Surgical Practice issued in 2002.**
- **Irrespective of seniority and experience, surgeons who wish to start using new techniques such as coblation should undergo appropriate training.**

Audit:

- **All ENT departments should have regular Morbidity & Mortality meetings to monitor adverse incidents affecting patient outcome. For tonsillectomy, data should be presented by surgeon, technique used for dissection and haemostasis and power settings if applicable, type of instrument used, and any difficulties encountered. It is the responsibility of the surgeon, and if appropriate his trainer, to follow up any identified problems appropriately.**
- **Use of single-use instruments should also be recorded, especially for cold steel dissection.**

Equipment:

- **There is an urgent need for new standards for diathermy machines so that the amount of power used is obvious to the user. Manufacturers of diathermy machines should be encouraged to produce machines with information on the total amount of energy delivered to patients.**
- **Hospitals should encourage the use of machines that provide clear information on power settings.**
- **Manufacturers of single-use instruments should be encouraged to improve the quality of the instruments.**

Research:

- **There is a need for further laboratory and clinical research to investigate the influence of diathermy and other 'hot' techniques on an open wound such as the tonsillar bed. In particular, there is a need to investigate the dose-response relationship between power used and complications.**

APPENDIX 1

Glossary of terms

Adenoidectomy	surgical removal of the adenoids
Adeno-tonsillectomy	adenoidectomy with tonsillectomy
BAO – HNS	British Association of Otorhinolaryngologists – Head and Neck Surgeons, also known as ENT-UK
Bipolar	incorporating two electrical poles (positive and negative)
Case ascertainment	the proportion of tonsillectomies performed in England and Northern Ireland that were reported to the Audit. A high proportion would be good case-ascertainment
CEU	Clinical Effectiveness Unit, an academic collaboration of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine
Coblation	electrosurgery with lower tissue temperatures than diathermy
Cold steel	traditional metal instruments used in surgical procedures
Confidence Interval (CI)	defines an interval around an estimated value within which the true value is likely to fall
Diathermy	a type of electrosurgery where heat is generated by an electric current
Dissection	surgical removal of tissue eg the tonsil along natural planes of cleavage
DH	Department of Health of England
ENT-UK	alternative name of British Association of Otorhinolaryngologists – Head and Neck Surgeons
Haemorrhage	flow of blood from a vessel
Haemostasis	surgical procedure of control and stopping of blood flow
HES	Hospital Episode Statistics, a database of all hospital admissions in the NHS in England
Intra-operative	during surgery
MHRA	Medicines and Healthcare products Regulatory Agency, Department of Health. This includes the body previously known as Medical Devices Agency
Monopolar	incorporating one electrical pole within a surgical instrument and another pole placed on a distant part of the patient's body
NPTA	National Prospective Tonsillectomy Audit
Odds ratio	the odds ratio is an estimate of relative risk, being a good approximation when risks are small (see relative risk)
Obstructive sleep apnoea	partial blockage of breathing during sleep by the tonsils, palate, tongue or adenoids
Pharyngeal	pertaining to the throat
Postoperative	following surgery
Quinsy	peri-tonsillar abscess as a complication of acute tonsillitis
Relative risk	the ratio of risk in one group compared to another. Values below 1 indicate that the risk is reduced; values above 1 indicate that the risk is increased
Tonsil	paired lymphoid tissue structures in the throat/oropharynx
Tonsillitis	inflammation of the tonsils
Tonsillectomy	surgical removal of the tonsils (usually both sides)

APPENDIX 2

Consent and data collection forms



National Prospective Tonsillectomy Audit
 www.tonsil-audit.org email:tonsil-audit@rcseng.ac.uk telephone: 020 7869 6622

NHS number:

Consent form (to be retained in patient’s notes)

Version 3 – 07/02/03

Name of Researcher: David Lowe. The Royal College of Surgeons of England.

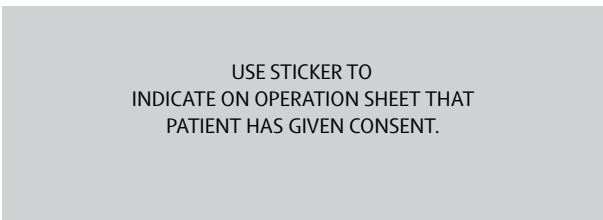
1. I confirm that I have read and understand the information sheet dated 23/05/03 (version 5) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from The Royal College of Surgeons of England or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

Name of Patient	Date	Signature
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or Name of Parent (if patient is less than 16 years)	Date	Signature
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Name of Person taking consent (if different from researcher)	Date	Signature
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Affix this sticker to the front of patient’s notes.



OPERATION SHEET FOR TONSIL AND ADENOID SURGERY




National Prospective Tonsillectomy Audit

www.tonsil-audit.org email:tonsil-audit@rcseng.ac.uk telephone: 020 7869 6622

(Affix address label here) Patient's Name: Birth date _ _ / _ _ / _ _ _ _ (dd/mm/yyyy)	Hospital: [precoded]
	Sex: _ (m/f)
	NHS number: <input type="text"/>
	Post code: _ _ _ _ _
	Has the patient given consent to take part in the audit? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is the patient currently a smoker? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know	
Initial operation date: _ _ / _ _ / 20 _ _	Planned as: <input type="checkbox"/> Day case <input type="checkbox"/> Inpatient
Responsible consultant ENT surgeon's name:	
Operating surgeon's name:	
"Operating" anaesthetist's name:	
Grade:	Consultant NTG/SAS¹ SpR SHO
Operating surgeon:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
"Operating" anaesthetist:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Supervising surgeon: ²	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Supervising anaesthetist: ³	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Operation:	<input type="checkbox"/> Tonsillectomy <input type="checkbox"/> Adenotonsillectomy
Primary Indication for surgery	<input type="checkbox"/> Recurrent acute tonsillitis <input type="checkbox"/> Chronic tonsillitis <input type="checkbox"/> Previous quinsy <input type="checkbox"/> Pharyngeal obstruction/OSA <input type="checkbox"/> Other (specify):
Tonsillectomy dissection type (more than one option possible):	
<input type="checkbox"/> Cold steel <input type="checkbox"/> Monopolar diathermy forceps <input type="checkbox"/> Bipolar diathermy forceps <input type="checkbox"/> Bipolar diathermy scissors <input type="checkbox"/> Coblation <input type="checkbox"/> KTP/Holmium laser <input type="checkbox"/> CO ₂ laser <input type="checkbox"/> Suction diathermy <input type="checkbox"/> Guillotine <input type="checkbox"/> Ultrasonic <input type="checkbox"/> Plastic instruments <input type="checkbox"/> Other (specify):	
Adenoidectomy dissection type (more than one option possible):	
<input type="checkbox"/> Curette <input type="checkbox"/> Suction diathermy <input type="checkbox"/> Microdebrider <input type="checkbox"/> Bipolar diathermy forceps <input type="checkbox"/> CO ₂ laser <input type="checkbox"/> KTP/Holmium laser <input type="checkbox"/> Coblation <input type="checkbox"/> Other (specify):	
Dissection Instruments used: <input type="checkbox"/> Reusable <input type="checkbox"/> Disposable	
Tonsillectomy dissection instrument setting (maximum setting used):	
_ _ units: <input type="checkbox"/> Watts <input type="checkbox"/> Joules <input type="checkbox"/> Other (specify):	
Width of diathermy forceps tips (manufacturer's specification):	
<input type="checkbox"/> <1.0mm <input type="checkbox"/> 1.0-2.0mm <input type="checkbox"/> 2.1-3.0mm <input type="checkbox"/> >3.0mm <input type="checkbox"/> Don't know	
Tonsillectomy haemostasis (more than one option possible): <input type="checkbox"/> Ties <input type="checkbox"/> Monopolar diathermy <input type="checkbox"/> Coblation	
<input type="checkbox"/> Bipolar diathermy <input type="checkbox"/> Adrenaline packs <input type="checkbox"/> Plain packs <input type="checkbox"/> Other (specify):	
Adenoidectomy haemostasis (more than one option possible):	
<input type="checkbox"/> Adrenaline packs <input type="checkbox"/> Plain packs <input type="checkbox"/> Post-nasal packs (postoperative) <input type="checkbox"/> Warm water <input type="checkbox"/> Monopolar diathermy <input type="checkbox"/> Bipolar diathermy <input type="checkbox"/> Other (specify):	
Tonsil haemostasis instrument setting _ _ units: <input type="checkbox"/> Watts <input type="checkbox"/> Joules <input type="checkbox"/> Other (specify):	
Surgical time (gag in to gag out): _ _ mins	
Operation note and postoperative instructions	
Completed by: Signature _____ Print name _____	
Outcome during initial stay (complete at time of discharge)	
HAS A CLINICALLY DELAYED DISCHARGE (according to your usual practice), RETURN TO THEATRE OR BLOOD TRANSFUSION OCCURRED? (IF YES - COMPLETE POSTOPERATIVE COMPLICATION SHEET) <input type="checkbox"/> Yes <input type="checkbox"/> No	
Discharge date: _ _ / _ _ / 20 _ _ (COMPLETE IF DISCHARGE DATE IS AS PLANNED)	

ENSURE ENTRY OF DATA VIA THE NPTA WEBSITE

1= non-training grade; 2= most senior surgeon in theatre; 3= most senior anaesthetist in theatre (see reverse for additional information)

POSTOPERATIVE COMPLICATION SHEET FOR TONSIL AND ADENOID SURGERY	
	<h2 style="margin: 0;">National Prospective Tonsillectomy Audit</h2> <p style="margin: 0; font-size: small;">www.tonsil-audit.org email: tonsil-audit@rcseng.ac.uk telephone: 020 7869 6622</p>
<p>(Affix address label here)</p> <p>Patient's Name:</p> <p>Birth date: __ / __ / __ __ __ __ (dd/mm/yyyy)</p>	<p>Hospital: [precoded]</p> <p>Sex: __ (m/f)</p> <p>NHS number: <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 15px; border: 1px solid black;" type="text"/></p> <p>Post code: __ __ __ __ __ __</p>
COMPLICATION DURING INITIAL STAY	
<p>Postoperative outcome (more than one option possible):</p> <p><input type="checkbox"/> Delayed discharge (please answer questions in Delayed discharge box)</p> <p><input type="checkbox"/> Return to theatre (please answer questions in Return to theatre box)</p> <p><input type="checkbox"/> Blood transfusion. Number of units: __ __</p>	
<p>Delayed discharge</p> <p>Reason for delay (more than one option possible):</p> <p> <input type="checkbox"/> Pain <input type="checkbox"/> Tonsil bleed <input type="checkbox"/> Adenoid bleed <input type="checkbox"/> Vomiting <input type="checkbox"/> Fever <input type="checkbox"/> Not known <input type="checkbox"/> Other (specify): </p>	
<p>Return to theatre</p> <p>If yes, number of hours after initial procedure: __ __ hours</p> <p>Bleeding site (more than one option possible):</p> <p> <input type="checkbox"/> Tonsil bed <input type="checkbox"/> Tongue base <input type="checkbox"/> Adenoid <input type="checkbox"/> Not known <input type="checkbox"/> Other (specify): </p>	
<p>Discharge date: __ / __ / 20__</p>	
READMISSION WITHIN 28 DAYS OF INITIAL SURGERY	
<p>Date of readmission: __ / __ / 20__</p> <p>Number of days after initial procedure: __ __ days</p>	
<p>Blood transfusion:</p> <p><input type="checkbox"/> Yes If yes, number of units: __ __</p>	
<p>Reason for readmission (more than one option possible):</p> <p> <input type="checkbox"/> Pain <input type="checkbox"/> Tonsil bleed <input type="checkbox"/> Adenoid bleed <input type="checkbox"/> Vomiting <input type="checkbox"/> Fever <input type="checkbox"/> Not known <input type="checkbox"/> Other (specify): </p>	
<p>Return to theatre:</p> <p><input type="checkbox"/> Yes If yes, number of days after initial procedure: __ __ days</p>	
<p>Bleeding site (more than one option possible):</p> <p> <input type="checkbox"/> Tonsil bed <input type="checkbox"/> Tongue base <input type="checkbox"/> Adenoid <input type="checkbox"/> Not known <input type="checkbox"/> Other (specify): </p>	
<p>Discharge date: __ / __ / 20__ (see reverse for additional information)</p>	

ENSURE ENTRY OF DATA VIA THE NPPTA WEBSITE

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