



annual report 2004

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical





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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 health care through the wide dissemination of our evidence-based research to surgeons, health care providers and consumers, both nationally and internationally.

Surgical Director's report 2004

This year sees the conclusion of the first seven years of the ASERNIP-S initiative. To date the project has been remarkably successful with over 30 peer-reviewed publications, in excess of \$5 million of funding and an increasing profile that has made the ASERNIP-S programme the most prominent organisation assessing new surgical technologies worldwide. Having now established our credentials as an excellent research organisation, it has become important not only to continue to conduct systematic reviews of new surgical technologies, but also to look at newer and more cost-effective inputs into the process of evaluating surgical technologies. Horizon scanning has become an important activity and we now have over 70 horizon scanning reports and summaries and many more procedures recorded on our database.

In more recent times ASERNIP-S has developed the accelerated systematic review in order to provide a more timely and efficient assessment of new technologies to hospitals, surgeons and consumers. Consumers have also been well served with excellent consumer summaries prepared on technologies reviewed and, with these, it is hoped that the results of ASERNIP-S research will not only reach surgeons and hospitals but also patients who are contemplating these new interventions.

This year Mr Peter Woodruff, Vice-President of the Royal Australasian College of Surgeons, has settled into his new role as Chairman of the ASERNIP-S Management Committee and we are grateful for the innovative ideas and approaches he has brought to the organisation. We would also like to acknowledge the contribution of Associate Professor Rosemary Roberts, who has been a member of the committee since its inception. Due to her retirement, she will no longer be a representative of the National Centre for Classification in Health (NCCH) on the committee. We thank her for her valuable input during this time and wish her well for the future. We also thank Professor David Scott for his important contribution during his time on the committee whilst Executive Director for Surgical Affairs.

2005 will be a challenging period for the ASERNIP-S project. We have an NHMRC Enabling Grant currently short-listed and we will need core funding from the Commonwealth Government to be renewed before July 2005. If, however, these two initiatives are successful, the next five years promises to be an even more exciting and dynamic period for the project.

It is important to acknowledge that the success of such an enterprise is ultimately reliant on the quality of the staff employed, and those who have served the project over the seven years have much to feel justly proud of. We are delighted to have the services of so many talented and innovative individuals and we look forward to offering training and career development to others joining this exciting enterprise.

Guy Maddern
Surgical Director





Systematic literature 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 the safety and efficacy of a new intervention with a standard intervention or provide a recommendation for use.

ASERNIP-S reviews

New assessments completed

Systematic literature reviews

- Intraoperative Ablation for the Treatment of Atrial Fibrillation
ASERNIP-S Report No. 38
- Live-Donor Liver Transplantation – Adult Donor Outcomes
ASERNIP-S Report No. 22
- Live-Donor Liver Transplantation – Adult Recipient Outcomes
ASERNIP-S Report No. 34

Accelerated systematic reviews

- Laparoscopic Ventral Hernia Repair
ASERNIP-S Report No. 41

Technology overviews

- Da Vinci Surgical Robotic System
ASERNIP-S Report No. 45

Systematic reviews for other organisations

- Carotid Percutaneous Transluminal Angioplasty with Stenting (MSAC)
ASERNIP-S Report No. 40
- Sentinel Lymph Node Biopsy in Breast Cancer – Diagnostic (MSAC)
ASERNIP-S Report No. 30
- Sentinel Lymph Node Biopsy in Breast Cancer – Safety and Efficacy (MSAC)
ASERNIP-S Report No. 50

Assessments in progress

Procedure nominations



Members of the Review Group assessing Live-Donor Liver Transplantation – Adult Outcomes

Ms Philippa Middleton - ASERNIP-S Research Manager
Mr Michael Duffield - ASERNIP-S Researcher
Professor Bernard Launois - Protocol Surgeon (until December 2001)
Associate Professor Stephen Lynch - Advisory Surgeon
Dr Rob Padbury - Invited Surgeon
Professor David Morris - Invited Surgeon (until 2003)
Professor Tony House - Invited Surgeon
Professor Peter Stanton - Other Specialty Surgeon
Mr Russell Stitz - Other Specialty Surgeon
Dr Debbie Verran - Nominated Surgeon
Professor Guy Maddern - ASERNIP-S Surgical Director and Chairman

systematic reviews

New assessments completed

Systematic literature reviews

Live-Donor Liver Transplantation – Adult Outcomes (Donor and Recipient)

ASERNIP-S Reports No. 22 and No. 34

Background

Liver transplantation may be the only hope of survival for those with end stage liver disease, but there are not enough deceased donor livers to meet the growing demand. Live liver donation, particularly of the right lobe of the liver, constitutes major surgery which exposes donors to morbidity and mortality risks.

Objective

To assess the safety of live-donor liver transplants (LDLT) for the donor and to determine if LDLT has comparable safety and efficacy outcomes to deceased donor liver transplantation for adult recipients.

Methods

Donors: We included any study which reported safety and efficacy outcomes for live liver donors.

Recipients: We included any study which reported safety and efficacy outcomes for adult recipients of livers from live donors.

Search: MEDLINE, EMBASE and other databases were searched up to December 2003. Relevant online journals and conference proceedings were also searched.

Results

Three hundred and seven (307) studies provided information on donor outcomes and 246 studies provided information on recipient outcomes. Most of the studies were case series, but some compared live-donor liver transplantation with deceased donor liver transplantation and there were

also comparisons between different types of grafts, for example. There is likely to have been both under-reporting and duplicate reporting, so the following results should be interpreted cautiously.

Donor outcomes: Overall reported donor mortality was 13 in about 6,000 procedures (0.2%) (117 studies). Mortality for right lobe donors to adult recipients is estimated to be 4-10 out of 2,000 (0.2 to 0.5%), and 2-6 out of 3,300 (0.06 to 0.18%) for left lobe donors to child recipients. The donor morbidity rate ranged from 0% to 100% with a median of 16% (131 studies). Biliary complications and infections were the most commonly reported donor morbidities. Nearly all donors had returned to normal function by three to six months (18 studies). On average, one in three potential donors eventually donated part of their liver.

Recipient outcomes: Adult recipient mortality ranged from 0% to 50%, with a median of 12.5% (115 studies). Death was most commonly due to various forms of infection, hepatic and multiple organ failure, and recurrent disease. Total complication rates ranged from 0% to 100% with a median of 45% (20 studies). The most common complications were biliary or hepatic complications or infections. Generally the complication rate and other outcomes were similar to those seen for adult deceased donor liver transplantation, except for biliary complications, which may have been more frequent in LDLT.

Costs: No clear cost differences were seen between live-donor liver transplantation and deceased donor liver transplantation (6 studies).

Conclusions and recommendations

Recipient outcomes are similar for adult-adult live-donor (AA LDLT) and deceased donor liver transplantation. There are small, but real, risks for live liver donors. Although live-donor liver transplantation has the potential to help address the demand for livers, its current impact on waiting lists is relatively small. 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 donor and recipient safety and recipient efficacy of live-donor liver transplantation:

Evidence rating: The available evidence was assessed as poor; however it is recognised that most of the evidence regarding the safety and efficacy of LDLT has to be derived from case series and registries. Even so, there are particular concerns about under-reporting of mortality and morbidity for both donors and recipients, which also contributes to the classification of 'poor'.

Safety – Donors: There is some risk of mortality and morbidity for LDLT donors, and the long-term risks are unknown. (Since there is no comparator (except not donating), safety can only be described in absolute terms.)

Efficacy – Donors: Not applicable, although clearly donors incur costs in terms of lost time and need for additional resources (financial and other).

Safety – Recipients: Cannot be determined.

Efficacy – Recipients: Cannot be determined.

Recommendations: The panel recommended that strict guidelines are necessary for the performance of AA LDLT, in particular with respect to the process of LDLT donor selection, and contraindications for donor selection, and to the process of listing potential LDLT recipients. The Transplantation Society of Australia and New Zealand has developed guidelines for the performance of AA LDLT, which can be accessed online at www.racp.edu.au/tsanz. Additionally, the panel acknowledged the poor evidence available for LDLT, and suggested that all LDLT procedures need to be submitted to a registry, and that any centres not prepared to submit data should not be authorised to be transplant centres.

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

Intraoperative Ablation for the Treatment of Atrial Fibrillation ASERNIP-S Report No. 38

Objective

The aim of this review was to assess the safety and efficacy of intraoperative ablation techniques for the treatment of atrial fibrillation (AF), in comparison to other surgical techniques, including cardiac surgery alone or the Maze-III procedure (the current gold standard).

Methods

Literature databases were searched from inception to January 13, 2004. Randomised controlled trials (RCTs), non-randomised comparative studies and case series of intraoperative ablation with any energy source (cryotherapy, radiofrequency, microwave, laser) and any standardised lesion pattern were included. Patients had to be 18 years of age or over with AF of any type; operations were via median sternotomy with cardiopulmonary bypass (CPB).

Results

There were 69 included studies; of these, there were 30 studies of cryotherapy ablation (CA), 29 studies of radiofrequency ablation (RFA), eight studies of microwave ablation (MWA), one case series of laser ablation and one non-randomised comparative study of RFA versus MWA.

Intraoperative ablation in general returned more patients to normal heart rhythm (sinus rhythm) than cardiac surgery alone. There was insufficient evidence to compare energy sources and there were no consistent differences in efficacy versus the Maze-III procedure. Less evidence was available to determine the safety of intraoperative ablation, although no differences in mortality were apparent versus cardiac surgery alone. Small numbers of cases of oesophageal perforation and circumflex artery stenosis were found. The oesophageal perforations were associated with unipolar non-irrigated RFA.

Conclusions and recommendations

Evidence rating: The available evidence was rated as poor. There were only two RCTs and variability in the energy source and ablation pattern limited the evidence.

Safety: Insufficient evidence was available to determine if intraoperative ablation was more or less safe than cardiac surgery alone, or the Maze-III procedure. Associated risks relating to longer bypass times, plus the risk of oesophageal perforation and circumflex artery injuries, are potential concerns.

Efficacy: Intraoperative ablation is at least as efficacious as either cardiac surgery alone or the Maze-III procedure.

Recommendations: A randomised controlled trial of intraoperative ablation should be performed, designed and powered sufficiently to measure long-term survival and stroke rate. Surgeons performing intraoperative ablation should also participate in a national audit.

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

Members of the Review Group assessing Intraoperative Ablation

for the Treatment of Atrial Fibrillation
Dr Susan Hazel - ASERNIP-S Researcher
Dr Marie Andrew - ASERNIP-S Researcher
Ms Rebecca Morgan - ASERNIP-S Researcher
Mr James Edwards - Protocol Surgeon
Mr Hugh Paterson - Advisory Surgeon
Mr Russell Stitz - Other Specialty Surgeon
Professor John Horowitz - Invited Member
Professor Guy Maddern - ASERNIP-S Surgical Director





accelerated systematic reviews

Laparoscopic Ventral Hernia Repair

ASERNIP-S Report No. 41

Objective

The aim of this review was to assess the safety and efficacy of laparoscopic ventral hernia repair in comparison with standard open ventral hernia repair.

Methods

Literature databases were searched from inception to January 2004. Comparative studies of laparoscopic versus open ventral hernia repair (randomised and non-randomised) were included. Studies reporting techniques other than the laparoscopic and open approaches were excluded from the review.

Results

There were 10 included studies; of these, two were randomised controlled trials and eight were non-randomised comparative studies. In terms of safety, more complications were reported for open repair patients than laparoscopic repair patients. Complications from the open approach tend to be wound-related, with the most commonly reported complications being seroma, haematoma, wound infection, the need for an aspiration drain and prolonged ileus. The most frequently reported complications from the laparoscopic approach include wound-related complications, such as seroma and the need for an aspiration drain, and procedure-related complications, such as enterotomy.

In terms of efficacy, the laparoscopic approach appears to have a lower rate of hernia recurrence (0% to 9.5% for laparoscopic versus 0% to 21.0% for open) and require a shorter hospital stay (0.8 to 5.0 days for laparoscopic versus

1.5 to 11.0 days for open), with a rate of conversion to open surgery of 0% to 14%. The duration of the operations was similar for the laparoscopic and open approaches.

Conclusions

Based on the current level of evidence, the relative safety and efficacy of the laparoscopic approach in comparison with the open approach is still uncertain. However, results from the included studies suggest some advantages for laparoscopic repair over open repair. The laparoscopic approach may be more suitable for straightforward hernias, and open repair reserved for the more complex hernias. As there is uncertainty about whether an open or laparoscopic approach should be used, it is important that patients are well informed of the risks and benefits of each technique. Laparoscopic ventral hernia repair appears to be an acceptable surgical operation that can be offered by surgeons proficient in advanced laparoscopic techniques.

Members of the Review Group assessing Laparoscopic Ventral Hernia Repair

Ms Clarabelle Pham - ASERNIP-S Researcher
Ms Philippa Middleton - ASERNIP-S Research Manager
Mr Scott Watkin - Protocol Surgeon
Professor Guy Maddern - ASERNIP-S Surgical Director

For the full review and executive summary, please access our website:
http://www.surgeons.org/asernip-s/publications_ventralhernia.htm

technology overviews

Da Vinci Surgical Robotic System

ASERNIP-S Report No. 45

The da Vinci surgical robotic system is a master-slave telerobotic system in which the surgeon remotely controls robotic arms from a video console using handles which transmit the surgeon's movements to the robot. Since its introduction into the Australian health care system (to the private Epworth Hospital in Melbourne), it has generated considerable interest from clinicians, patients and the wider community. The report aimed to provide information regarding the use of the da Vinci surgical robotic system for all types of surgery, and address cost and resource use issues, legal, regulatory and company issues, surgical training and other policy issues in the context of the Australian health care system. It was hoped that this information would assist decision-makers in formulating their own evidence-based recommendations regarding the use and uptake of the da Vinci system.

We systematically searched the literature for English language studies of any type reporting the use of the da Vinci system for any surgical application. We included 67 studies across a range of surgical specialty areas. The three key areas were urology, cardiac surgery and general surgery, together accounting for 56 of the 67 studies. Only eight of the studies were comparative and none were randomised controlled trials.

At present there is insufficient evidence to determine the safety or efficacy of robotic surgery compared with conventional open or laparoscopic surgery for any surgical application. Small sample sizes and short durations of follow-up characterise the majority of studies. However, in trend terms: operative times were generally longer using the robotic system, reflecting increased set-up times and learning curve issues; length of hospital stay may be shorter, but is influenced by hospital protocols; and rates of complications appeared to be similar.

The case series and case reports established the feasibility of robotic surgery in a wide range of surgical procedures, and detailed procedural and technical complications associated with the use of the robotic system. Most authors were positive about their experiences; however, they also reported problems adjusting to the robotic system and set-up and a range of technical difficulties. A learning curve (or a volume effect) was evident in many of the included studies. As experience with the robotic system increased, operative times, complications and conversions all tended to decrease.

Robotic surgery offers some benefits over conventional laparoscopic or open surgery; however, there is a significant learning curve and substantial costs involved both in the initial purchase and ongoing servicing and maintenance of the system. Frequent hardware and software updates can be expected, as with any computer-based equipment. Given the paucity of studies comparing robotic surgery with conventional surgery, high quality randomised trials and thorough economic evaluations are required. Those contemplating the purchase of a da Vinci surgical robotic system should consider whether sufficient procedures can be done to overcome the learning/volume effect and offset the start-up and fixed costs associated with the system.

For the full report and executive summary, please visit our website at http://www.surgeons.org/asernip-s/publications_robotics.htm



systematic reviews for other organisations

- Carotid Percutaneous Transluminal Angioplasty with Stenting (MSAC)
ASERNIP-S Report No. 40
- Sentinel Lymph Node Biopsy in Breast Cancer – Diagnostic (MSAC)
ASERNIP-S Report No. 30
- Sentinel Lymph Node Biopsy in Breast Cancer – Safety and Efficacy (MSAC)
ASERNIP-S Report No. 50



assessments **in progress**

Systematic literature reviews

- Bioengineered Skin Substitutes for the Management of Burns and Wounds.
ASERNIP-S Report No. 46
- Laparoscopic Radical Prostatectomy
ASERNIP-S Report No. 48
- Lung Volume Reduction Surgery (Update) – collaboration with the Canadian Coordinating Office for Health Technology Assessment (CCOHTA).
ASERNIP-S Reports No. 33 and No. 51
- Paravertebral Blocks for Anaesthesia and Analgesia
ASERNIP-S Report No. 47
- Unicompartmental Knee Arthroplasty
ASERNIP-S Report No. 44

Accelerated systematic reviews

- Colorectal Stents
ASERNIP-S Report No. 49

MSAC reviews

- Intacs Implants for Keratoconus
- Stents and Coils for Cerebral Aneurysms

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 stapling of pharyngeal pouch
- Laparoscopic adhesion division
- Laparoscopic hemi-hepatectomy
- Palatal procedures for snoring
- Peritonectomy for colon cancer
- Permanent dermal fillers
- 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 at <http://www.surgeons.org/asernip-s/publications7.htm>



data collection

Government-initiated research audits

- Endoluminal Repair of Abdominal Aortic Aneurysms
- The National Breast Cancer Audit

Audit of Endoluminal Repair of Abdominal Aortic Aneurysms

Objective

The aim of the audit is to provide the Australian Government Department of Health and Ageing with information on the mid- to long-term safety and durability of the procedure. Reports are submitted to the Government every six months and to surgeons annually.

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 average age was 75 years. About 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 1.7%. 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. Nearly 30% of patients required additional procedures during or within 24 hours of the original procedure. Subsequently, 22 patients (2.3%) required further operative treatment relating to their aneurysms. Overall, 15 patients (1.5%) have had their endoluminal repair converted to open repair. Audit results are comparable with those reported worldwide.

The future

Follow-up of this cohort of patients will continue until late 2006.

Members of the Reference Group overseeing audit

Ms Maggi Boulton - ASERNIP-S Audit Manager
Associate Professor Robert Fitridge
Mr Michael Denton
Professor James May
Professor John Harris
Professor Kenneth Myers
Mr John Anderson
Mr Michael Lawrence Brown
Dr Wendy Babidge - ASERNIP-S Programme Manager
Professor Guy Maddern - ASERNIP-S Surgical Director

For reports, patient information and data entry forms please access our website:
<http://www.surgeons.org/asernip-s/auditAAA.htm>

National Breast Cancer Audit

The last year has proven to be a busy and productive time for the National Breast Cancer Audit. In May 2004, the new web-based audit program was formally launched at the RACS Annual Scientific Congress in Melbourne. We have had considerable uptake in the first six-month pilot phase from Australian and New Zealand surgeons, with the audit accruing an average of 2,300 patients per month as surgeons retrospectively and prospectively enter cases. In October 2004, the online database contained over 30,000 episodes of early breast cancer, dating back to 1998.

The Breast Section of the RACS has played an important role in assisting ASERNIP-S in the development of the next stage of the audit. This stage will see the progression to a full clinical audit, ensuring that participating surgeons can measure their own performance against that of their peers as well as against the best currently available evidence. The online system enables surgeons to view information about their own data in several ways. Surgeon feedback will be sought in early 2005 to guide the development of new online reports to complement the current set.

Our consumer partners, the Breast Cancer Network Australia, have continued to provide valuable consumer input to the management of the audit and have been strong allies in our attempts to secure sustained long-term funding.

Affinity Health has renewed its support of the audit in 2004/2005. Their enthusiastic support has been instrumental in maintaining the infrastructure and resources of the audit whilst long-term funding was sought. The State Quality Officials Forum has also agreed to fund the audit during 2005.

A fruitful collaboration and commitment between the audit and the National Breast Cancer Centre (NBCC) has continued under the guidance of Emeritus Professor Tom Reeve and Director, Dr Helen Zorbas. The NBCC has supported the audit since its inception in 1998 and has continued to provide advice and guidance in the last year. Future joint endeavours will include collaboration on the update of the current clinical practice guidelines for early breast cancer with a view to ensuring that any proposed quality thresholds are evidence-based, as well as providing support in the production of publications.

NET-S

New and Emerging Techniques –*Surgical*

NET-S

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



New and Emerging Techniques –Surgical

NET-S horizon scanning project

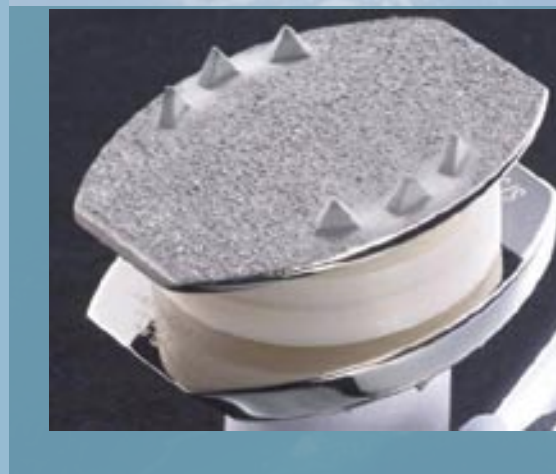
Since 1999, ASERNIP-S has been conducting and shaping an Australian-based New and Emerging Techniques - Surgical (NET-S) horizon scanning project. This project identifies and assesses advances in surgery that are likely to impact on the Australian or New Zealand health systems in the near future, i.e. they are on the *horizon* of introduction into Australasian health care systems. Assessments are written as either prioritising summaries or longer reports. All available evidence for the technology is collated, extracted and summarised in a concise form. The amount of evidence varies substantially due to the early state of development of the procedures. The completed documents can be used for clinical guidance and can provide information for government policy and planning.

The NET-S project has reached several milestones this year. The NET-S database now contains all procedures identified in the scanning process. This will ensure a more reliable and regular monitoring of developments that are still in the experimental phase, plus provide a facility to keep track of completed assessments. We have continued to work closely with the National Horizon Scanning Unit and together, as the Australian and New Zealand Horizon Scanning Network, we have become a member of the European Information Network on New and Changing Health Technologies (EuroScan). The EuroScan network facilitates information exchange on important emerging drugs, devices, procedures, processes and settings in health care. Selected assessments from the 11 current member countries are searchable from the EuroScan website (<http://www.euroscan.bham.ac.uk/technology.htm>).

Selected websites are scanned daily, weekly or monthly, depending on the number of articles on each website, their relevance and how regularly the content is updated. Site content ranges from relevant journal pages to news sites, specialty surgery pages, device manufacturer sites and licensing agencies. Email alerts also provide a source of new developments, most of which arrive weekly in the NET-S inbox. Occasionally nominations are received from the 'Nominating a procedure' form on the NET-S website.

Lists of relevant procedures and sources are compiled and filtered on a regular basis, using a set of established criteria to determine which require immediate assessment, which should be checked again in 12 months time and which can be archived. The majority of developments are reviewed as prioritising summaries, with more developed procedures assessed as reports. Prioritising summaries are available from ASERNIP-S on request and their titles are published on the NET-S website. Reports are available directly from the NET-S website.

The NET-S project has proven to be an effective method of identifying and evaluating new developments in surgery. With the assistance of several already established horizon scanning networks and their publications, the NET-S project will continue to evolve as a valuable resource for ensuring the safest and most efficacious procedures are introduced into the Australasian health systems.



NET-S on the web

The NET-S website is accessible via: <http://www.surgeons.org/asernip-s/net-s>

The NET-S database of procedures is now available for browsing or searching for particular topics across various specialties. Completed publications and links to information such as publications by other Health Technology Assessment agencies can be accessed here. Online forms are also available for those wishing to nominate a new technique, comment on completed summaries or reports, or be included in our mailing list to automatically receive the NET-S newsletter, *NET-Scope*.

Currently there are 21 NET-S horizon scanning prioritising summaries available on request:

- Bioabsorbable joint implants (PLA96)
- Botox® (*C. botulinum* type A toxin) injections combined with surgery
- Dermal regeneration template (Integra®) for deep hand burns
- Gatekeeper reflux repair system for the treatment of gastroesophageal reflux disease
- Human collagen-based wound dressing
- Injectable silicone biomaterial for treatment of faecal incontinence
- Intracavernosal plaque excision method for treatment of Peyronie's disease
- Laparoscopic hepatic artery infusion pump placement for the treatment of colorectal liver metastases
- Laser tissue welding using protein-based solder
- Minimally invasive branched stent technique for repair of aortic aneurysms
- Minimally invasive oesophagectomy
- Modification of the Tan-Bianchi procedure
- Non-invasive expandable prosthesis
- OP-1 putty
- Radiofrequency energy for the treatment of faecal incontinence
- Robotically assisted left ventricular (LV) epicardial lead implantation for biventricular pacing
- Self-sealing, wedge-shaped, sutureless sclerotomy
- Skip laminectomy for treatment of spinal disorders
- Stretta® procedure
- Temperature-controlled radiofrequency tonsil ablation (TCRF-TA)
- VALR surgical system.

To receive a copy of a summary, contact the NET-S Project Officer via email: net-s.asernip@surgeons.org

There are also 5 new NET-S horizon scanning reports available for download:

- Collagen meniscal implants
- Essure™ system for tubal sterilisation
- Intraoperative radiation therapy in early stage breast cancer
- Minimally invasive oesophagectomy
- The Tan-Bianchi procedure and modifications.

Horizon scanning prioritising summaries in preparation

- INFUSE® bone graft for the treatment of open tibial fractures
- Spinal interbody fusion with Hydrosorb™ cages
- Fetoscopic tracheal occlusion using a detachable balloon

Horizon scanning reports in preparation

- Endoscopic treatments for GORD
- Artificial intervertebral (lumbar) disc replacement
- Artificial cervical disc replacement



Project activities for 2004

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

Consumer information

ASERNIP-S aims to improve the quality of health care by providing information on the safety and effectiveness of new surgical procedures to health care providers and consumers.

We inform consumers (and surgeons) through our consumer summaries. These are short summaries of the systematic literature reviews, written in easy-to-read language and posted on our website at <http://www.surgeons.org/asernip-s/consumerinfo.htm>. In our efforts to find new ways to reach surgeons and the general public, this year we also distributed patient information leaflets on three procedures to surgeons and peak consumer groups in Australia.

ASERNIP-S welcomes consumer involvement in the preparation of our consumer information. Since 2002 we have been most fortunate to have two consumer representatives on the ASERNIP-S Management Committee, Barbara Beacham and Jane Doyle. They join consumer information groups set up after each review to prepare the consumer information in plain English. These groups, which also include surgeons from the review group and ASERNIP-S staff, continue to work successfully to produce documents informing consumers of the latest research.

This year the following consumer summaries were prepared:

- Holmium laser prostatectomy for benign prostatic hyperplasia
- Post-vasectomy testing to confirm sterility
- Vacuum-assisted closure for the management of wounds
- Spinal cord stimulation (neurostimulation)
- Implantable spinal infusion devices for chronic pain and spasticity.

The following patient information leaflets were distributed:

- Off-pump coronary artery bypass surgery with the aid of the Octopus Tissue Stabilizer® (update and re-appraisal)
- Laparoscopic live-donor nephrectomy (2nd update and re-appraisal)
- Radiofrequency ablation for the treatment of liver tumours.

The consumer representatives provide input into the preparation of all our consumer information, including submissions to the publications of peak consumer organisations in Australia and the Royal Australasian College of Surgeons (RACS). Publications have appeared in *RACS Surgical News* (April, May, June August and October), *Health/Insite news* (July and November) and *Australian Health Review* (September). The consumer perspective helps us to produce information that is relevant to the needs of consumers.

The ASERNIP-S consumer summaries are available at <http://www.surgeons.org/asernip-s/consumerinfo.htm>. If you would like more information, please contact us at consumer.asernip@surgeons.org

Promotional activities

Peer-reviewed publications 2004

Audige L, Bhandari M, Griffin D, Middleton P, Reeves BC. Systematic reviews of nonrandomized clinical studies in the orthopaedic literature. *Clin Orthop* 2004 Oct; 427: 249-57

Chapman AE, Kiroff G, Game P, Foster B, O'Brien P, Ham J, Maddern GJ. Laparoscopic adjustable gastric banding in the treatment of obesity: A systematic review. *Surgery* 2004; 135(3): 326-351

Tooher R, Sutherland P, Costello A, Gilling P, Rees G, Maddern G. A systematic review of holmium laser prostatectomy for benign prostatic hyperplasia. *Journal of Urology* 2004; 171(5): 1773-1781

Tooher R, Maddern G, Simpson J. Surgical fires and alcohol-based skin preparations. *ANZ Journal of Surgery* 2004; 74: 382-385

Boult M, Babidge W, Maddern G, Fitridge R and on behalf of the Audit Reference Group. Endoluminal repair of abdominal aortic aneurysm - contemporary Australian experience. *European Journal of Vascular and Endovascular Surgery* 2004; 28(1): 36-40

Cuncins-Hearn A, Saunders C, Walsh D, Borg M, Buckingham J, Frizelle F, Maddern G. A systematic review of intraoperative radiotherapy in early breast cancer. *Breast Cancer Research and Treatment* 2004; 85: 271-280

GRADE Working Group. Grading quality of evidence and strength of recommendations. *British Medical Journal* 19 June 2004; 328 (8 pages). P Middleton is a member of the Working Group.

Tooher RL, Rao MM, Scott DF, Wall DR, Francis DMA, Bridgewater FHG, Maddern GJ. A systematic review of laparoscopic live-donor nephrectomy. *Transplantation* August 15 2004; 78(3): 404-414

Tooher R, Boult M, Maddern GJ, Rao MM. Final report from the ASERNIP-S audit of laparoscopic live-donor nephrectomy. *ANZ Journal of Surgery* 2004; 74: 961-963.

Other publications 2004

ASERNIP-S has moved. *RACS Surgical News*, Vol. 5 No. 3 April 2004

ASERNIP-S News. *RACS Surgical News*, Vol. 5 No. 4 May 2004

Online National Breast Cancer Audit a World-first. *RACS Surgical News*, Vol. 5 No. 5 June 2004

ASERNIP-S releases new systematic and accelerated systematic reviews. *HealthInsite News*, 2 July 2004

NET-S horizon scanning project values your input. *RACS Surgical News*, Vol 5 No 7 August 2004

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) assess new surgeries. *Australian Health Review*, Vol 28 No 1 September 2004

Technology overview new for ASERNIP-S. *RACS Surgical News*, Vol 5 No 9 October 2004

New Patient Information Leaflets. *HealthInsite News*, 15 November 2004

Surgical Evidence – The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical Experience. *Global Surgery* 2004.

2004 Presentations

- Tooher, R. *Strategies for implementing pressure ulcer guidelines*. Area Awareness Module. Flinders University. Adelaide, Australia, February 2004

- Maddern G. *Skills courses: the College view*. Clinical Skills and Simulation Conference 04. Waikato Clinical School. Hawaii, USA, April 2004

- Maddern G. *Surgical Simulation: the evidence*. Clinical Skills and Simulation Conference 04. Waikato Clinical School. Hawaii, USA, April 2004

- Fitridge R, Boult M, Babidge W, Maddern G. *Endoluminal repair of abdominal aortic aneurysm – Australian audit*. ISCVS World Congress. Hawaii, USA, April 2004

- Bevington E, Kollias J, Malycha P, Tyson S, Roder D, Babidge W, Cuncins-Hearn A, Maddern G. *RACS National Breast Cancer Audit - Re-operation rates for invasive breast cancer in Australia and New Zealand*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Fitridge R, Boult M, Babidge W, Maddern G. *Endoluminal repair of abdominal aortic aneurysm – contemporary Australian experience*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Griffin T, Tooher R, Nowakowski K, Lloyd M, Maddern G. *Post-vasectomy testing to confirm sterility: a systematic review*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Kollias J, Malycha P, Cuncins-Hearn A, Tyson S, Babidge W, Maddern G. *The National Breast Cancer Audit: A selected comparison of outcomes with published overseas data*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Maddern G. *Interpreting different types of surgical research*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004 Plenary

- Maddern G. *National Breast Cancer Audit: a model of CRC database*. Colorectal Cancer National Database Workshop. Melbourne, Australia, May 2004

- Maddern G. *New procedure audit - does it make a difference?* Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Pham C, Middleton P, Maddern G. *Vacuum-assisted closure: an accelerated systematic review*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Rao M, Scott D, Wall D, Francis D, Bridgewater F, Maddern G. *Laparoscopic live-donor nephrectomy: a systematic review*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Sutherland L, Middleton P, Anthony A, Hamdorf J, Cregan P, Scott D, Maddern G. *Surgical simulation: a systematic review*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Tooher R, Middleton P, Babidge W, Maddern G. *Awareness and use of ASERNIP-S systematic reviews in Australian surgeons*. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Melbourne, Australia, May 2004

- Tooher R, Middleton P, Babidge W, Maddern G. *Awareness and use of ASERNIP-S systematic reviews in Australian surgeons*. HTAi. Krakow, Poland, May/June 2004

- Tooher R, Middleton P, Simpson B, Babidge W, Maddern G. *Developing criteria for prioritising topics referred for systematic review*. HTAi. Krakow, Poland, May/June 2004

- Cufone L, Pham C. *Vacuum assisted closure - An accelerated systematic review*. RACS Scientific meeting. Waite Institute, Adelaide, September 2004

- Middleton P, Tooher R, Griffin T, Pham C, Hopewell S. *How different are conference abstracts of surgical RCTs from their subsequent full publication?* 12th Cochrane Colloquium 2004. Ottawa, Canada, October 2004

- Hazel S, Edwards J, Paterson H, Stotz R, Horowitz J, Maddern G. *A systematic review of intraoperative ablation for the treatment of atrial fibrillation*. ASCTS Annual Scientific Meeting 2004. Noosa, Australia, October 2004

- Kollias J, Babidge W, Boult M, Cuncins-Hearn A, Tyson S, Maddern G. *A web-based system of clinical audit for early breast cancer*. Leura V International Conference for Breast Cancer 2004. Sydney, Australia, November 2004

- Kollias J, Malycha P, Cuncins-Hearn A, Tyson S, Babidge W, Maddern G. *The National Breast Cancer Audit: A selected comparison of outcomes with published overseas data*. Leura V International Conference for Breast Cancer 2004. Sydney, Australia, November 2004.

Externally-commissioned projects

NHMRC consultancy

ASERNIP-S staff continue to work as evidence-based methodological experts on the NHMRC's guidelines assessment register. Philippa Middleton and Rebecca Tooher are presently working with two groups developing evidence-based clinical practice guidelines: the Australian Paediatric Endocrine Group are developing clinical practice guidelines for the management of type 1 diabetes in children and adolescents, and the Australian Cancer Network are updating guidelines for the management of cutaneous melanoma.

In 2004 we were also invited to participate in several working groups reviewing the methodology and processes for the development of national clinical practice guidelines endorsed by the NHMRC. We have contributed to the development of an expanded (interim) hierarchy of evidence for all types of research questions and are presently helping to develop a system for grading the strength of recommendations made in clinical practice guidelines.

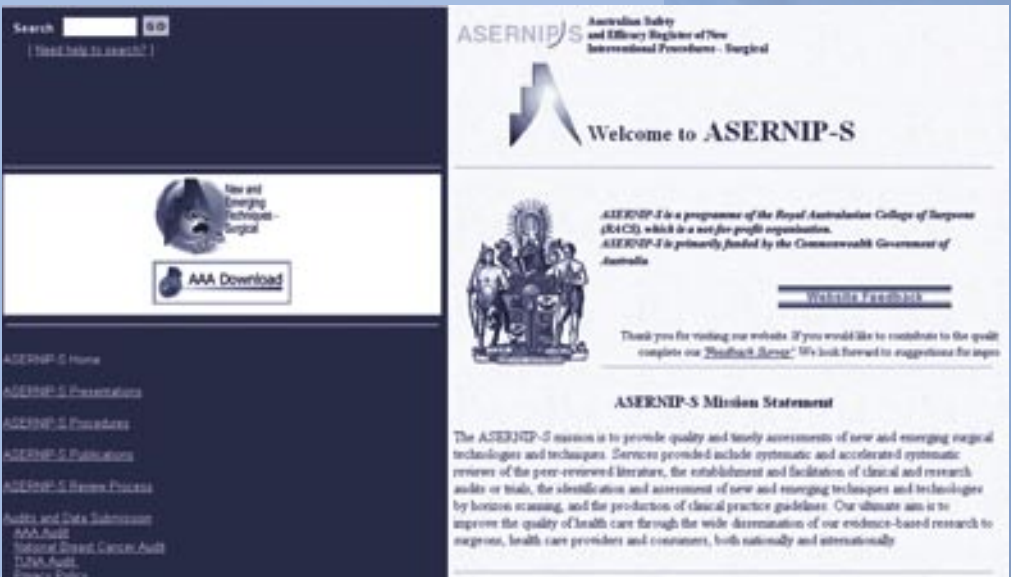
ASERNIP-S website

The ASERNIP-S website can be accessed directly or reached via 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/net-s>



ASERNIP-S Management Committee 2004

The members of the ASERNIP-S Management Committee are:

- Mr Peter Woodruff , *Chairman and RACS Vice-President*
- Professor Bruce Barraclough, *RACS Fellow*
- Ms Barbara Beacham, *Consumer Representative, Health Rights and Community Action*
- 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 Executive General Manager*
- Mr Brian Johnston, *Chief Executive, Australian Council on Healthcare Standards*
- Dr Michael Kitchener, *Medical Services Advisory Committee*
- Professor Guy Maddern, *Programme Surgical Director*
- A/Professor Rosemary Roberts, *Director, National Centre for Classification in Health*
- Professor David Scott, *RACS Executive Director for Surgical Affairs*



Left to right:
A/Professor Rosemary Roberts
Ms Daliah Moss (proxy
for Dr David Hillis)
Ms Heather McDonald (proxy
for Mr Brian Johnston)
Ms Barbara Beacham
Mr Peter Woodruff
A/Professor Sally Green
Professor Guy Maddern
Professor Kingsley Faulkner
Dr David Hailey

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.



Education and training

Training opportunities for staff

A Canadian distance learning course on health technology was judged to be extremely useful by a researcher who completed the course in early 2004. Three researchers attended an intensive course on meta-analysis in Melbourne with faculty from Cambridge University and the University of Leicester. One researcher also attended a seminar given by Professor Jeremy Grimshaw from the University of Ottawa which was part of the Australasian Cochrane Contributors' meeting. One data management staff member took part in a meeting on audits and registries in Australia, and a researcher with responsibility for our web pages participated in a web accessibility course.

ASERNIP-S was fortunate to have a three-week visit from Professor Karen Facey from Scotland at the end of 2004. She ran a series of seminars about aspects of health technology assessment and provided individual training and advice to staff.

Medical students

This year one fourth-year medical student from the University of Adelaide was based at ASERNIP-S for the development of his research proposal. He undertook a particularly challenging design for a randomised controlled trial (RCT) of a new 'corkscrew' treatment for stroke and, under guidance from senior staff, produced an excellent piece of work. In 2005 we will have three students placed at ASERNIP-S and their projects will be focused on areas of more direct research interest to ASERNIP-S. Two students will develop proposals for RCTs assessing robotic-assisted surgery and one student will work with the National Breast Cancer Audit to develop a research proposal using information from the audit database.

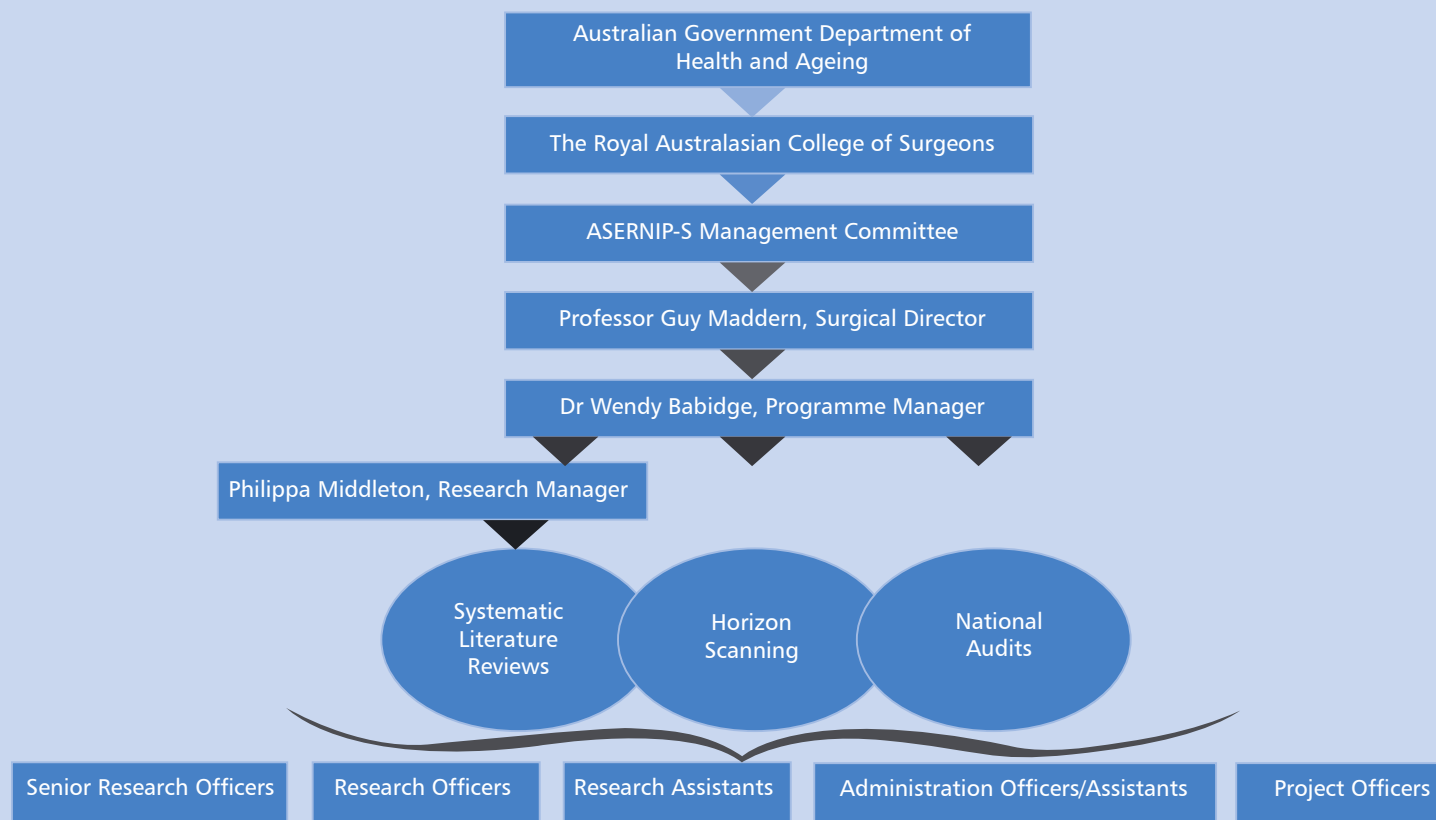
Personnel

During 2004, Dr Bronni Simpson, Rebecca Morgan and Michael Duffield left ASERNIP-S to pursue further studies. Marielle Esplin, Dr Susan Hazel and Claire Dunstall left to take up other positions. Dr Afsha Chugtai returned to the United Kingdom. We welcomed back Elen Shute; last year she left to complete an M.Phil in Quaternary Science at the University of Cambridge and she now supports researchers at ASERNIP-S in conducting systematic reviews.

ASERNIP-S

staff profiles

- Professor Guy Maddern
- Dr Wendy Babidge
- Philippa Middleton
- Eleanor Ahern
- Maggi Boulton
- Dr Afsha Chugtai
- Lynette Cufone
- Astrid Cuncins-Hearn
- Michael Duffield
- Claire Dunstall
- Mariëlle Esplin
- Jane Franklin
- Dr Tabatha Griffin
- Dr Susan Hazel
- Louise Kennedy
- Rebecca Morgan
- Clarabelle Pham
- Elen Shute
- Dr Bronni Simpson
- Dr Rebecca Tooher
- Sarah Tyson
- Rosemary Wong



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 programme 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.



ASERNIP-S Programme Manager
Dr Wendy Babidge

Dr Wendy Babidge has managed the ASERNIP-S programme since its inception. She has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business. Dr Babidge has a particular interest in the development of unique assessment methodologies for surgical procedures. She is also keen to foster collaboration between Health Technology Assessment groups world-wide.



ASERNIP-Research Manager
Philippa Middleton

Philippa Middleton joined ASERNIP-S in April 2001. Her main role is to maintain the high quality of ASERNIP-S outputs, particularly systematic reviews and other HTA reports. She divides her time between ASERNIP-S and the Cochrane Collaboration, where she coordinates 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 health care can be based on the most reliable evidence available.



ASERNIP-S Consumer Project Officer
Eleanor Ahern

Eleanor Ahern has a Master of Arts Degree in politics and is completing an Advanced Diploma of Arts in Professional Writing at Adelaide TAFE. She has a background in medical studies. Eleanor has worked as a freelance editor and is now writing consumer information for ASERNIP-S.



ASERNIP-S Senior Research Officer (Audit Manager)

Maggi Boulton

Maggi Boulton has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. Maggi has worked extensively in a diverse range of scientific environments and has written computer applications and databases for commercial and scientific use. Research work at ASERNIP-S has involved conducting systematic literature reviews. Currently she develops and manages national audits and is the ASERNIP-S Privacy Officer.



ASERNIP-S Research Assistant

Dr Afsha Chughtai

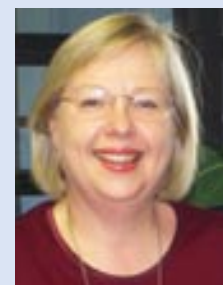
Dr Afsha Chughtai joined ASERNIP-S in September 2003 as a Research Assistant. She has a BSc (Hons) in Food Science from The University of Nottingham, UK and a PhD in Microbiology from The University of Reading and The Institute of Food Research, UK. At ASERNIP-S, Afsha supported researchers in conducting systematic reviews and prepared horizon scanning summaries and reports. Afsha left ASERNIP-S in March 2004.



ASERNIP-S Project Officer

Lynette Cufone

Lynette Cufone joined ASERNIP-S in December 2003 on a part-time basis. She has a science degree from the University of Adelaide, majoring in Genetics, Pharmacology and Physiology. At ASERNIP-S she is involved in the NET-S horizon scanning project.



ASERNIP-S 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 is involved with the National Breast Cancer Audit and conducts systematic literature reviews.



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. Michael left ASERNIP-S in December 2004.



ASERNIP-S Administrative Assistant

Claire Dunstall

Claire Dunstall joined ASERNIP-S in December 2002, on a part-time (casual) basis. This year she completed a Bachelor of Commerce at Adelaide University with a triple major in international business, management and marketing. At ASERNIP-S, Claire provides administrative assistance, data entry and clerical support to research and administration staff. Claire left ASERNIP-S in December 2004.



ASERNIP-S Research Assistant

Mariëlle Esplin

Mariëlle Esplin joined ASERNIP-S in January 2003 as a Research Assistant. She has a degree in Science with Honours in Zoology from the University of Adelaide and a degree in Applied Science in Occupational Therapy with Honours from the University of South Australia. At ASERNIP-S, Mariëlle assisted with the NET-S horizon scanning project and supported researchers in conducting systematic literature reviews. She also provided assistance with website and computer administration. Mariëlle left ASERNIP-S in June 2004.

**ASERNIP-S Administrative Officer****Jane Franklin**

Jane Franklin joined ASERNIP-S in January 2001 to provide additional administrative support to the project. Jane brings with her a sound background in Banking and Customer Service and has a Certificate II in Business (Office Administration).

**ASERNIP-S 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 conducts systematic literature reviews and manages the website.

**ASERNIP-S Research Officer****Dr Susan Hazel**

Dr Susan Hazel graduated as a veterinary surgeon and worked for three years as a vet in Australia and the UK, before completing a PhD in 1994 at the Child Health Research Institute, Adelaide. After holding postdoctoral positions in Stockholm and Sydney, Susan ran a cancer research laboratory at the Institute of Medical and Veterinary Science (IMVS) in Adelaide, before joining ASERNIP-S in September 2003. At ASERNIP-S she conducted systematic reviews, and commenced an Advanced Diploma of Arts in Professional Writing at Adelaide TAFE. Susan left ASERNIP-S in December 2004.

**ASERNIP-S Administrative Assistant****Louise Kennedy**

Louise Kennedy joined ASERNIP-S in December 2002, on a part-time (casual) 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 Horizon Scanning Project Officer****Rebecca Morgan**

Rebecca joined the ASERNIP-S team in September 2003 as a Research Assistant. The majority of her time has been spent working on the NET-S horizon scanning project, where she is responsible for conducting the scanning, and ensuring the process remains efficient by regularly reviewing sources used at ASERNIP-S and at other international HTA agencies. Rebecca is also involved with the Breast Audit. Rebecca has a science degree and Honours in Anatomical Science from the University of Adelaide. Rebecca left ASERNIP-S in December 2004.

**ASERNIP-S Research Officer****Clarabelle Pham**

Clara Pham joined ASERNIP-S in January 2003. She has a Bachelor of Science Degree, majoring in Physiology and Pharmacology, 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 and assists with the coordination of the NET-S horizon scanning project.

**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 has now returned to ASERNIP-S, where she continues to support researchers in conducting systematic reviews.

**ASERNIP-S Research Officer****Dr Bronni Simpson**

Dr Bronni Simpson joined ASERNIP-S in October 2001. Bronni has a Bachelor of Science Degree, Honours Degree in Animal Nutrition from the University of New England NSW, and a PhD in the molecular biology field from the University of South Australia. At ASERNIP-S Bronni conducted systematic literature reviews. She was also involved in developing the New and Emerging Techniques - Surgical (NET-S) horizon scanning project, preparing guidelines for systematic reviews and website administration. Bronni left ASERNIP-S in June 2004 to pursue further studies.

**ASERNIP-S 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, in addition to writing systematic literature reviews in surgery, Rebecca also 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.

**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 Administrative Officer****Rosemary Wong**

Rosemary Wong joined ASERNIP-S in November 2000 on a part-time basis. Her role is 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.

Appendices

Appendix A
Hierarchy of evidence

Appendix B
The ASERNIP-S review process

Appendix C
The ASERNIP-S classification system

Appendix D
Reports and publications prior to 2004

Appendix A

Hierarchy of evidence

Designation of levels of evidence¹

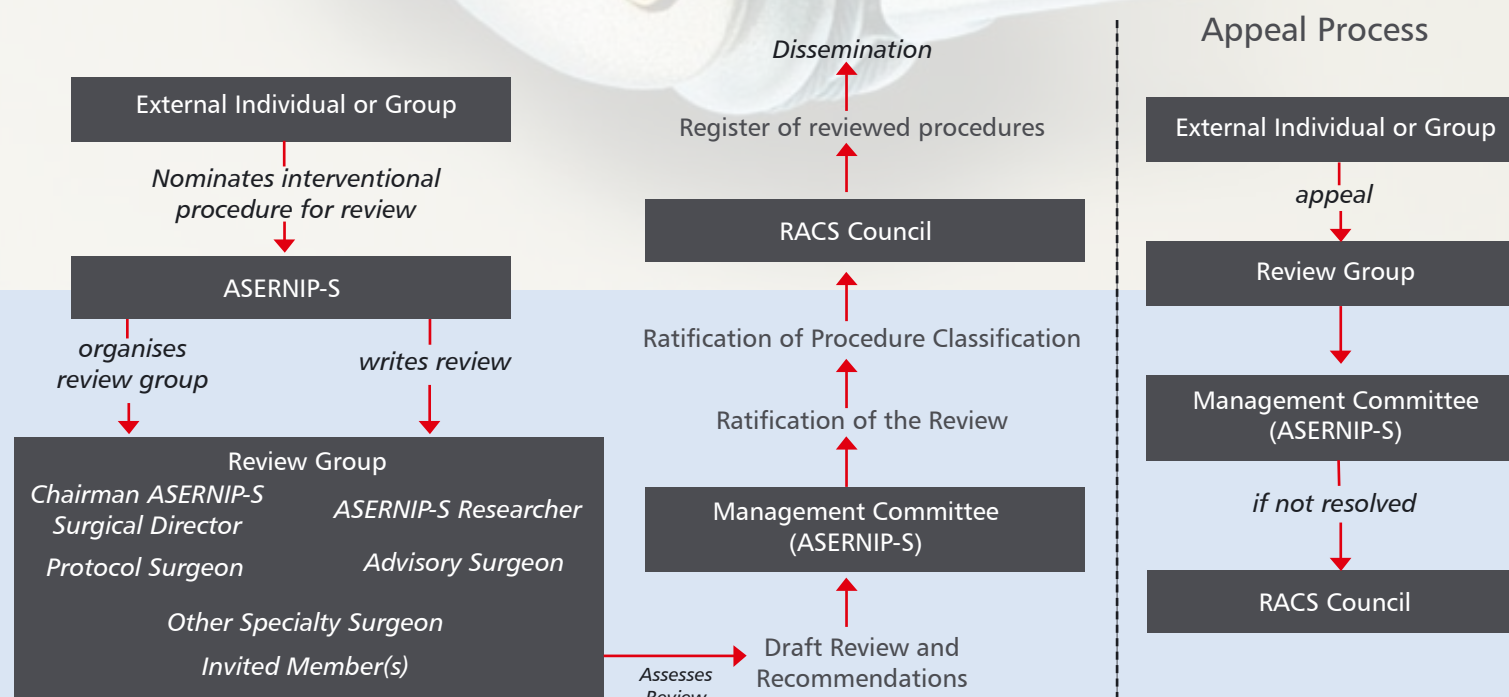
Level of	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or 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.

Poor

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 2004

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
Lung Volume Reduction Surgery: Update & re-appraisal, May 2000

ASERNIP-S Report No. 9
Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity, June 2000

ASERNIP-S Report No. 17
Ultrasound-Assisted Lipoplasty: Update & re-appraisal, July 2000

ASERNIP-S Report No. 10
Off-Pump Coronary Artery Bypass Surgery with the Aid of Octopus Tissue Stabilisers, November 2000

ASERNIP-S Report No. 16
Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction: Update & re-appraisal, November 2000

Babidge WJ, Maddern GJ. Evidence-based surgery at ASERNIP-S. Can this improve quality in surgical practice? *Journal of Quality in Clinical Practice* 2000; 20(4):164–166

Boult M, Fraser R, Jones N, Osti O, Liddell J, Dohrmann P, Donnelly P, Maddern G. Percutaneous endoscopic laser disectomy: a systematic review. *Australian and New Zealand Journal of Surgery* 2000; 70(7): 475–479

EU Hernia Trialists Collaboration. Mesh compared with non-mesh methods of open groin hernia repair — systematic review of randomised controlled trials. *British Journal of Surgery* 2000; 87: 854–859

EU Hernia Trialists Collaboration. Laparoscopic compared with open methods of groin hernia repair — systematic review of randomised controlled trials. *British Journal of Surgery* 2000; 87: 860–867

Maddern GJ. Evidence-based surgical research – consumers to benefit. *The Australian Health Consumer*. The Consumers' Health Forum of Australia newsletter, Summer 2000; (1): 12-13

Maddern GJ. This is ASERNIP-S. *International Network of Agencies for Health Technology Assessment (INAHTA) Newsletter* 2000; VIII(1): 3

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