

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

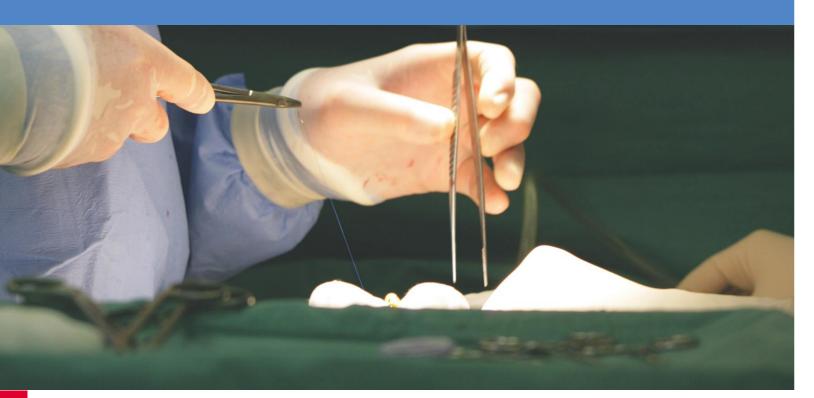




Mission statement

The ASERNIP-S mission is to provide quality and timely assessments of new and emerging surgical technologies and techniques. Services provided include systematic reviews, accelerated systematic reviews and technology overviews of the peer-reviewed literature, the establishment and facilitation of clinical and research audits or trials, the identification and assessment of new and emerging techniques and technologies by horizon scanning, and the production of clinical practice guidelines.

Our ultimate aim is to improve the quality of healthcare through the wide dissemination of our evidence-based research to surgeons, healthcare providers and consumers, both nationally and internationally.





Guy Maddern Surgical Director

Surgical Director's report

he ASERNIP-S project continues to enjoy increasing worldwide recognition as the premier assessment body for horizon scanning of new surgical technologies. The year has seen a number of important changes. Firstly, our Chairman, Mr Peter Woodruff, has stepped down from this position and is to be replaced by Dr Russell Stitz, President of the Royal Australasian College of Surgeons. This will help to maintain the important role of ASERNIP-S within the Royal Australasian College of Surgeons and facilitate close links with the Council.

Following negotiations, this year ASERNIP-S became a formal Medical Services Advisory Committee (MSAC) contractor to conduct new technology assessments within the surgical field. This important body determines whether reimbursement is to be available for newly arriving technologies into the Australian surgical scene.

The Commonwealth Government has also acknowledged our important and pioneering work in surgical horizon scanning and has provided funding for this to continue for at least the next twelve months. Additional funding has also been made available so that review work for new technologies,

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that perhaps do not have a change in medical benefits funding but do, nonetheless, require assessment, can also be performed. The list of projects requiring assessment continues to grow and at present the ability to deal with them in a timely fashion remains an enormous challenge for the ASERNIP-S staff.

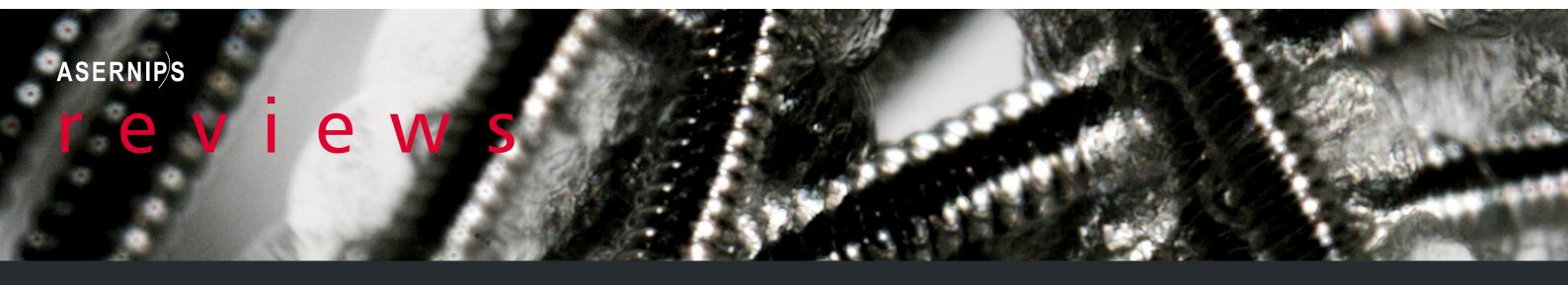
The primary difficulty for the project is the lack of a clear commitment to long-term funding. It is essential that five-year funding be provided in order to recruit and retain the highly specialised and excellent staff we currently have working with us. Already a number of individuals have felt the situation is sufficiently unstable that they have

chosen other career options in order to secure their futures. This is regrettable as the pool of excellent researchers is not huge within the Australasian scene and, having once trained them to the high standards required for this project, to lose them due to financial instability is highly regrettable.

In addition to assessing new technologies, ASERNIP-S has also been involved with the Breast Audit and Endoluminal Abdominal Aortic Aneurysm Audit and these both continue to be highly successful activities. The availability of this infrastructure at the College has led to the Australian and New Zealand Audit of Surgical Mortality and the development of an electronic-based trainee logbook to function within the ASERNIP-S facility as part of the newly created Research and Audit Division. The ability of the College to have such an effective research entity is clearly demonstrated by the ready uptake of these new initiatives.

The year 2006 promises to be a very exciting period for ASERNIP-S as the Health Technology Assessment International (HTAi) conference will be held in Adelaide. This will provide the opportunity to showcase the work of ASERNIP-S and further develop its credentials as the premier surgical health technology assessment organisation.

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New assessments completed

Systematic literature reviews

- Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis ASERNIP-S Report no. 44
- Paravertebral blocks for anaesthesia and analgesia ASERNIP-S Report no. 47

Accelerated systematic reviews

• Laparoscopic radical prostatectomy ASERNIP-S Report no. 48

Systematic reviews for other organisations

- Intrastromal corneal ring segments for ectasia and keratoconus (MSAC reference 1083)
- Comparison of lung volume reduction surgery with medical management of emphysema (CCOHTA)
 ASERNIP-S Report no. 33
- Lung volume reduction surgery for emphysema: systematic review of studies comparing different procedures (CCOHTA)
 ASERNIP-S Report no. 51

Assessments in progress

Procedure nominations

Systematic reviews

Systematic reviews involve a review of a clearly formulated question using systematic and explicit methods to identify, critically appraise and summarise relevant studies (published and unpublished) according to predetermined criteria. Reported outcomes can be synthesised either quantitatively or narratively or can include meta-analysis to statistically analyse and summarise the results of the included studies. Systematic reviews are fundamental tools for decision-making by health professionals, consumers and policy makers as they provide conclusions based on research evidence.

Accelerated systematic reviews

Accelerated systematic reviews (ASRs) are produced in response to a pressing need for a systematic summary and appraisal of the available literature for a new or emerging surgical procedure. ASRs use the same methodology as full systematic reviews, but may restrict the types of studies considered (for example, by only including comparative studies and not case series) in order to produce the review in a shorter time period than a full systematic review.

Technology overviews

A technology overview aims to provide information to assist decision-makers to make their own evidence-based recommendations. Unlike a systematic review, the technology overview does not attempt to compare a new intervention with a standard intervention or provide a recommendation for use.





Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis ASERNIP-S Report no. 44

Background

Three surgical options available to treat unicompartmental osteoarthritis of the knee are unicompartmental knee arthroplasty (UKA), total knee arthroplasty (TKA) or high tibial osteotomy (HTO). Although these three options may all be used to treat unicompartmental osteoarthritis, they are often used in different patient populations. However, there is considerable overlap in indications for all three options.

Objective

The aim of this review was to assess the safety and efficacy of UKA compared to TKA and HTO in medial or lateral osteoarthritis.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, Cochrane Library and Current Contents from inception to April 2004. The Clinical Trials Database (US), NHS CRD (UK) NHS HTA (UK), National Research Register (UK) and Current

Controlled Trials (mRCT) were also searched in May 2004. Additional articles were identified through the reference sections of the articles retrieved.

Study selection: Randomised controlled trials and non-randomised comparative studies assessing patients treated with unicompartmental knee arthroplasty compared with either total knee arthroplasty or high tibial osteotomy were included for review. Efficacy outcomes included knee function and pain scores, range of motion, operative time, length of stay, knee failure and revision. Safety outcomes included complications such as deep vein thrombosis and infection.

Results

Fourteen comparative studies were identified for inclusion.

Nine studies compared UKA and TKA: one RCT and eight nonrandomised comparative studies. Six studies compared UKA
and HTO: two RCTs and four non-randomised comparative
studies.

In terms of knee function and postoperative pain, UKA appeared similar to TKA and HTO at five years follow-up although there was much variability. Range of motion was better in UKA compared to TKA.

Overall rates of complications after UKA and TKA appeared similar, although deep vein thrombosis (DVT) was reported more often after TKA. There were more complications after HTO than UKA; the main complications reported were DVT and wound complications.

Survival of UKA prostheses was around 85 - 95%, compared to at least 90% for TKA at ten years follow-up. Survivorship for HTO appeared to be less than 85%. It was not clear whether there were more revisions after UKA than TKA, but it appeared there were fewer revisions of UKA compared to HTO.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of unicompartmental knee arthroplasty:

Evidence rating

The evidence base in this review is rated as average.

Safety

Unicompartmental knee arthroplasty is considered at least as safe as total knee arthroplasty and high tibial osteotomy.

Efficacy

In terms of function, unicompartmental knee arthroplasty appears to be at least as efficacious as total knee arthroplasty and high tibial osteotomy. In terms of knee survival, the efficacy of unicompartmental knee arthroplasty compared to total knee arthroplasty and high tibial osteotomy cannot be determined.

Recommendations

Current trials in progress should reduce some uncertainty surrounding the treatment of osteoarthritis in the knee. The continuing contribution of data to national joint registries will aid in validating the current trends, particularly in knee survival after unicompartmental or total knee arthroplasty.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm

Paravertebral block for anaesthesia and analgesia

ASERNIP-S Report no. 47

Objective

The objective of this review was to make recommendations on the safety and efficacy of thoracic and lumbar paravertebral blocks on the basis of a systematic assessment of the peer-reviewed literature. Paravertebral block (PVB) for surgical anaesthesia was compared to general anaesthesia or other regional anaesthetic techniques, while the postoperative analgesia provided by PVB was compared to regional blocks or analgesic drugs.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, The Cochrane Library, Science Citation Index and Current Contents from inception to December 2004. The Clinical Trials Database (US), NHS Centre for Research and Dissemination, NHS Health Technology Assessment (UK), National Research Register (UK), National Institute of Health (US) and Meta Register of Controlled Trials were also searched in December 2004.

Study selection: Randomised controlled trials, historical and/or non-randomised comparative studies, case series and case reports were included for review. Included comparative studies concerned the comparators, defined as general anaesthesia (GA) or any other method of analgesia (eg. epidural, opioids). Efficacy outcomes included surgical anaesthesia, pain scores and length of hospitalisation. Safety outcomes included complications such as pneumothorax, nausea and vomiting, local anaesthetic toxicity and urinary retention.

Data collection and analysis: Data from the included studies were extracted by the ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Relative risks with 95% confidence intervals were calculated for some outcomes in individual RCTs where it helped the interpretation of results.

Results

A relatively large evidence base of reasonable quality (57 studies including 15 RCTs and describing over 1000 PVB procedures) was available for this systematic review of PVB. However the ability to draw firm conclusions was limited by the high number of indications (two for anaesthesia and nine for analgesia), and the diversity of outcomes and how they were measured. In addition, although nine RCTs of analgesia using PVB were located, the comparators were thoracic epidural block (3 trials), no additional intraoperative analgesia (2 trials), morphine (1 trial), interpleural local anaesthetic (1 trial), nerve block (1 trial) and one trial compared bolus and continuous PVB.

For anaesthesia, PVB seems to be a safe procedure which substantially reduces nausea and vomiting in comparison to GA, although there is a small risk of pleural and vascular punctures and epidural spread with PVB. While clearly any form of regional block will have more failures than GA, the PVB failure rate was no higher than 20% and patients were more satisfied with PVB than with GA. There was some indication that PVB could achieve shorter hospital stays than GA, but this was poorly reported in the studies.



Paravertebral block for anaesthesia and analgesia (continued)

For analgesia, PVB appears to result in about the same degree of effective block as other forms of regional analgesia. The results for pain relief and nausea and vomiting were not as clear due to limited evidence, however PVB appeared to be as effective as the comparators. As for anaesthesia, there is a small risk of punctures and epidural spread, which would increase if multiple PVB procedures were required (for example, in treating chronic pain).

There was little information about the technical difficulty or learning curve for PVB, and no information was available which compared the costs of PVB with GA for anaesthesia, or PVB with local analgesia. However a very small amount of cost data from two studies indicated that between about A\$500 to \$1,000 could be saved by avoiding an overnight stay after PVB.

Classification and recommendations

On the basis of the evidence presented in this systematic review, The ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of PVB for anaesthesia and analgesia:

postoperatively.

Paravertebral blocks at the level of the thoracic and lumbar vertebrae are at least as effective as (1) GA and other regional anaesthetic techniques for anaesthesia during surgery, and (2) analgesic drugs and other regional blocks for analgesia postoperatively.

anaesthetic techniques for anaesthesia during surgery, and

(2) analgesic drugs and other regional blocks for analgesia

Clinical and research recommendations

PVB is an advanced technique, which requires a degree of expertise and competence. It is recommended that anaesthetists wishing to use the PVB technique undergo appropriate training and supervised instruction until competent, and there should be ongoing audit of their performance.

Additional high quality, prospective randomised controlled trials would strengthen the evidence base for the PVB technique. Cost-effectiveness studies, taking into consideration the Australian healthcare context should also be considered.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm



Australia nominated laparoscopic radical prostatectomy for review by ASERNIP-S due to the need for a timely assessment of the literature for this procedure, in particular complication rates and surgical margin rates.

Objectives

To compare the safety, efficacy and costs associated with laparoscopic radical prostatectomy compared with open radical prostatectomy through a systematic assessment of the literature. A secondary objective was to assess the contribution of learning curve to efficacy outcomes.

Methods

A systematic search of online databases (from 1996 to December 2004) and the internet was undertaken, without language restriction. Comparative studies that reported safety or efficacy outcomes of transperitoneal laparoscopic radical prostatectomy (TLRP) or extraperitoneal endoscopic radical prostatectomy (EERP) or roboticassisted radical prostatectomy (RALRP) compared to open radical retropubic prostatectomy (RRP) or radical perineal prostatectomy (RPP) were included. Comparisons between different laparoscopic approaches were also included.

Results

There were 21 studies comparing open and laparoscopic approaches; 13 comparing transperitoneal (TLRP) to open (RRP) radical prostatectomy, three comparing extraperitoneal (EERP) to open

prostatectomy, and five comparing robotic-assisted (RALRP) to open prostatectomy. There were nine studies comparing different laparoscopic approaches, six comparing EERP and TLRP and three comparing RALRP with TLRP. There were no randomised controlled trials, ten concurrently controlled comparisons (level III-2), 17 historically controlled comparisons (level III-3) and three comparisons using concurrent and historical controls (level III-2/3).

In terms of safety, there did not appear to be any important differences in the complication rate between laparoscopic and open approaches; however, blood loss and transfusions were lower for the laparoscopic approaches. In terms of efficacy, operative times were longer for laparoscopic than open prostatectomy but length of stay and duration of catheterisation were shorter. There was no consistent pattern of analgesia use across the included studies. Positive margin rates were similar and there did not appear to be any important differences between laparoscopic and open prostatectomy when tumour stage or margin location were taken into consideration. Recurrence-free survival was poorly reported but did not appear to differ between the two approaches. Continence and potency were not well reported but appeared similar between the two approaches, though continence may have recovered more quickly after laparoscopic than open prostatectomy and potency may have recovered more quickly after robotic-assisted prostatectomy compared with open. Quality of life did not differ between TLRP and RRP in two studies.

There were no important differences between laparoscopic approaches.

Cost and resource use issues

Cost and resource use issues were not well reported in any of the included studies; however, in three economic models open radical prostatectomy was found to be less expensive than laparoscopic prostatectomy, and costs would only become equivalent if operative times and/or length of stay for the laparoscopic approaches were to fall. However, none of the models used a patient-relevant effectiveness outcome such as potency, continence or survival and therefore do not provide a great deal of guidance for decision-makers with regard to cost effectiveness.

Learning curve

Six studies reported outcomes in such a way that the effect of increasing experience with the laparoscopic approaches could be tracked. As experience with the laparoscopic approaches increased most clinical outcomes improved, including conversions to the open procedure, complications, blood loss, transfusions and operative time, but not length of hospital stay and duration of catheterisation. There were no clear effects of increasing experience for positive margins rate or continence and potency outcomes.

Conclusions

Laparoscopic radical prostatectomy is emerging as an alternative to open radical prostatectomy for treating localised prostate cancer. However at the present time there is insufficient comparative data regarding continence, potency and survival.

There did not appear to be any clear differences between the laparoscopic approaches. Robotic-assisted prostatectomy offers the promise of shorter operative times than standard laparoscopic approaches and may produce a quicker recovery of continence and potency than open prostatectomy.

A clear learning curve for laparoscopic prostatectomy was documented which affected many clinical outcomes. Although it was not possible to determine from the included studies how many laparoscopic procedures must be completed to negotiate this learning curve, the introduction of LRP should be closely monitored. Previous experience in laparoscopy and/or open radical prostatectomy is required and outcomes during the initial phase of the learning curve should be carefully documented.

Recommendations

- A national audit of laparoscopic radical prostatectomy, including robotic-assisted LRP, should be instituted to monitor the introduction of the technique into the Australian healthcare system. The audit could be carried out under the auspices of ASERNIP-S and arranged in conjunction with the Urological Society of Australia and the Royal Australasian College of Surgeons.
- Hospital credentialling committees should monitor the progress of surgeons introducing LRP into their practice at regular intervals, paying particular regard to rates of complications and surgical margins during the learning phase.
- 3. Economic evaluations taking into consideration the Australian healthcare context should be conducted.

For the full review and executive summary, please visit the publications page of our website at http://www.surgeons.org/asernip-s/publications.htm

Systematic reviews for other organisations

- Intrastromal corneal ring segments for ectasia and keratoconus (MSAC reference 1083)
- Comparison of lung volume reduction surgery with medical management of emphysema (CCOHTA)
- Lung volume reduction surgery for emphysema: systematic review of studies comparing different procedures (CCOHTA)



Assessments in progress

Systematic literature reviews

- Bioengineered skin substitutes for management of burns Report no. 46
- Bioengineered skin substitutes for management of wounds Report no. 52
- Surgical simulation (update)
 Report no. 53

Accelerated systematic reviews

- Self-expanding metallic stents (SEMS) for relieving malignant colorectal obstruction Report no. 49
- Endoscopic treatments for gastroesophageal reflux disease (GORD)
 Report no. 54

MSAC reviews

- Endovascular treatments for intracranial aneurysms (MSAC reference 33)
- Endovascular neurointerventional procedures (MSAC reference 1093)

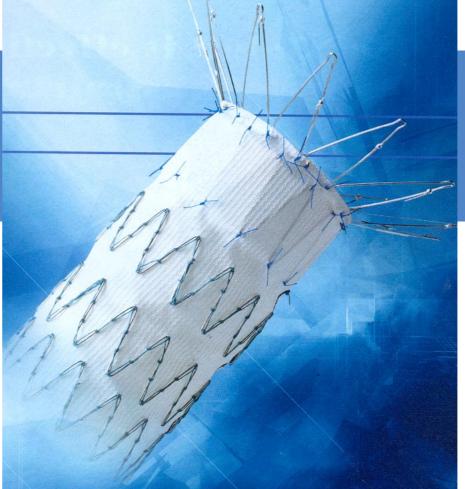
Procedure nominations

The following nominations have been received by the ASERNIP-S Management Committee and will be assessed by ASERNIP-S in the future:

- Computer-assisted cardiac surgery
- Endoscopic ablation of Barrett's oesophagus for severe dysplasia
- Endoscopic thoracic sympathectomy
- Endovascular intracranial aneurysm surgery
- Endoscopic stapling of pharyngeal pouch
- Laparoscopic adhesion division
- Laparoscopic hemi-hepatectomy
- Palatal procedures for snoring
- · Peritonectomy for colon cancer
- · Permanent dermal fillers
- Radiofrequency ablation of liver tumours (update)
- Radiofrequency ablation of tumours (not liver)
- Refractive keratoplasty
- Small vessel angioplasty
- Spinal endoscopy
- Spinal fusion apparatus
- Thermal capsular shrinkage (for shoulder ligament laxity)
- Transoral laser resection for laryngeal cancer
- Transpupillary thermotherapy
- Use of biological osteoinductive agents for treatment of fractures (non-union).

To nominate a new procedure for review by ASERNIP-S, visit the website and use an online form or download a PDF version on the publications page at www.surgeons.org/asernip-s/publications.htm





Audit of endoluminal repair of abdominal aortic aneurysms

The procedure

The procedure involves the elective repair of abdominal aortic aneurysms (AAA) using an endovascular graft. The graft is inserted through an incision in the femoral artery and positioned within the aorta at the site of wall weakening (the aneurysm) in order to prevent rupture.

Objective

The procedure is being audited to provide the Australian Government Department of Health and Ageing with information on the mid-term and long-term safety and effectiveness of endoluminal repair of abdominal aortic aneurysms to help inform them when making future funding decisions.

Methods

Patients who underwent the endoluminal repair of abdominal aortic aneurysms between 1 November 1999 and 16 May 2001 were enrolled in the audit by their surgeons. Initial patient information included pre-operative details, procedural information and early post-operative complications. Follow-up for this cohort of patients is continuing. Information collected includes aneurysm size, additional procedures and complications relating to the original procedure.

Results

Nearly 1000 patients were enrolled in this Australian audit. The majority of patients were male (86%), and the average age at the time of the procedure was 75 years. Nearly half of the patients listed were regarded as unsuitable candidates for open surgical repair. Peri-operative mortality (death within 30 days of the procedure)

was 1.8%. For patients surviving to mid-term follow-up (up to 5 years) the clinical success rate is 93%, failure being recorded for those patients with type 1 or 3 endoleaks, enlarging aneurysms, conversion to open repair, aneurysm-related death, or graft limb obstruction. During mid-term follow-up, 10% of patients have had additional procedures relating to their aneurysms. Overall, 16 patients (1.7%) have converted to open repair and 13 patients (1.4%) have had postoperative ruptures. Audit results are comparable with those reported worldwide.

The future

Follow-up of this cohort of patients will continue until mid-2006. Final results from the audit with full statistical reporting will be submitted to the Australian Government Department of Health and Ageing by 31 October 2006.

Members of the Audit Reference Group

Associate Professor Robert Fitridge
Mr Michael Denton
Professor James May
Professor John Harris
Professor Kenneth Myers
Mr John Anderson

Mr Michael Lawrence Brown

Ms Maggi Boult, ASERNIP-S Morbidity Audit Manger Dr Wendy Babidge, RACS Director Research & Audit Professor Guy Maddern, ASERNIP-S Surgical Director

Reports are submitted to the Government every six months and information about the audit is disseminated to surgeons and the public via the ASERNIP-S website and through publications in peerreviewed literature.

To view or download audit reports, patient information and data entry forms please access our website:

http://www.surgeons.org/asernip-s/audit.htm

National Breast Cancer Audit

The last year has proven to be a busy and productive time for the National Breast Cancer Audit under the direction of Mr James Kollias (Audit Clinical Director). Around 40,000 episodes of early breast cancer have been submitted to the audit, over half of these since the introduction of the online data entry system in May.

In addition to providing support to surgeons contributing to the audit significant progress was made toward establishing the National Breast Cancer Audit as a full clinical audit. An outlier process, which had been under development during 2004, was finalised during 2005. The process was ratified in February 2005 by the Council of the Royal Australasian College of Surgeons and endorsed by the Breast Section Executive at the RACS Annual Scientific Congress. A booklet, detailing the outlier process was distributed to all full members of the Breast Section in June 2005.

The last year has also seen the development of a new version of the web-based data entry system. The system is being revised to accommodate changes in the treatment of early breast cancer and incorporate suggestions made by participants. Version 2 will be launched in 2006 and participants will be offered an increased number of reports, improved security and a more user-friendly interface. Breast surgeons will also be able to measure their current performance agains the quality thresholds that were developed for the outlier process.

Significant effort has been put into obtaining data from institutions at which similar data for the treatment of early breast cancer is collected. Aligning institutional data with the National Breast Cancer Audit is a valuable process and ensures that surgeons do not have to enter similar data twice.

Our consumer partners, the Breast Cancer Network Australia (BCNA), have continued to be strong advocates for the audit and provide valuable input to the management of the audit. We are particularly grateful for their help in attempting to secure sustained long-term funding.

The National Breast Cancer Centre (NBCC) has also continued to support the audit in 2005, being involved with governance and, like the BCNA, providing invaluable help in the development of the quality thresholds and the outlier process. A contractual arrangement with the NBCC has facilitated the writing of two research papers using audit data

Funding for 2005 was provided by the State Quality Officials Forum through the Australian Council for Safety and Quality in Health Care. We have also appreciated financial support provided by Affinity Health which was instrumental in maintaining the infrastructure and resource of the audit whilst long-term funding was sought.

NET-S

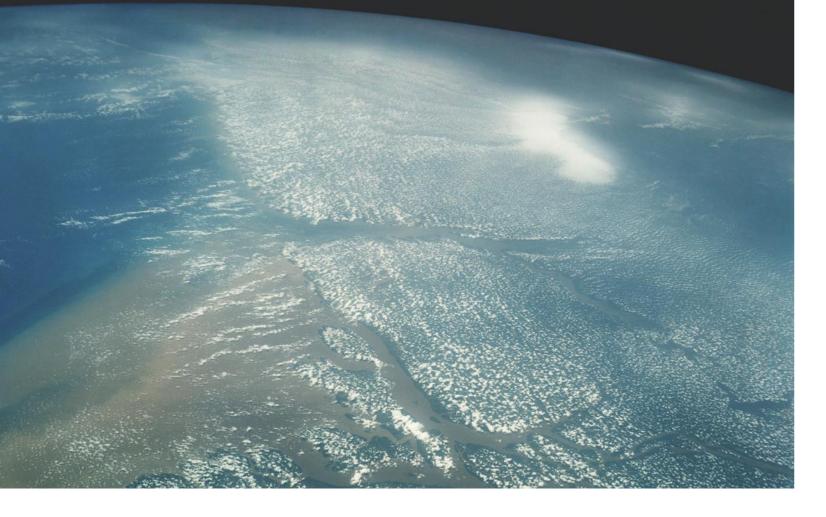
New and Emerging Techniques -Surgical



NET-S

- Horizon scanning project
- NET-S on the web
- Horizon scanning reports in preparation





NET-S horizon scanning project

The New and Emerging Techniques - Surgical (NET-S) project was established in 1999 with the primary aim of identifying and assessing advances in surgery that are likely to cause a significant impact on the Australian and New Zealand health systems in the near future. Assessments of these new technologies are presented in the form of prioritising summaries or horizon scanning reports. Prioritising summaries are concise documents that provide the reader with some background of the technology and present the evidence available pertaining to the safety and efficacy of the product or procedure. If a substantial amount of evidence is available for a particular technology, a horizon scanning report will be written. These documents can be used for clinical guidance as well as provide the information required for government policy and planning. Both prioritising summaries and horizon scanning reports are available on the NET-S website: http://www.surgeons.org/asernip-s/nets.htm.

Prior to writing these assessments, the scanning process takes place to locate emerging surgical technologies.

Selected websites are scanned daily, weekly or monthly, with the frequency of scanning being determined by the amount of information available and how regularly the site is updated. These sites range from journal pages to medical news sites, specialty surgical sites and device manufacturer sites. In addition to this, NET-S receives email alerts as well as

occasional nominations for the assessment of a technology by surgeons. This process yields lists of relevant procedures or technologies which are compiled and filtered monthly. Using an established criteria, these procedures are categorised for immediate assessment, monitoring for 12 months or archiving.

To date, there are over 900 procedures/technologies contained within the NET-S database. This database serves as a guide during the scanning process and allows us to monitor the development of new devices or procedures over time. In addition to this, the database serves as a means of tracking the progress of technology assessments. The NET-S program works closely with the National Horizon Scanning Unit (NHSU) which is based at the University of Adelaide. Working together, NET-S and the NHSU are part of the Australian and New Zealand Horizon Scanning Network (ANZHSN) which is a member of the European Information Network on New and Changing Health Technologies (EuroScan). Euroscan is a collaborative network of health technology assessment agencies which facilitates information exchange on the evaluation of emerging technologies. Technology assessments by ANZHSN can be accessed from http://www.horizonscanning.gov.au and via the Euroscan website (http://www.euroscan.bham.ac.uk/index.htm).

The HealthPACT Committee, a sub-committee of MSAC at the Department of Health and Ageing, oversees this work.

The NET-S project continues to evolve and provide valuable assessments of emerging surgical technologies as well as alerting the Australian health system of technologies which may significantly benefit Australians.

NET-S on the web

The NET-S website has recently undergone a complete redesign to enable easier access and navigation. It is accessible via: http://www.surgeons.org/asernip-s/nets.htm

All summaries and horizon scanning reports are available for download on the NET-S website. Contact details are provided for readers who wish to nominate a new technique or comment on completed summaries or reports.

There are 36 prioritising summaries available:

- Bioabsorbable joint implants (PLA96) for rheumatoid arthritis
- Botox® (C. botulinum type A toxin) injections combined with surgery for migraine treatment
- CardioWest Total Artificial Heart
- CorCap™ Cardiac Support Device
- Crosseal™ fibrin sealant
- Dermal regeneration template (Integra®) for deep hand burns
- Direct transcervical carotid angioplasty and stenting
- Enterra® Therapy Gastric Electrical Stimulation (GES) system for the treatment of the symptoms of medically refractory gastroparesis
- Fetoscopic tracheal occlusion using a detachable balloon
- Gatekeeper reflux repair system for the treatment of gastroesophageal reflux
- Gynelase™ diode Endometrial laser intrauterine thermotherapy (ELITT™) for menorrhagia
- Hydrosorb cages for spinal fusion
- INFUSE® bone graft for open tibial fractures
- Human collagen-based wound dressing
- Injectable silicone biomaterial for faecal incontinence
- Intracavernosal plaque excision method for peyronie's disease
- Laparoscopic hepatic artery infusion pump placement for colorectal liver metastases
- Laser tissue welding using a protein-based solder for repair of blood vessels
- Minimally invasive branch stent technique for aortic aneurysms
- Minimally invasive oesophagectomy
- Modification of the Tan-Bianchi procedure for infantile hypertrophic pyloric stenosis
- Non-invasive extendable prosthesis to maintain limb length equality
- OP-1 Putty for failed posterolateral spinal fusion
- Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) System
- Robotically-assisted left ventricular (LV) epicardial lead implantation
- Radiofrequency energy for faecal incontinence
- Safe-Cross® radiofrequency total occlusion crossing system
- Skip laminectomy for spinal disorders
- Sutureless, wedge-shaped, self-sealing pars plana sclerotomy
- Stretta procedure for gastroesophageal reflux
- Temperature controlled radiofrequency tonsil ablation (TCRF-TA)
- Transcend® Implantable Gastric Stimulator (IGS) for the treatment of obesity
- Tranvaginal pelvic reconstruction using mesh for genitourinary prolapse
- VALR surgical system for lung cancer and chronic obstructive pulmonary disease
- VectorVision® computer-assisted minimally invasive stereotactic surgery platform for orthopaedic and nasal procedures
- Vertical expandable prosthetic titanium rib for thoracic insufficiency syndrome.

There are 2 new NET-S horizon scanning reports available:

- Endokeratoplasty
- Injectable silicone biomaterial implants.



Horizon scanning reports in preparation

• Enterra® Therapy Gastric Electrical
Stimulation (GES) system for the treatment
of the symptoms of medically refractory
gastroparesis





Project activities

- Consumer information
- Promotional activities
- Externally-commissioned projects
- ASERNIP-S website
- ASERNIP-S Management Committee
- Representation on external committees
- Education and training
- Personnel

Consumer information

ASERNIP-S informs consumers (and surgeons) of the latest surgical research through our consumer summaries. These are short summaries of the systematic literature reviews, written in easy-to-read language and posted on the consumer information page and publications page on our website (http://www.surgeons.org/asernip-s/). Double-sided patient information leaflets are also available for some of our reviews.

In 2005 ASERNIP-S staff continued to prepare consumer information in collaboration with our two consumer representatives, Barbara Beacham and Jane Doyle, together with surgeons from the review group concerned.

This year the following consumer summaries were prepared:

- Laparoscopic ventral hernia repair
- Intraoperative ablation for the treatment of atrial fibrillation
- Live-donor liver transplantation adult outcomes
- Unicompartmental knee replacement for unicompartmental osteoarthritis
- Laparoscopic radical prostatectomy
- Paravertebral block for anaesthesia and analgesia.

Publications on the work of ASERNIP-S have appeared in RACS Surgical News (March, September and November), HealthInsite news (September) and General Surgeons Australia newsletter (August and December).

In July we met with representatives of the Royal Australasian College of General Practitioners and the SA Divisions of General Practice to explore ways in which doctors and patients could learn more about our research and how to access it. In November we met with representatives of the National Heart Foundation to introduce the work of ASERNIP-S and discuss common areas of interest.

For more information, please visit the consumer information page of our website at

http://www.surgeons.org/asernip-s/consumer.htm or contact us at consumer.asernip@surgeons.org

Promotional activities

Peer-reviewed publications 2005

Boult M, Cuncins-Hearn A, Tyson S, Kollias J, Babidge W, Maddern G. National Breast Cancer Audit: establishing a web-based data system. *ANZ Journal of Surgery* October 2005, 75 (10): 844

Cuncins-Hearn A, Boult M, Babidge W, Zorbas H, Villanueva E, Evans A, Oliver D, Kollias J, Reeve T, Maddern G. The National Breast Cancer Audit: Overview of invasive breast cancer management". ANZ J Surgery (in press)

Hazel SJ, Paterson HS, Edwards JRM, Maddern GJ. Surgical treatment of atrial fibrillation via energy ablation. *Circulation 2005*, 111: e103-e106

Maddern GJ, Middleton PF, Tooher R, Babidge WJ. Evaluating new surgical techniques in Australia: the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical experience. Surgical Clinics of North America (in press)

Middleton PF, Sutherland L, Maddern GJ. Transanal endoscopic microsurgery: a systematic review. *Dis Colon Rectum 2005*, 48(2): 270-284

Mundy L, Merlin TL, Parrella A, Babidge WJ, Roberts DE, Hiller JE. The Australia and New Zealand Horizon Scanning Network. *Australian Health Review 2005*, 29:395-397

Sutherland Leanne M, Williams John AR, Padbury Robert TA, Gotley David C, Stokes Bryant and Maddern Guy J. Radiofrequency ablation of liver tumours: a systematic review. *Archives of Surgery* (in press)

Tooher R, Griffin T, Shute E, Maddern G. Vaccinations for wastehandling workers. A review of the literature. *Waste Management and Research 2005*, 23: 79-86

Tooher R, Middleton P, Pham C, Fitridge R, Rowe S, Babidge W, Maddern G. A Systematic review of strategies to improve prophylaxis for venous thromboembolism in hospitals. *Annals of Surgery 2005*, 241: 397-415

Other publications 2005

ASERNIP-S Patient Information Leaflets, *General Surgeons Australia Newsletter*, December 2004

Live-Donor Liver Transplantation – Adult Outcomes (Donor and Recipient) *RACS Surgical News*, Vol. 6 No. 2, March 2005

ASERNIP-S Update, *General Surgeons Australia*Newsletter, August 2005

New Reviews from ASERNIP-P, *RACS Surgical News*, Vol 6 No. 8 September 2005

New reviews on Unicompartmental Knee Replacement and Laparoscopic Radical Prostatectomy, *HealthInsite*, September 2005

ASERNIP-S Update, *General Surgeons Australia*Newsletter, December 2005

INAHTA members pool information on health technology assessments, *RACS Surgical News 2005* Vol.6 No.10 November/December 2005

2005 presentations

Fitridge R, Boult M, Maddern G. *ASERNIP-S Audit of Endoluminal Repair of Abdominal Aortic Aneurysm in Audit*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Perth, Australia, May 2005

Kollias J, Cuncins-Hearn A, Boult M, Babidge W, Maddern G. *Axillary* management and sentinel node biopsy for invasive breast cancer: Data from the National Breast Cancer Audit. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Perth, Australia, May 2005

Kollias J, Cuncins-Hearn A, Boult M, Babidge W, Maddern G. *Current Management of DCIS: Data from the National Breast Cancer Audit.* Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Perth, Australia, May 2005

Kollias J, Cuncins-Hearn A, Boult M, Babidge W, Maddern G. *Royal Australasian College of Surgeons National Breast Cancer Audit Update.*Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Perth, Australia, May 2005

Watkin S, Pham C, Middleton P, Watkin S, Maddern G. *Laparoscopic ventral hernia repair: an accelerated systematic review.* Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Perth, Australia, May 2005

Maddern G, From science to clinic - how can we make progress? Surgical Interventions and outcomes - evidence, implementation and monitoring. Copenhagen, Denmark, June 2005

Maddern G, New surgical technologies - can safety and efficacy be assessed? RCSEd Quincentary Congress. Edinburgh, Scotland, June 2005

Babidge W, Banerjee S, Miller J, Smith J, Norrani H, Cuncins-Hearn A, Mensinkai S. *Comparison of lung volume reduction surgery (LVRS) with medical management (M) of emphysema*. HTAi. Rome, Italy, June 2005

Maddern G. *HTA in the hospital setting: the Australian experience*. HTAi. Rome, Italy, June 2005

Maddern G. Why surgery has a poor evidence base. HTAi. Rome, Italy, June 2005

Merlin T, Weston A, Tooher R. *Revising a national standard: redevelopment of the Australian NHMRC evidence hierarchy.* HTAi. Rome, Italy, June 2005

Middleton P. HTA - what if it's not a drug? HTAi. Rome, Italy, June 2005

Boult M, Cuncins-Hearn A, Babidge W, Kollias J, Maddern G. *Auditing* the surgical care of early breast cancer: improving outcomes through jurisdictional reporting. 3rd Australasian Conference on Safety and Quality in Health Care. Adelaide, Australia, July 2005

Maddern G. Impacts of Medical Technology in Australia. *Roundtable Meeting of the Productivity Commission*. Melbourne, Australia, July 2005

Tooher R, Middleton P, Pham C, Fitridge R, Rowe S, Babidge W, Maddern G. *A systematic review of strategies to improve prophylaxis for venous thromboembolism in hospitals.*3rd Australasian Conference on Safety and Quality in Health Care. Adelaide, Australia, July 2005

Babidge W. *The National Breast Cancer Audit* (invited presentation). National Breast Cancer Centre. Sydney, Australia, August 2005

Maddern G. Facilitated Debate: Accessing healthcare technology. MIAA Annual Conference - Developments in Healthcare Technology. Sydney, Australia, August 2005

Kollias J, Cuncins-Hearn A, Boult M, Babidge W, Maddern G. *The Royal Australasian College of Surgeons National Breast Cancer Audit*. Fifth Scientific Meeting of the Australasian Society for Breast Disease. Surfers Paradise, Australia September 2005

Maddern G. New surgical technologies and its accreditation. 3rd Beijing International Symposium on Organ Transplantation Tsinghua University. Beijing, China, September 2005

Merlin T, Weston A, Tooher R (Levels working party). Re-assessing and revising "levels of evidence" in the critical appraisal process. XIII Cochrane Colloquium. Melbourne, Australia, October 2005

Merlin T, Middleton P, Salisbury J, Grimmer K, Coleman K, Weston A, Hillier J, Tooher R (NHMRC Guidelines Assessment Register). Ways to ensure evidence-based clinical practice guidelines are of high quality (workshop). XIII Cochrane Colloquium. Melbourne, Australia, October 2005

Middleton P, Tooher R Salisbury J, Grimmer K, Coleman K, (GRADES working party). Assessing the body of evidence and grading recommendations in evidence-based clinical practice guidelines. XIII Cochrane Colloquium. Melbourne, Australia, October 2005

Externallycommissioned projects

ASERNIP-S has been appointed to the NHMRC Guideline Assessment Register (GAR) as a body with expertise in evidence-based health care. The main GAR task is to help developers of clinical practice guidelines achieve the requirements set out by the NHMRC for evidence-based guidelines. In 2004-5 ASERNIP-S assisted the Australasian Paediatric Endocrinology Group to produce guidelines on Type 1 diabetes and these guidelines received NHMRC endorsement in 2005. During 2005 ASERNIP-S has been assisting with the update of the Melanoma guidelines and this update is planned to be submitted to NHMRC in 2006. Rebecca Tooher and Philippa Middleton played key roles in the redrafting of NHMRC's Minimum Requirements for Guideline Developers which has also involved development of new levels and grades of evidence.

ASERNIP-S website



The ASERNIP-S website was recently redesigned to coincide with the redevelopment of the RACS website. The fresh new look has been well received by users of the website. The ASERNIP-S website can be accessed directly or reached via the Research and Audit Division page of the RACS website. It is updated regularly and all completed systematic literature reviews, accelerated systematic reviews, technology overviews, consumer summaries and annual reports are available for download. Peer-reviewed publications, general publications of the Royal Australasian College of Surgeons, government and consumer organisations, and conference presentations are also listed. We have links to affiliated organisations, consumer groups, peer-reviewed journals and other organisations. Additionally, the website for the New and Emerging Techniques – Surgical (NET-S) horizon scanning project is linked via the home page.

The ASERNIP-S website address is http://www.surgeons.org/asernip-s/

The RACS website address is http://www.surgeons.org

The NET-S website address is http://www.surgeons.org/asernip-s/nets.htm



ASERNIP-S Management Committee 2005

The members of the ASERNIP-S Management Committee are:

Dr Russell Stitz Chairman, and RACS President

(from June 2005)

Mr Peter Woodruff Chairman, and RACS Vice-President

(to May 2005)

Professor Bruce Barraclough RACS Fellow

Ms Barbara Beacham Consumer Representative, Health Rights and

Community Action (to November 2005)

Ms Jane Doyle Consumer Representative

Professor Kingsley Faulkner RACS Fellow

A/Professor Sally Green Director Australasian Cochrane Centre
Dr David Hailey Health Technology Assessment Expert

Dr David Hillis RACS Chief Executive Officer

Ms Kerry Innes Acting Director, National Centre for

Classification in Health

Mr Brian Johnston Chief Executive, Australian Council on

Healthcare Standards

Dr Michael Kitchener Medical Services Advisory Committee

(to May 2005)

Professor Guy Maddern ASERNIP-S Surgical Director

Dr John Quinn RACS Executive Director for Surgical Affairs

In May 2005 Mr Peter Woodruff resigned from the committee due to the completion of his term as RACS Vice-President. We thank him for his excellent contribution while Chairman of the committee. In May 2005 Dr Michael Kitchener resigned from the committee due to completion of his term on the Medical Services Advisory Committee. We thank him for his valuable contribution during his time on our committee. In November 2005 Ms Barbara Beacham resigned from her position as a Consumer Representative on the committee. Over the last four years Barbara offered expert guidance to ASERNIP-S in the development of our consumer information. We thank her for the pivotal role she played in this area and wish her well for the future.

Terms of Reference

- To meet on a regular basis.
- To agree on programme schedules, plans and tasks required to meet programme objectives.
- To provide leadership and guidance to the programme to focus on a strategy to meet programme objectives.
- To be responsible for identifying resource requirements and, wherever possible, organising provision of these resources.
- To exercise direction over programme activities, approve plans and monitor their execution.
- To make decisions on issues which threaten to affect the progress of the programme and ensure adequate contingency management is in place.
- To delegate measures of effectiveness and efficiency and monitor programme performance against these criteria.

Representation on external committees

ASERNIP-S staff were represented on the following committee

- Health Policy Advisory Committee on Technology (HealthPACT) Dr Wendy Babido
- Medical Device Evaluation Committee (MDEC), a statutory committee which provides independent advice to Therapeutic Goods Administration (TGA) – Professor Guy Maddern
- National Breast Cancer Centre Data Advisory Group Professor Guy Madders
- International Network of Agencies for Health Technology Assessment (INAHTA) Professor Guy Maddern, Directo
- Medical Device Incident Review Committee (MDIRC), a sub-committee of the Medical Device Evaluation Committee (MDEC)
 Professor Guy Maddern, Chair
- Health Technology Advisory Group (HTAG) Professor Guy Maddern, Chair

Education and training

Training opportunities for staff

Courses and conferences attended by staff members in 2005 included:

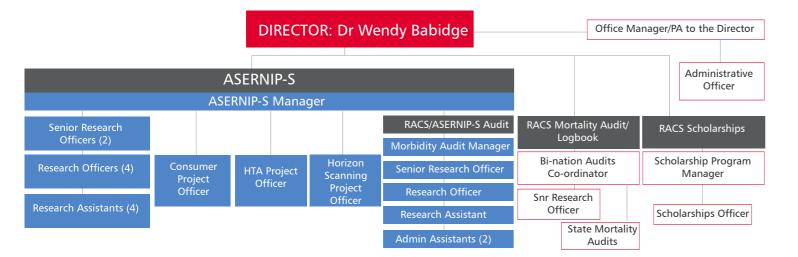
- Australasian Cochrane Centre Workshops on 'Developing a protocol for a systematic review' and 'An introduction to analysis', Adelaide, April
- Annual Scientific Congress of the Royal Australasian College of Surgeons, Perth, May
- Adobe InDesign course, Adelaide, May
- HTAi conference, Rome, June
- 13th Annual Meeting of INAHTA, Rome, June
- Comprehensive web content writing course, Melbourne, June
- 3rd Australasian Conference on Safety and Quality in Health Care, Adelaide, July
- MIAA Annual Conference, Sydney, August
- "Making multidisciplinary cancer care a reality" forum, National Breast Cancer Centre, Adelaide, August
- XIII Cochrane Colloquium, Melbourne, October
- ACEBCP Evidence Based Clinical Practice Workshop Program, Adelaide, November
- National standard for credentialling and defining the scope of clinical practice workshops, Adelaide, December.

Medical students

ASERNIP-S has supervised research proposal development for three students this year. Sheng-Wen (David) Cheng worked with the audit staff of the National Breast Cancer Audit to develop a research proposal examining regional variations in management for ductal carcinoma in situ (DCIS) using data from the audit. Danielle Carlson developed a research proposal to compare the clinical outcomes of robotic and manual total hip arthroplasty. Niyati Sharma developed a research proposal for a randomised controlled trial to compare the safety and effectiveness of totally endoscopic coronary artery bypass grafting using the da Vinci robotic system and conventional coronary artery bypass grafting.



Research and Audit Division – Royal Australasian College of Surgeons Organisational chart



ASERNIP-S Surgical Director Professor Guy Maddern

RP Jepson Professor of Surgery, University of Adelaide, was appointed inaugural Surgical Director of ASERNIP-S in October 1997. Since that time Professor Maddern has been involved in developing the ASERNIP-S program for the Royal Australasian College of Surgeons. Professor Maddern is a practising hepatobiliary surgeon based at The Queen Elizabeth Hospital, Head of the Division of Surgery and Director of the Basil Hetzel Institute for Medical Research in Adelaide.



Director, Research and Audit, Royal Australasian College of Surgeons Dr Wendy Babidge

Dr Wendy Babidge was made a Director of the Royal Australasian College of Surgeons (RACS) in June 2005 and is responsible for the Division of Research and Audit. This Division currently supports 27 staff members, working in the areas of ASERNIP-S, Audits and Scholarships. As well as managing the ASERNIP-S program in 2005, Wendy oversees the administration of the RACS morbidity and mortality audits, the provision of scholarships for surgical research and the fundraising activities associated with this. Wendy has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business. Another major focus of the Division is to establish a secure web-based system at the RACS for the purpose of training.



ASERNIP-S Manager Kerin Williams

Kerin Williams joined ASERNIP-S in November 2005 as Manager of ASERNIP-S. She has a Bachelor of Arts (Psychology, Sociology and Philosophy), Graduate Diploma Social Science, and an Advanced Diploma in Management (Business), has commenced a Master in Public Health/Business Management qualification, and is a Registered Nurse. Kerin has managed State and National projects for the Department of Health and Ageing over the past 10 years in the area of adolescent mental health and suicide prevention. She has recently been employed as Program Manager for the Southern Division of General Practice, and has also managed her own consultancy practice specialising in health and education projects where there is a need to develop multidisciplinary collaborative working relationships.



ASERNIP-Research Manager Philippa Middleton

Philippa Middleton joined ASERNIP-S in April 2001. Her main role was to maintain the high quality of ASERNIP-S outputs, particularly systematic reviews and other HTA reports. She divided her time between ASERNIP-S and the Cochrane Collaboration, where she coordinated Australian activities for the Cochrane Pregnancy and Childbirth group. She has an Honours Degree in Science, a Graduate Diploma in Library Studies and a Masters in Public Health. She is particularly interested in how to minimise bias and maximise the quality of biomedical research, so that decisions in healthcare can be based on the most reliable evidence available. Philippa left ASERNIP-S in October 2005 to work for the Cochrane Collaboration and the University of Adelaide Department of Obstetrics and Gynaecology.



ASERNIP-S Consumer Project Officer

Eleanor Ahern

Eleanor joined ASERNIP-S in October 2000. She has a Master of Arts Degree in International Relations and an Advanced Diploma of Arts in Professional Writing. She has a background in medical studies. Eleanor has worked as a freelance editor and now writes consumer information for ASERNIP-S.



ASERNIP-S Research Assistant

Christine Barber

Chris Barber joined ASERNIP-S in August 2005 to conduct systematic reviews. She previously worked as a researcher at the Institute of Medical and Veterinary Science investigating the relationship between the intervertebral disc and the vertebral body in osteoporosis of the human lumbar spine. She has a Bachelor of Science degree majoring in molecular biology and genetics from Flinders University. Chris recently completed a Bachelor of Health Sciences, Honours in Pathology from the University of Adelaide, focusing on the assessment of osteoporosis and bone quality in the human lumbar spine.



ASERNIP-S Morbidity Audit Manager

Maggi Boult

Maggi Boult has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. She joined ASERNIP-S in 1998 and during her tenure has developed and implemented surgical audits for RACS and for the Federal Government. Maggi is also the ASERNIP-S Privacy Officer.



ASERNIP-S Research Officer

Dr Alun Cameron

Dr Alun Cameron joined ASERNIP-S in August 2005. He has a BSc in Biochemistry (with Medical Biochemistry), and studied cell signalling mechanisms in African trypanosomes during his PhD. Since then he has worked in the field of connective tissue research at Manchester University in the UK, prior to moving to Adelaide.



ASERNIP-S Senior Research Officer

Astrid Cuncins-Hearn

Astrid Cuncins-Hearn joined ASERNIP-S in September 2001. Her academic qualifications include both Bachelor and Master of Science degrees specialising in biomechanics from the University of Guelph in Canada. After working in the areas of surgical biomechanical research, and trauma and cancer outcomes databases in both Canada and Australia, Astrid joined ASERNIP-S as a research officer where she was involved with the National Breast Cancer Audit and conducting systematic literature reviews. Astrid left ASERNIP-S in September to take up a new position as Senior Research Officer in the Research and Audit Division of the Royal Australasian College of Surgeons.



ASERNIP-S Administrative Assistant

Sarah Devitt

Sarah joined ASERNIP-S in June 2005 as an administrative assistant to the Audit Manager. Sarah came to ASERNIP-S with extensive administrative experience in private enterprise at the executive secretary level. Sarah has a Degree in Commerce and has previous experience in marketing and hospital administration.



ASERNIP-S Office Manager and PA to the Director, Research and Audit

Ann Duff joined ASERNIP-S in February 2005 having most recently worked for the Royal District Nursing Service of South Australia. Ann has had extensive administrative experience working for many years in the State Government, predominantly in Ministerial offices. At ASERNIP-S Ann is the Office Manager and Personal Assistant to the Director, Research and Audit.



ASERNIP-S Research Officer

Michael Duffield

Michael Duffield joined ASERNIP-S in September 2003 to conduct systematic reviews. He has a Bachelor of Science degree, with Honours, from the University of Adelaide, and is in the final stages of completing his PhD, which has involved a molecular biological and electrophysiological investigation of ion channel gating. In 2005 Michael commenced studies in medicine at Flinders University, but he still works at ASERNIP-S on a part-time basis.



ASERNIP-S Administrative Officer

Jane Franklin

Jane Franklin joined ASERNIP-S in January 2001 to provide administrative support to the program. Jane has a background in banking and customer service and a Certificate II in Business (Office Administration).



ASERNIP-S Senior Research Officer

Dr Tabatha Griffin

Dr Tabatha Griffin joined ASERNIP-S in April 2003. She has a Bachelor of Science degree in plant and environmental biology with Honours. She also completed a PhD at Flinders University in 2001 in the fields of ecology and entomology. At ASERNIP-S Tabatha initially conducted systematic literature reviews and managed the website. She recently moved to a new position as Senior Research Officer in the Breast Audit.



ASERNIP-S Administrative Assistant

Louise Kennedy

Louise Kennedy joined ASERNIP-S in December 2002, on a part-time basis. She has a Certificate III in Business (Office Administration), and has studied several Information Technology subjects. Louise previously worked in clerical positions for the Commonwealth Public Service. At ASERNIP-S, Louise provides assistance to the administrative officers and audit projects.



ASERNIP-S Project Officer (NET-S)

Irving Lee

Irving Lee joined ASERNIP-S in January 2005 as the NET-S Project Officer. His academic qualifications includes a Bachelor degree in Science (Biomedical), majoring in Physiology and Pharmacology, and an Honours degree in Obstetrics and Gynaecology. At ASERNIP-S, Irving conducts daily horizon scanning for new surgical techniques, writes prioritising summaries/reports and maintains the NET-S database.



ASERNIP-S Research Assistant

Nicholas Marlow

Nicholas Marlow joined ASERNIP-S in November 2005. Nicholas holds a Bachelor of Arts majoring in Anthropology and Japanese, an Honours degree in Anthropology and a Graduate Diploma in Public Health, all from the University of Adelaide. At ASERNIP-S, he has just started work on the Endovascular Neurointerventional Procedures project.



ASERNIP-S HTA Project Officer

Amy McLennan

Amy McLennan joined the ASERNIP-S team in November 2005. She has a Bachelor of Medical Science with majors in physiology and neuroscience, a Diploma in French from Flinders University, and a Bachelor of Science with Honours in anatomical sciences from the University of Adelaide. At ASERNIP-S, Amy provides support to several committees that deal with aspects of health technology assessment.



ASERNIP-S Research Assistant

Pauline McLoughlin

Pauline McLoughlin joined ASERNIP-S in January 2005 as a Research Assistant. She has a Bachelor of Health Sciences degree from the University of Adelaide. In 2004, she completed an Honours Degree in Public Health, in the area of asylum seeker mental health. At ASERNIP-S, Pauline conducts prioritising summaries and horizon scanning reports for the New and Emerging Techniques – Surgical (NET-S) horizon scanning project. She also assists in conducting systematic literature reviews, and helps with data entry and analysis for the National Breast Cancer Audit.



ASERNIP-S Research Assistant Claire Miller

Claire Miller joined ASERNIP-S in August 2005. She has a Bachelor of Health Sciences degree, majoring in Public Health and Psychology, from the University of Adelaide. In 2004, she completed an Honours degree in Psychology, with an emphasis on health psychology. Her Honours thesis focused on health behaviours and attitudes around self-administered cancer screening techniques. She has also worked in a histopathology and cytopathology laboratory. At ASERNIP-S Claire is working as a research assistant and is currently involved with the National Breast Cancer Audit.



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ASERNIP-S Research Officer

Clarabelle Pham

Clara joined ASERNIP-S in January 2003. She has a Bachelor of Science Degree, majoring in Physiology and Pharmacology, an Honours Degree in Obstetrics and Gynaecology, and a Graduate Diploma in Public Health from the University of Adelaide. At ASERNIP-S Clara conducts systematic literature reviews.



ASERNIP-S Research Officer

Dr John Pockett

Dr. Pockett joined ASERNIP-S in November 2005 to conduct systematic reviews. He has recently completed a PhD in Materials Science. This follows a Bachelor of Science degree in Physics and Maths and a career mainly in research and development across a range of industries including with medical devices such as gamma cameras, X-ray image intensifiers and laser equipment. He has also run a consultancy in industrial research and development. It is expected that his expertise in cutting-edge technologies and materials science will become a useful resource to the ASERNIP-S team as new technologies and materials become increasingly utilised in surgical procedures.



ASERNIP-S Research Assistant

Elen Shute

Elen Shute joined ASERNIP-S as a Research Assistant in April 2003. She holds a Bachelor of Arts from Flinders University, with Honours in Environmental Studies. After leaving to complete an M.Phil in Quaternary Science at the University of Cambridge, she returned to ASERNIP-S to support researchers in conducting systematic reviews. Elen left ASERNIP-S in May 2005 to work in the United Kingdom.



ASERNIP-S Research Officer

Prema Thavaneswaran

Prema Thavaneswaran joined ASERNIP-S in January 2005 to conduct systematic reviews. She has a Bachelor of Science degree with Honours from the University of Adelaide. Prema is in the final stages of completing her PhD, which involved investigations of the prenatal programming of the Insulin Resistance Syndrome in the aged guinea pig.



ASERNIP-S Senior Research Officer

Dr Rebecca Tooher

Dr Rebecca Tooher joined ASERNIP-S in August 2002. A qualified audiologist, Rebecca has a Bachelor of Arts and a Postgraduate Diploma of Audiology. Her PhD (awarded in 2003) focused on the quality of life and psychosocial wellbeing of young people who use cochlear implants to hear. At ASERNIP-S, Rebecca writes systematic literature reviews, contributes to grant applications and other applications for funding, conducts evaluation research of ASERNIP-S activities, and is involved in external consultancies including guideline development support for the NHMRC. She assists the Research Manager to supervise ASERNIP-S review projects and train ASERNIP-S research staff.



ASERNIP-S Research Officer

Sarah Tyson

Sarah Tyson joined ASERNIP-S as a researcher after operating the RACS Breast Audit as a separate project for four years. She has a science degree from the University of Adelaide majoring in Clinical and Experimental Pharmacology & Toxicology, and Biochemistry. Prior to her appointment Sarah was engaged in several other complex projects in the health and disability sectors.



ASERNIP-S Research Assistant

Amber Watt

Amber Watt joined ASERNIP-S in August 2005 as a Research Assistant. She holds a Bachelor of Medical Science from Flinders University, with majors in Physiology and Neuroscience. At ASERNIP-S, Amber supports researchers in conducting systematic literature reviews in addition to assisting with the NET-S horizon scanning project.



ASERNIP-S Administrative Officer

Rosemary Wong

Rosemary Wong joined ASERNIP-S in November 2000. Her role was to provide administrative assistance to the project, data entry and clerical support to research staff. Rosemary previously worked at the Drug and Alcohol Services Council in the Education Unit. In April Rosemary transferred from ASERNIP-S to take up a position as Scholarship Officer in the Division of Research and Audit at the Royal Australasian College of Surgeons.



ASERNIP-S Research Assistant

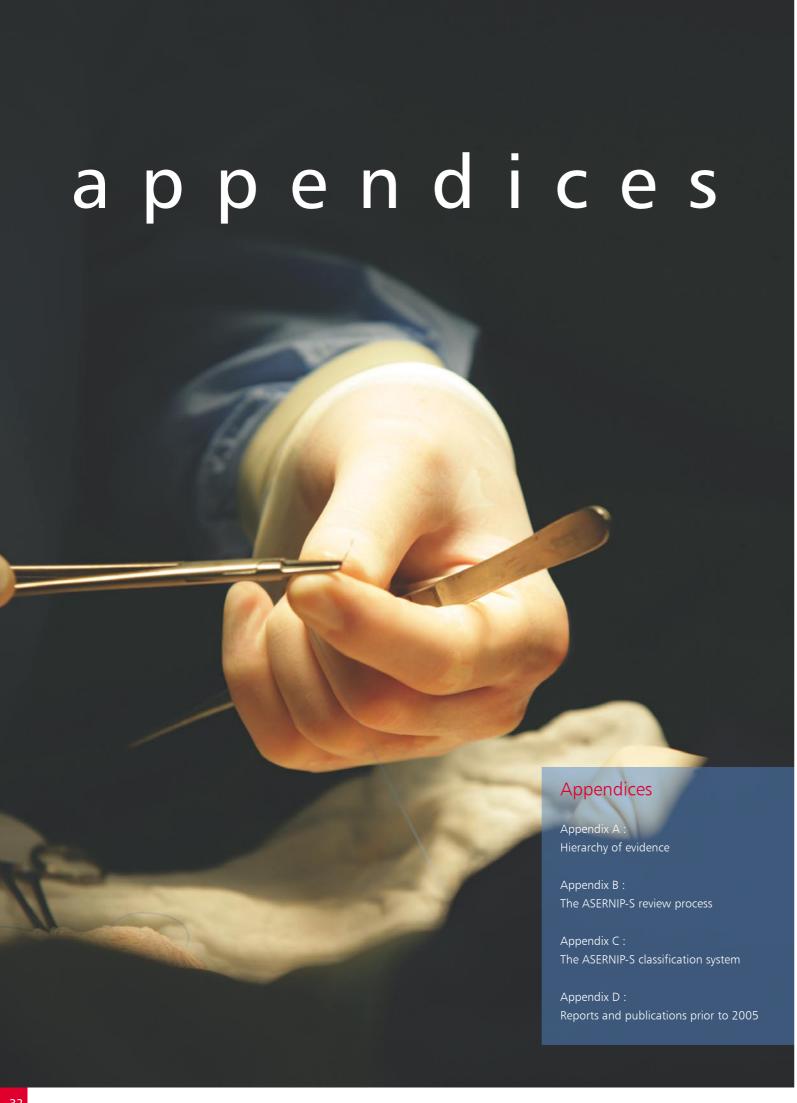
Luis Zamora

Luis Zamora joined ASERNIP-S in November 2005 as a Research Assistant. He has a Bachelor of Biotechnology Degree, majoring in Biochemistry and Microbiology, and an Honours Degree in Obstetrics and Gynaecology from the University of Adelaide. At ASERNIP-S Luis is involved in the NET-S horizon scanning project.





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Appendix A Hierarchy of evidence

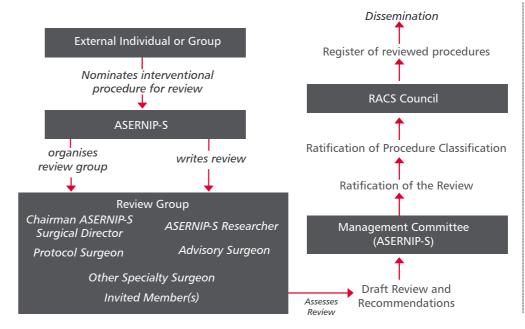
Designation of levels of evidence¹

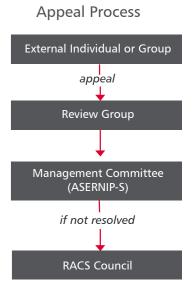
Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time-series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case-series, either post-test or pre-test/post-test.

This table should be referenced in the reference list of the review as follows:

1. NHMRC. How to Use the Evidence: Assessment and Application of Scientific Evidence, pp 8. Canberra: NHMRC. 2000.

Appendix B ASERNIP-S review process





Appendix C ASERNIP-S classification system

Following the systematic review of a new surgical procedure a statement is prepared covering each of the following three areas. If further research is required to obtain data on either the safety and/or efficacy of a procedure then recommendations will be given regarding the most appropriate method for doing this.

Evidence rating

The evidence for ASERNIP-S systematic reviews is classified as Good, Average or Poor, based on the quality and availability of this evidence. High-quality evidence is defined here as having a low risk of bias and no other significant flaws. While high-quality randomised controlled trials are regarded as the best kind of evidence for comparing interventions, it may not be practical or ethical to undertake them for some surgical procedures, or the relevant randomised controlled trials may not yet have been carried out. This means that it may not be possible for the evidence on some procedures to be classified as good.

Good

Most of the evidence is from a high-quality systematic review of all relevant randomised trials or from at least one high-quality randomised controlled trial of sufficient power. The component studies should show consistent results, the differences between the interventions being compared should be large enough to be important, and the results should be precise with minimal uncertainty.

Average

Most of the evidence is from high-quality quasi-randomised controlled trials, or from non-randomised comparative studies without significant flaws, such as large losses to follow-up and obvious baseline differences between the comparison groups. There is a greater risk of bias, confounding and chance relationships compared to high-quality randomised controlled trials, but there is still a moderate probability that the relationships are causal.

An inconclusive systematic review based on small randomised controlled trials that lack the power to detect a difference between interventions and randomised controlled trials of moderate or uncertain quality may attract a rating of average.

Poo

Most of the evidence is from case series, or studies of the above designs with significant flaws or a high risk of bias. A poor rating may also be given if there is insufficient evidence.

Safety

At least as safe compared to comparator* procedure(s) This grading is based on the systematic review showing that the new intervention is at least as safe as the comparator.

Safety cannot be determined

This grading is given if the evidence is insufficient to determine the safety of the new intervention.

Less safe compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as safe as the comparator.

Efficacy

At least as efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is at least as efficacious as the comparator.

Efficacy cannot be determined

This grading is given if the evidence is insufficient to determine the efficacy of the new intervention.

Less efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as efficacious as the comparator.

Recommendations regarding the need for further research

In order to strengthen the evidence base regarding the procedure it may be recommended that either:

- an audit be undertaken, or
- a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The Royal Australasian College of Surgeons recognises that it may not always be possible to undertake a controlled clinical trial. Under such circumstances, it is recommended that, at the very least, data be contributed to an audit for further assessment, in collaboration with ASERNIP-S, until such time as a controlled clinical trial is undertaken.

*A comparator may be the current "gold standard" procedure, an alternative procedure, a non-surgical procedure or no treatment (natural history)

Appendix D Reports and Publications prior to 2005

1998

Maddern G. Surgery and evidence-based medicine. A new Australian registry promises to strengthen the push towards evidence-based surgery. *Medical Journal of Australia 1998*; 169: 348–349

1999

ASERNIP-S Report No. 1 Minimally Invasive Parathyroidectomy, June 1999

ASERNIP-S Report No. 2 Lung Volume Reduction Surgery, June 1999

ASERNIP-S Report No. 3 Laparoscopic Live Donor Nephrectomy, June 1999

ASERNIP-S Report No. 4 Ultrasound-Assisted Lipoplasty, October 1999

Introducing ASERNIP-S: The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (1999) *Keeping You Informed (New Zealand Health Technology Assessment newsletter)* December Issue No. 5.

2000

ASERNIP-S Report No. 5

Percutaneous Endoscopic Laser Disectomy: Update & re-appraisal, February 2000

ASERNIP-S Report No. 6

Arthroscopic Subacromial Decompression using the Holmium: YAG Laser: Update & re-appraisal, February 2000

ASERNIP-S Report No. 7

Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction, February 2000

ASERNIP-S Report No. 8

Laparoscopic-Assisted Resection of Colorectal Malignancies, February 2000

ASERNIP-S Report No. 15

Laparoscopic Live-donor Nephrectomy: Update & re-appraisal, May 2000

ASERNIP-S Report No. 18

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