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The ASERNIP-S mission is to provide quality and timely assessments of new and emerging surgical technologies and techniques. Services provided include systematic and accelerated systematic reviews of the peer-reviewed literature, the establishment and facilitation 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.

Mission Statement
Foreword

This year sees the conclusion of the sixth year of the ASERNIP-S Programme and with it the appointment of the third Chairman of ASERNIP-S, Mr Peter Woodruff replacing Mr Kingsley Faulkner, who has retired as Chairman of ASERNIP-S and President of the Royal Australasian College of Surgeons.

Kingsley’s involvement, support and enthusiasm for the ASERNIP-S Programme has been remarkable and it has been possible to persuade him to stay on the Management Committee of ASERNIP-S. The appointment of Mr Peter Woodruff, Vice-President of the College, to the Chairmanship will provide a further stimulus of new ideas and approaches which will continue to invigorate the ongoing direction and activities of ASERNIP-S.

With the change in management comes an expanding number of staff, now in excess of 18, involved in providing administrative support, systematic reviews and horizon scanning as well as maintaining the audit databases under the control of ASERNIP-S. With the increasing pressure on space in the South Australian College of Surgeons offices new office space will be required for the programme in 2004.

As the number of staff has increased, so too has the range of activities that ASERNIP-S is currently undertaking. In addition to the core work of systematic reviews of the evidence underlying new surgical procedures, there has been a significant rise in the number of horizon scanning reports prepared, and accelerated systematic reviews, which enable rapid presentation of the state-of-the-art literature to surgeons, consumers and hospitals.

Horizon scanning activities will continue to focus on new surgical procedures but will work in unison with the newly formed horizon scanning activities funded by the Australian and State Governments and based within the University of Adelaide’s Department of Public Health. This synergy should greatly help in the quality and appropriateness of horizon scanning, a relatively new approach to providing Government health planners and practitioners with the current status of new procedures as they arise from either the research environment or clinical practice.

Audits (Transurethral needle ablation, endoluminal grafting and breast surgery) continue to be major activities within ASERNIP-S and it is anticipated that over the next few years this type of activity will increase. The new web-based application of the National Breast Cancer Audit presents some unique challenges but these are far outweighed by the advantages the Internet offers in providing a secure system for Australasian breast surgeons to utilise.

ASERNIP-S is becoming increasingly known within the Australian healthcare sector and recently had the dubious honour of being specifically mentioned on the ABC TV drama series MDA as a source of definitive information regarding new surgical technologies. Although not a household word, and certainly not a household acronym, it does perhaps represent the increasing credibility and profile that ASERNIP-S is acquiring.

At the same time as the Australian profile increases, internationally ASERNIP-S is becoming known as the pre-eminent expert in assessing new and emerging surgical procedures. Our presence at the International Network of Agencies for Health Technology Assessment (INAHTA) Conference in Canmore, Canada, this year provided us with not only a forum to present some aspects of our work but also involved us in leading a workshop on assessing new technologies. This involvement has led to our election to the Board of INAHTA which will further help us maintain a significant international profile.

As always, the success of such an enterprise depends solely on the quality, dedication and intellectual capabilities of the staff employed. Our current team is a truly remarkable collection of intellectuals from diverse backgrounds. The main challenge as Surgical Director is containing their enthusiasm and channelling it into new and hitherto unserved areas of new surgical assessment and reporting. While all members of the ASERNIP-S team have played significant roles in its ongoing success, the substantial contribution made by Wendy Babidge as Programme Manager and Philippa Middleton as Research Manager cannot be underestimated. The ongoing success of the ASERNIP-S initiative would seem to be in very safe hands.

Professor Guy Maddern
Surgical Director ASERNIP-S Programme
Royal Australasian College of Surgeons
New Assessments Completed

Systematic Literature Reviews
• Holmium Laser Prostatectomy for Benign Prostatic Hyperplasia ASERNIP-S Report No. 23
• Laparoscopic Live-donor Nephrectomy: Second update and re-appraisal ASERNIP-S Report No. 35
• Post-vasectomy Testing to Confirm Sterility ASERNIP-S Report No. 39
• Surgical Simulation ASERNIP-S Report No. 29

Accelerated Systematic Reviews
• Implantable Spinal Infusion Devices for Chronic Pain and Spasticity ASERNIP-S Report No. 42
• Spinal Cord Stimulation/Neurostimulation ASERNIP-S Report No. 43
• Vacuum-assisted Closure of Wounds ASERNIP-S Report No. 37

MSAC Systematic Reviews
• Radiofrequency Ablation of Liver Tumours Report No. 36
• Transanal Endoscopic Microsurgery Report No. 32

Assessments in Progress

Procedure Nominations
Systematic Literature Reviews

Systematic reviews are fundamental decision-making tools for health professionals, consumers and policy makers. They begin with formulation of a clear question, and development of clinically relevant selection criteria for deciding which studies to include or exclude in the review. Then a comprehensive search is done to find all the studies that potentially meet the selection criteria. For systematic reviews of health care interventions (such as most of the ASERNIP-S reviews on new surgical procedures), we employ the well-known hierarchy of evidence (Appendix A), which judges randomised controlled trials (RCTs) or systematic reviews of RCTs to be the highest level evidence and because there are robust methods developed for pooling these study designs.

However, since these designs are not common in surgery, we usually also consider other study designs such as nonrandomised comparisons and case series. We also critically appraise each study, to give readers some idea of any potential biases that may influence the findings of a particular study. When we have evidence of a high level and of a high quality, and where it is sensible to combine outcomes across studies, we may do a meta-analysis, a statistical pooling of results. Even if these conditions do not apply, we synthesise the studies in a structured tabular and narrative form, so that readers can see the findings of the review and judge how we have arrived at these, in contrast to less structured reviews, where this is not usually possible.

A flow chart of the ASERNIP-S process is given in Appendix B, the ASERNIP-S classification system in Appendix C, and a full list of reports and publications in Appendix D.

Accelerated Systematic Reviews

Accelerated systematic reviews are produced in response to a pressing need for a systematic summary and appraisal of the available evidence for a new or emerging surgical procedure. This need may arise if the uptake of the new technique or technology appears to be inappropriate given the evidence available at the time (it may be diffusing too quickly or too slowly). Alternatively, there may be uncertainty or controversy regarding the clinical or cost effectiveness of the new procedure, or there may be significant concerns regarding its safety or indications for use in particular populations.

Accelerated systematic reviews 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.

New Assessments Completed

There have been four new systematic literature reviews and three accelerated systematic literature reviews completed in 2003 for ASERNIP-S and two on behalf of MSAC.

Systematic Literature Reviews

Holmium Laser Prostatectomy for Benign Prostatic Hyperplasia

Objective

The objective of this review was to assess the safety and efficacy of holmium laser prostatectomy, both holmium laser resection of the prostate (HoLRP) and holmium laser enucleation of the prostate (HoLEP), in comparison with transurethral resection of the prostate (TURP) — the current standard treatment for benign prostate hyperplasia.

Methods

Both HoLRP and HoLEP, of any design, and the TURP arm of randomised controlled trials (RCTs) with sample sizes greater than 50 patients, date restricted to 1995 onwards, were included for comparison. The specified outcomes were perioperative, short-term and long-term morbidity and mortality rates, urodynamic outcome, symptom relief and cost effectiveness.

Results

Three RCTs comparing HoLRP and TURP and two RCTs comparing HoLEP and TURP were identified. For each of the holmium procedures there was also one non-randomised comparative study and a number of case series (13 for HoLRP and 10 for HoLEP). With the exception of one of the randomised trials, the quality of the available evidence was poor, with the other RCTs lacking information regarding methods of randomisation, allocation concealment and blinding. The majority of studies were characterised by relatively short follow-up periods and significant losses to follow-up.
In terms of the primary safety issue from a clinical perspective — blood loss — both of the holmium laser procedures (HoLRP and HoLEP) were found to be superior to TURP in terms of a number of key indicators (transfusion rates, postoperative bladder irrigation, duration of catheterisation and length of hospital stay), although blood loss itself was not often reported due to measurement difficulties. There did not appear to be a difference between the holmium laser procedures and TURP for rates of stricture or urinary tract infection.

However, for other safety outcomes, such as mortality and rates of perforation, it was difficult to make any firm conclusions due to a lack of high quality data. In terms of efficacy, the holmium laser procedures appear to be equivalent to TURP for symptom relief. TURP was found to be superior to the holmium laser procedures in terms of operative times and retrieved more tissue than HoLRP. The addition of the mechanical morcellator in the HoLEP technique appeared to result in more tissue being retrieved than in TURP. Both the holmium laser techniques and TURP were found to retrieve adequate tissue for postoperative histology to detect undiagnosed prostate cancer.

The lack of long-term follow-up in the majority of holmium laser studies meant that no conclusion could be drawn about the long-term durability of the procedures in comparison to TURP.

Conclusion and recommendations

Classifications

Evidence rating – On balance, the evidence base was rated as average. However, for some outcomes the evidence base was poor and as a result no conclusive findings could be determined for these outcomes.

Safety – The holmium laser procedures are considered at least as safe as TURP in terms of blood loss, rates of stricture and urinary tract infection. In terms of other safety indicators the relative safety of the holmium laser procedures could not be determined.

Efficacy – The holmium laser procedures appeared to be at least as efficacious as TURP in the short term but long-term efficacy could not be determined.

Recommendations

Additional high quality randomised controlled trials would strengthen the evidence base for the holmium laser procedures. However, at this stage, the priority for research should probably focus on providing long-term follow-up and addressing problems with losses to follow-up which threatened the validity of many of the included studies.

Centres considering introducing the holmium laser procedures should ensure that surgeons have adequate experience in transurethral resection techniques and preferably previous experience in laparoscopic and laser surgery. An appropriate programme of supervised training could best be developed by the Urological Society of Australasia.
Laparoscopic Live-donor Nephrectomy: 2nd Update and Re-appraisal

Objective
The objective of this review was to assess the safety and efficacy of laparoscopic live-donor nephrectomy (LLDN) in comparison with open live-donor nephrectomy (OLDN) — the current standard approach for living donor nephrectomy.

Methods
Literature databases were searched from inception to March 2003 inclusive. Comparative studies of LLDN versus OLDN (randomised and non-randomised) were included. Studies that utilised hybrid open laparoscopic approaches were excluded from the review, as were studies where indications were mixed unless the results of live-donor nephrectomy could be separated. The specified outcomes were perioperative, short-term and long-term donor morbidity and mortality rates, donor convalescence, and recipient graft function and survival.

Results
There were 72 included studies; of these, 44 were comparative and 28 were case series or case reports. The quality of the available evidence was average. There was only one randomised controlled trial and six non-randomised comparative studies with concurrent controls identified. The RCT was of average to good quality; however, the non-randomised concurrently controlled studies were limited by poor reporting of methodological detail such as inclusion/exclusion criteria, matching and losses to follow-up. The rest of the comparative evidence used historical controls and was therefore limited by the historical nature of the data such that systematic differences in data collection methods, hospital protocols, donor health status and kidney selected for transplant may have biased the results.

In terms of safety, for donors, there did not appear to be any distinct difference between the laparoscopic and open approaches. No donor mortality was reported for either procedure and the complication rates were similar although the types of complications experienced differed between the two procedures. The conversion rate for LLDN to an open procedure ranged from 0% to 13%. In terms of efficacy, LLDN appears to be a slower operation with longer warm ischaemia times than OLDN but this did not appear to have resulted in increased rates of delayed graft function for recipients. Donor postoperative recovery and convalescence (parenteral narcotic use, time to oral intake, time to ambulation, length of hospital stay and return to work) appeared to be superior for LLDN, making it a potentially more attractive operation for living donors. While in the short-term graft function and survival did not appear to differ between the two techniques, long-term complication rates and allograft function remain somewhat unclear at this point in time and further long-term follow-up is required.

Conclusion and recommendations
Classifications
Evidence rating – the available evidence base was rated as average.

Safety – LLDN was rated at least as safe as OLDN for donors in the short-term, although long-term complication rates have not yet been fully established.

Efficacy – LLDN was rated at least as efficacious as OLDN for donors, with advantages in terms of convalescence. Graft function and survival appear to be similar for recipients in the short term but long-term efficacy could not be determined at this time.
Post-vasectomy Testing to Confirm Sterility

Objective
The objective of this review was to make evidence-based recommendations on the appropriate protocol for post-vasectomy testing to confirm sterility. Post-vasectomy semen analysis (PVSA) is the traditional method of confirming sterility after vasectomy. However, the protocol for PVSA is not universal and varies substantially between practitioners in the endpoints accepted, number of tests and the timing of tests.

Methods
Electronic databases were systematically searched up to and including March 2003 for studies that reported the results of post-vasectomy testing to confirm sterility and contained data on at least one of the specified outcomes. Specific outcomes were time to azoospermia, number of ejaculations to azoospermia, time to loss of sperm motility, pregnancy, repeat vasectomy, patient compliance with test protocol, sperm function post-vasectomy and histological analysis of vas deferens specimens.

Results
There were large losses to follow-up with some studies reporting up to 66% loss. While compliance varied greatly between studies, it did not appear to depend on the number of tests in the post-vasectomy testing protocol or the timing of the first or last tests.

There was high variability in the time taken to reach azoospermia although the median percentage of azospermic patients consistently stayed over 80% from three months onwards and after 20 ejaculations. There was always an increase in the percentage of patients reaching azoospermia between the first and second tests, and this increase became smaller when the initial tests were conducted later.

A small proportion of patients exhibited persistent non-motile sperm and some patients showed the reappearance of sperm after azoospermia had been shown. The reappearance of sperm occurred up to 22 months post-vasectomy.

Pregnancies that were confirmed by DNA analysis showed that pregnancy could occur 10 years post-vasectomy, regardless of the PVSA protocol used.

Conclusions and Recommendations:
The evidence presented in this review supports a post-vasectomy testing protocol with only one test (showing azoospermia) at three months post-vasectomy and after a minimum of 20 ejaculations. If the sample is positive at three months, then periodic testing can continue until azoospermia is reached. In patients who do not reach azoospermia after prolonged testing, cautious assurance of success could be given provided only low levels of non-motile sperm are present. No evidence was found to support a recommendation for histological testing of the excised vas deferens. The proposed protocol could considerably reduce costs of post-vasectomy testing.

Members of the Review Group assessing Post-vasectomy Testing to Confirm Sterility:
- Dr Tabatha Griffin and Dr Rebecca Tooher
  ASERNIP-S Researchers
- Mr Mark Lloyd
  Invited Member
- Dr Kris Nowakowski
  Invited Member
- Professor Guy Maddern
  ASERNIP-S Surgical Director

For the full review, please access our website. The Executive Summary is also available from this site.
http://www.surgeons.org/asernip-s/publications_vasectomy.htm
did not show better results than groups with no training at all, and there were not enough data to determine if video simulation was better than standard training or the use of models. Model simulation may have been better than standard training, and cadaver training may have been better than model training. Unfortunately none of the RCTs made a comparison between computer simulation and model training.

Conclusions and Recommendations.

Classifications

Evidence rating

Poor - on the grounds that there was insufficient evidence because most of the RCTs were flawed and outcomes were often not comparable across studies.

Safety - Not applicable for this review.

Efficacy - Efficacy cannot be determined. The inconclusive outcome of this review may be related to small sample sizes and the validity and reliability of outcome measurements.

Research Recommendations

It was recommended that further research must be done in the context of training to particular performance standards. Ideally studies should be multicentre trials with standardised approaches, with sufficient participants. The skills being evaluated should be part of a standard surgical skills training course, not just stand-alone technical skills. Additionally, once efficacy has been determined cost-benefit analyses could be attempted.

Members of the Review Group assessing Surgical Simulation:

Dr Leanne Sutherland and
Ms Philippa Middleton
ASERNIP-S Researchers

Mr Adrian Anthony
Protocol Surgeon

Mr Patrick Cregan
Advisory Surgeon

Mr Jeffrey Hamdorf
Nominated Surgeon

Professor David Scott
Other Specialty Surgeon

Professor Guy Maddern
ASERNIP-S Surgical Director

For the full review, please access our website.
The Executive Summary is also available from this site.
http://www.surgeons.org/asernip-s/publications_simulation.htm

Surgical Simulation

Objective

The aim of this review was to evaluate the effectiveness of surgical simulators, in comparison to each other, no training, or other methods of surgical training, on the basis of a systematic assessment of the literature.

Methods

Search strategy – Studies were identified by searching MEDLINE, PREMEDLINE, PREMEDLINE and MEDLINE, EMBASE, psycINFO, CINAHL, Current Contents, Cochrane Library, and Science Citation Index Expanded from inception to week 3 2003. NHS Centre for Research and Dissemination (UK), NHS Health Technology Assessment (UK) and National Research Register (UK), were searched on 25/03/2003. Additional articles were identified from references of the retrieved studies.

Study selection – Randomised controlled trials (RCTs) assessing any training technique using at least some elements of surgical simulation compared with any other methods of surgical training, or no surgical training were included for review. The articles included must have contained information on at least one of the following outcomes of the new or comparative intervention: measures of surgical task performance, whether objective or subjective; measures of satisfaction with training techniques.

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. It was not considered appropriate to pool results across studies, because outcomes were not comparable. Relative risks (RR), for dichotomous outcome measures or weighted mean differences (WMD), for continuous outcome measures with 95% confidence intervals (CI) were calculated for some outcomes in individual RCTs where it was thought that this would aid in the interpretation of results.

Results

Twenty-six RCTs with 668 participants were able to be included although the quality of the RCTs was often poor. Computer simulation generally showed better results than no training at all but was not convincingly superior to standard training (such as surgical drills) or video simulation (particularly when assessed by operative performance). Video simulation did not show better results than groups with no training at all, and there were not enough data to determine if video simulation was better than standard training or the use of models. Model simulation may have been better than standard training, and cadaver training may have been better than model training. Unfortunately none of the RCTs made a comparison between computer simulation and model training.
Accelerated Systematic Reviews

Implantable Spinal Infusion Devices for Chronic Pain and Spasticity

Objective
To assess the effectiveness and safety of implantable spinal infusion devices by accelerated systematic review. For some patients with chronic pain and spasticity, systemic analgesia and conservative therapies are ineffective. The management of chronic pain is a challenging task because of the complex nature of pain. Methods to deliver medication to the intrathecal space have been developed as an alternative to chronic systemic administration, in an attempt to reduce adverse effects such as tolerance, dependency and neurotoxicity. Implantable spinal infusion devices allow for an alternative route of drug administration, with the drug delivered directly into the spinal canal. Intrathecal morphine and intrathecal baclofen are the “gold standard” drugs currently used in the implantable spinal infusion devices.

Methods
MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index were searched, using Boolean search terms, from the inception of the databases until April 2003. The Internet was also searched in February 2003. Searches were conducted without language restriction.

Results
Literature base
After a brief search of the literature, 79 studies were identified, including two systematic reviews, eight randomised controlled trials (RCTs), one non-randomised comparative study, three cost-effectiveness studies, 42 case series and 23 case reports. One RCT and six case series were included. Seven RCTs were excluded as they were internal comparisons assessing the efficacy of intrathecal baclofen compared to intrathecal saline. The non-randomised comparative study was excluded as it compared infusion methods, but did not add to the evidence base provided by the included case series. Six case series (four with chronic pain indications, and two spasticity indications) were selected and included with regard to patient numbers and length of follow-up to present a snapshot of safety and efficacy.

Safety
The use of implantable spinal infusion devices appears safe. Drug-related adverse events do occur, as they do when chronically administered via the systemic route, although perhaps less than for systemic administration. Device-related adverse events occur with replacement or revision rates ranging from 3 to 17% and the explantation rate varying from 0 to 21% in the reviewed literature.

Efficacy
Infusion of drugs via implantable spinal infusion devices appears efficacious, with significant reductions in pain measured via visual analogue scales for pain. Improvements in care and activities of daily living were reported for patients with spasticity. The included RCT also showed a reduction in toxicity, when compared to medical management, and this reduction in toxicity impacted on the cumulative survival of the group implanted with the spinal infusion device.

Cost Effectiveness
Cost effectiveness studies showed that implantable spinal infusion devices are less costly, in the long-term, when compared to medical management. Short-term costs of implantable infusion devices are high, due to the cost of screening, the device itself and implantation of the device. Implantable infusion devices were not cost-effective when circumstances of high adverse events and high cost of care were simulated. Therefore it is important to carefully select a patient group suitable for implantation and likely to retain the implant.

Conclusion
Infusion of opioid agents for treatment of chronic pain or baclofen for treatment of spasticity, intrathecally via implantable infusion devices, appears safe and effective; however, this could be explored more extensively in a full systematic review.

For the full review, please access our website. The Executive Summary is also available from this site. http://www.surgeons.org/asernip-s/publications_infusion.htm
Spinal Cord Stimulation / Neurostimulation

Objective
To assess the effectiveness and safety of SCS by accelerated systematic review. Spinal cord stimulation (SCS) is used to treat chronic intractable pain, mostly of the trunk or the extremities, but it is also used to treat anginal pain. SCS is thought to work by stimulating nerve fibres in the spinal cord, which inhibits pain signals to the brain.

Methods
MEDLINE and PREMEDLINE were searched up to April 2003 and The Cochrane Library Issue 2, 2003 was searched for reports of randomised controlled trials (RCTs) comparing SCS with an alternative treatment, placebo or no treatment. RCTs were included if they reported pain or pain relief as an outcome.

Results
Nine RCTs of SCS covering five indications were included – four angina trials, one failed back surgery syndrome, two critical limb ischaemia, one complex regional pain syndrome, and one painful diabetic neuropathy. SCS was more effective in terms of pain relief or reducing anginal attacks when compared with placebo or delayed implantation, but no difference was seen in the comparisons with CABG or switching SCS on and off in the same patient. For critical limb ischaemia, SCS was more effective in relieving pain than analgesia alone, but no difference was seen when SCS plus best medical treatment was compared with best medical treatment alone. For complex regional pain syndrome, SCS was more effective in relieving pain than physiotherapy, but no difference was seen between SCS and placebo for painful diabetic neuropathy. Most reported complications were electrode or lead displacements, which required reintervention and repositioning, although these complications are decreasing as the technology improves. A small number of implant and battery failures have been noted, as has one duodenal perforation and two dural punctures. Infection at the implant site seems to be relatively common.

Conclusions
SCS was shown to be effective in relieving pain in only some of the included studies, but the small patient numbers may have limited the ability of studies to detect clinically important differences. SCS appears to be relatively safe, although the long-term safety and effectiveness of SCS have not yet been evaluated.

For the full review, please access our website. The Executive Summary is also available from this site. http://www.surgeons.org/aser nip-s/publications_neurostimulation.htm

Vacuum-Assisted Closure of Wounds

Objective
To assess whether the management of non-healing wounds using vacuum-assisted closure (VAC) therapy will result in improved efficacy and safety outcomes compared with conventional methods.

Methods
MEDLINE, PREMEDLINE, EMBASE, Current Contents and PubMed were searched from inception up to July 2003 and The Cochrane Library Issue 3, 2003 was searched for randomised controlled trials (RCTs) comparing VAC with an alternative treatment. The York (UK) Centre for Reviews and Dissemination databases, Clinicaltrials.gov, National Research Register, Grey Literature Reports, relevant online journals and the Internet were searched in July 2003. The search terms were as follows: (vacuum or suction) and (wound healing), (vacuum assisted or vacuum-assisted) and (wound or closure), topical negative pressure, (subatmospheric or sub-atmospheric) and pressure. Studies containing safety and efficacy data on the VAC technique in the form of randomised controlled trials (RCTs), other controlled or comparative studies and case series with consecutive patients and stating the type of wound, were included.

Results
Six RCTs of vacuum-assisted closure covering four indications (two on pressure sores and ulcers, one on diabetic foot ulcers, one on skin grafts and two on chronic and complex wounds) were reviewed. Also included in the review were four non-randomised comparative studies (three on sternal wounds and one on skin grafts) and seven case series studies (two each on skin grafts and chronic wounds and one each for pressure sores and ulcers, diabetic foot ulcers and sternal wounds). There is a paucity of high quality RCTs on VAC therapy for wound management with sufficient sample size and adequate power to detect differences, if there are any, between VAC and standard dressings. However, based on the data from the included studies, VAC appeared to be more effective than the conventional methods for management of skin grafts, foot ulcers and various chronic and complex wounds. No significant difference could be detected between VAC and use of traditional gauze dressings or the Heelpoint system for management of pressure sores and ulcers. One patient with a pressure ulcer that failed to heal with VAC developed sepsis and three patients with diabetic foot ulcers required amputation. Other complications included periwound maceration, infection and minor discomfort with the application of high pressures.

Conclusion
Although most studies were probably too small to detect significant differences, some results did show VAC to result in better healing than standard methods, with few serious complications. With proper training to ensure appropriate and competent use, VAC is simple to use and appears to be a promising alternative for the management of various wound types.

For the full review, please access our website. The Executive Summary is also available from this site. http://www.surgeons.org/aser nip-s/publications_vacuum.htm
MSAC Systematic Reviews

Radiofrequency Ablation for Liver Tumours

Transanal Endoscopic Microsurgery

Assessments in Progress

ASERNIP-S: Report No 22
Adult to Adult Live-donor Liver Transplantation; Donor Outcomes

Report No 30
Sentinel Lymph Node Biopsy in Breast Cancer

Report No 33
Lung Volume Reduction Surgery update – collaboration with the Canadian Coordinating Organization for Health Technology Assessment (CCOHTA)

Report No 34
Adult to Adult Live-donor Liver Transplantation; Recipient Outcomes

Report No 38
Intraoperative Ablation for Atrial Fibrillation

Report No. 41
Laparoscopic Ventral Hernia Repair (accelerated systematic review)

Report No. 44
Unicompartmental Knee Surgery

MSAC
Carotid Percutaneous Transluminal Angioplasty with Stenting

Procedure Nominations

The following nominations have been received by the ASERNIP-S Management Committee and will be assessed by ASERNIP-S in the future:
• Bioplastique (injectable silicone)
• Colonic stents
• Computer-assisted cardiac surgery
• Endoscopic ablation of Barrett’s oesophagus for severe dysplasia
• Endoscopic intracranial aneurysm surgery
• Endoscopic stapling of pharyngeal pouch
• Laparoscopic adhesion division
• Laparoscopic hemicolecctiony
• Microwave endometrial ablation
• Palatal procedures for snoring
• Permanent dermal fillers
• Radiofrequency ablation of tumours
• Refractive keratoplasty
• Small vessel angioplasty
• Spinal endoscopy
• Spinal fusion apparatus
• Thermal capsular shrinkage (for shoulder ligament laxity)
• Trans-oral laser resection for laryngeal cancer
• Transpupillary thermotherapy
• Use for biological osteoinductive agents for treatments 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
ASERNIP-S Initiated Research Audits
- Laparoscopic Live-donor Nephrectomy

Government Initiated Research Audits
- Endoluminal Repair of Abdominal Aortic Aneurysms
- Transurethral Needle Ablation of the Prostate (TUNA)
- The National Breast Cancer Audit (clinical audit)
Clinical and research audits facilitated by ASERNIP-S during 2003
• Laparoscopic Live-donor Nephrectomy (national research audit)
• Endoluminal Repair of Abdominal Aortic Aneurysms (national research audit)
• Trans-Urethral Needle Ablation for Urinary Outflow Obstruction (national research audit)
• National Breast Cancer Audit of Early Breast Cancer (clinical audit)

Definitions:
A national research audit aims to answer specific research questions, such as the long-term safety and effectiveness of a procedure, by the use of routine data collection. It is an alternative to controlled trials, where it is not pragmatic or ethical to conduct a trial, or where questions remain unanswered following a trial. It may also show whether the benefits expected from the evidence provided by a randomised controlled trial were achieved when a procedure has been adopted into the wider framework of clinical practice. ASERNIP-S believes that surgeons, government and consumers stand to benefit from this type of comprehensive national research audit because they will help improve Australian health outcomes.

A clinical audit is a “quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.”

This definition is endorsed by the National Institute of Clinical Excellence. Principles for Best Clinical Audit 2002.
ASERNIP-S Initiated Research Audits

In the current funding cycle the Australian Government Department of Health and Ageing did not allocate funding for ASERNIP-S to conduct audits arising after systematic review of a procedure. However due to the re-appraisal of the laparoscopic live-donor nephrectomy (LLDN) procedure in 2003, ASERNIP-S consolidated an existing data set for procedures performed between May 1997 and April 2003, to inform the systematic review.

Government Initiated Research Audits

ASERNIP-S is undertaking two national research audits following specific funding recommendations made by the Australian Government Department of Health and Ageing. The remit of these audits is to gather mid- to long-term information regarding safety and efficacy in order to inform government funding decisions.

Endoluminal Repair of Abdominal Aortic Aneurysms

This audit has been in progress since November 1999, and is expected to run for at least five years. The aim of the audit is to provide information on the long-term safety and durability of the graft. Between 1 November 1999 and 16 May 2001 over 950 patients underwent the procedure and their information was entered into the audit. Whilst no new patients have been accepted after 16 May 2001, follow-up of this cohort is continuing. Our aim is to ensure that the data set is complete and robust. A progress report is submitted to the Australian Government Department of Health and Ageing every six months. Reports were submitted in May and November 2003.

Further information about the audit is available from the ASERNIP-S web page at: http://www.surgeons.org/asernip-s/auditAAA.htm. Audit reports, patient information and data entry forms are available.

Trans-Urethral Needle Ablation for Urinary Outflow Obstruction (TUNA)

The TUNA audit is collecting data for all patients undergoing the procedure after 1 November 2002. Interim funding has been made available to surgeons performing the procedure; however they must submit their data to ASERNIP-S in order to facilitate a long-term study of the procedure. Further information relating to this audit is available from the ASERNIP-S web page: http://www.surgeons.org/asernip-s/auditTUNA.htm

The National Breast Cancer Audit (clinical audit)

The National Breast Cancer Audit has been conducted with the support of the Breast Section of the Royal Australasian College of Surgeons (RACS) since 1998. The audit collects data on surgery performed on breast cancer patients in Australasia. This information enables breast surgeons to compare their own breast surgery practices with that of other breast surgeons. Since August 2002, this audit has been managed by ASERNIP-S.
New and Emerging Techniques – Surgical

ASERNIP-S horizon scanning project

NET-S on the web
We list these technologies, and filter them for their potential horizon scanning impact, and produce a prioritising summary on the procedures that are likely to have an impact on the health system.

The prioritising summaries are then used to inform decisions, within ASERNIP-S, to determine which procedures require a full horizon scanning report.

A horizon scanning report and an impact summary are then written, with the intent that they will be submitted to Euroscan, a collaborative international network of HTA agencies which exchange information and evaluate emerging technologies. The Australian Horizon Scanning Network is in the process of becoming a member of Euroscan.

ASERNIP-S horizon scanning project

In 1999, ASERNIP-S, in conjunction with the Royal Australasian College of Surgeons’ New Technology Committee, established an Australian based Horizon Scanning Project – New and Emerging Techniques — Surgical (NET-S) which focuses specifically on new and emerging surgical techniques and technologies. The term ‘horizon scanning’ is used to denote the identification of new and emerging surgical techniques that are on the ‘horizon’ of introduction into Australian health care. NET-S aims to provide an early warning system for the identification of surgical techniques and technologies prior to their introduction into routine clinical practice. This information can be used for clinical guidance and can provide information for government policy and planning, through the evaluation of safety and efficacy and consideration of financial implications.

We have recently started working collaboratively with the National Horizon Scanning Unit, as part of the Australian Horizon Scanning Network, which seeks to provide policy and planning advice to the Australian Health Ministers’ Advisory Council (AHMAC) and the Australian Government through the Medical Services Advisory Committee (MSAC).

As a result, we have updated our methodology to align with that of the network.

- We scan unpublished and published surgical information on the Internet daily. This results in the identification of about 20 new surgical techniques and technologies per week. In addition:
  - The Fellows of the Royal Australasian College of Surgeons are periodically surveyed.
  - Abstracts that are presented at relevant specialty meetings are monitored.
  - Specialist journal table of contents are checked.
  - Links are being established with organisations such as medical device manufacturers.
  - Input from surgeons, consumers and other relevant groups are solicited via the NET-S website.

- We list these technologies, and filter them for their potential horizon scanning impact, and produce a prioritising summary on the procedures that are likely to have an impact on the health system.

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NET-S on the Web

The NET-S website is accessible via: http://www.surgeons.org/asernip-s/net-s
NET-S is also accessible through the ASERNIP-S and RACS websites.

The NET-S database is currently undergoing change due to current collaborations and membership of the Australian Horizon Scanning Network. It is envisaged that the new database will be available in early 2004.

Completed publications and links to information such as publications by other Health Technology Assessment agencies are available. Forms for nominating new techniques and an email registration can be accessed for those wishing to be included on our database to receive the NET-S newsletter, NET-Scope, which is published several times a year.

Techniques and technologies that have been reviewed and are available for download include:
- Artificial cervical disc replacement
- Artificial intervertebral disc replacement
- Coblation for skin resurfacing
- Electrolytic ablation of tumours
- Endoluminal stenting of the thoracic aorta
- Endoscopic dacryocystorhinostomy
- Endoscopic laser foraminoplasty
- Epiduroscopy
- Extracorporeal shockwave lithotripsy for calcific tendonitis
- Implantable artificial lung
- Implantable total artificial heart
- Injection snoreplasty
- Intracapsular tension ring
- Intradiscal electrothermal therapy (IDET)
- Intraluminal closure of patent ductus arteriosus (PDA) in infants
- Irrigating scalpel for adhesiolysis
- Kyphoplasty
- Laparoscopic cystectomy
- Laparoscopic pyeloplasty
- Laparoscopic radical prostatectomy
- Laser discectomy
- Meniscal transplantation
- Metal hip resurfacing prosthesis
- Minimally invasive placement of pectus bar
- MRI-guided focused ultrasound for the treatment of uterine fibroids
- Partial left ventriculectomy
- Percutaneous endoscopic sigmoid colostomy
- Percutaneous endoscopic thoracic discectomy (with laser)
- Percutaneous vertebroplasty
- Radiofrequency ablation of varicose veins (VNUS Closure®)
- Sacral nerve stimulation for faecal incontinence
- Sacral nerve stimulation for treatment of urge incontinence
- Secondary transperitoneal cryotherapy for carcinoma of the prostate
- Subfacial endoscopic perforator surgery (SEPS) for chronic venous insufficiency
- Suspension suture for nasal valve stenosis
- Thoracic discectomy
- Thyroplasty type II
- Transaxillary thyroidectomy
- Transurethral electrovaporisation of the prostate
- Use of Transcyte™

Horizon Scanning
Reports in preparation

- Endokeratoplasty / Posterior lamellar keratoplasty (update)
- Essure® system for tubal sterilisation
- Collagen meniscal implants for treatment of meniscal injury

Electronic links for reports are available via:
http://www.surgeons.org/asernip-s/net-s/procedures.htm

To nominate a new procedure, visit the NET-S website and use an online form or PDF version, http://www.surgeons.org/asernip-s/net-s/nominating.htm

To comment, visit
http://www.surgeons.org/asernip-s/net-s/commenting.htm
Project Activities for 2003
Consumer Information

This year, we have worked with our Management Committee consumer representatives and surgeons to make the consumer information more accessible and relevant to consumers’ needs. Consumer summaries are short summaries of the systematic literature reviews produced by ASERNIP-S researchers, written in easy-to-read language. These documents help the consumer to access the latest in evidence-based research on new surgical procedures.

Early this year, ASERNIP-S contacted relevant consumer organisations to introduce our work and invite participation in the development of the consumer information. As a result, numerous consumer organisations have been added to our mailing list and in some cases reciprocal web links have been established.

We have worked with our two consumer representatives, Ms Barbara Beacham and Ms Jane Doyle, to produce articles on consumer issues and the activities of ASERNIP-S. Publications have appeared in the RACS Surgical News (March and September 2003), the Consumers Health Forum newsletter HealthUpdate (March and September 2003) and the Department of Health and Ageing HealthInsite newsletter (October 2003).

Consumer summaries are now prepared in collaboration with consumer information groups, comprised of two surgeons from each Review Group, our consumer representatives and ASERNIP-S staff. The group meets by teleconference to discuss the first draft of a consumer summary. Comments on subsequent drafts are made by email and incorporated into the final document. This year the following consumer summaries have been prepared:

- Laparoscopic Adjustable Gastric Banding for the Treatment of Obesity (update)
- Radiofrequency Ablation for the Treatment of Liver Tumours
- Laparoscopic Live-donor Nephrectomy (second update and re-appraisal).

We continue to look at new ways of presenting consumer information, and have drawn on the expertise of a group of surgeons in the preparation of a brochure in relation to one procedure.

ASERNIP-S has a new consumer email address: consumer.asernip@surgeons.org so that consumers and consumer organisations can contact us directly. Consumer summaries are available at: http://www.surgeons.org/asernip-s/consumerinfo.htm
Promotional Activities

Peer-reviewed publications 2003


Other publications

ASERNIP-S: Providing information. RACS Surgical News Vol. 4, No. 2, March 2003


The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S), Consumers Health Forum – Health Update, Issue 8, September 2003


ASERNIP-S releases two new systematic reviews, HealthInsite Newsletter, 1 October 2003

Presentations


Maddern G, M Boult, Babidge W. Results and Outcomes of ASERNIP-S Audit for Laparoscopic Live-Donor Nephrectomy. Annual Scientific Congress of the Royal Australian College of Surgeons (ASC). Brisbane, Australia, 6–9 May 2003

Malycha P. Audit Perspective on DCIS. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Brisbane, Australia, 6–9 May 2003

Malycha P. Audit Perspective on Invasive Breast Cancer. Annual Scientific Congress of the Royal Australasian College of Surgeons (ASC). Brisbane, Australia, 6–9 May 2003


Babidge W. National Breast Cancer Audit, Breast Cancer Network of Australia, Melbourne, 28 May 2003


Maddern G. Horizon Scanning. Presentation to Chief Executive Officers, Chief Executives and Staff, SA Department of Human Services, DHS, Adelaide, 17 October 2003


Babidge W. National Breast Cancer Audit. RACS Surgical Audit Taskforce, Melbourne, 28 October 2003

Middleton P. Australian Horizon Scanning Network, Euroscan, 21 November 2003
Externally Commissioned Projects

ASERNIP-S continues to expand its role into areas of implementation research and guidelines.

National Institute of Clinical Studies

In 2003, ASERNIP-S completed a review for the National Institute of Clinical Studies (NICS), which is an organisation that advances health care by reducing the gap between evidence and clinical practice.

• Interventions to improve uptake of venous thromboembolism prophylaxis in hospitals

Venous thromboembolism (VTE) is a significant problem for surgical and medical hospitalised patients leading to the possibility of serious illness and risk of death. A number of clear evidence-based guidelines are available which outline the appropriate use of prophylaxis to prevent deep vein thrombosis (DVT) and pulmonary embolism (PE). In spite of the existence of such evidence, the problem of VTE in hospitalised patients persists, and it is clear that evidence-based guidelines and recommendations are underutilised. This study reviewed strategies for improving the uptake of prophylaxis for venous thromboembolism in hospitalised medical and surgical patients. A number of active strategies used together, incorporating a method for reminding clinicians to assess patients for risk of deep vein thrombosis, and assisting the selection of appropriate prophylaxis, are likely to result in the best outcomes.


Tonkin Consultancy

• Vaccinations for workers in the solid waste industry: A review of the literature

A review on ‘Vaccinations for workers in the solid waste industry’ was commissioned by Tonkin Consulting, a local engineering consultancy firm, on behalf of Work Cover South Australia. ASERNIP-S was asked to review the evidence for the need for vaccination of workers in the solid waste industry. No evidence could be located that indicated an increased risk of infection with blood or waste-borne pathogens for these workers. The review has been used by Tonkin Consulting, in collaboration with a medical expert, to develop an evidence-based recommendation about appropriate vaccination policy for these workers.

NHMRC consultancy

• Clinical practice guidelines for the management of type 1 diabetes in children and adolescents

ASERNIP-S is acting as consultant for the National Health and Medical Research Council’s evidence-based guideline development program. Our role is to monitor the quality of guidelines developed on behalf of the NHMRC and provide expertise in evidence-based methods and literature review for the external guideline development groups. We are presently assisting the Australian Paediatric Endocrine Group who are developing evidence-based guidelines for the management of type 1 diabetes in children and adolescents. As this is a new program for the NHMRC, we are working with them to develop processes that are effective in ensuring high quality evidence-based guidelines are produced while at the same time providing appropriate assistance to the external developers of the guidelines.

Cook Australia Project

ASERNIP-S is providing audit and research advice to Cook Australia for the assessment of the ‘flex’ endograft for the Therapeutics Goods Authority.

ASERNIP-S Website

The ASERNIP-S website is updated regularly and all completed systematic literature reviews, accelerated systematic reviews, 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 as well as conference presentations are also listed. We have links to affiliated organisations, consumer groups, peer-reviewed journals and other organisations. Additionally, the website for 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 NET-S website address is http://www.surgeons.org/asernip-s/net-s
ASERNIP-S Credentials Committee Survey

Each year ASERNIP-S sends notifications of reviews we have completed to the Credentials Committees of hospitals and health services throughout Australia. The aim of this survey is to determine the impact of ASERNIP-S health technology assessments on practice and policy at Australian hospitals. This year we altered the survey slightly in order to obtain a more thorough understanding of the ways in which these notifications are used.

Notifications were regarded as useful by the majority of respondents. A high proportion of recipients (72%) read the notifications and nearly half also passed them on to relevant others. A further 17% of respondents tabled them at Medical Advisory Committee (MAC) meetings. However, only 12% of respondents reported accessing a copy of a full ASERNIP-S review, suggesting that short summaries of ASERNIP-S reviews are the optimal format for use by Credential Committees.

The usefulness of ASERNIP-S notifications is dependent on the relevance of the review topics to surgical practice at the hospital. In many small rural or regional hospitals the surgical procedures and technologies reviewed by ASERNIP-S are not performed. In these cases ASERNIP-S notifications are used mainly to keep staff abreast of the cutting edge in surgical practice. In hospitals where new surgical techniques are performed often, notifications are seen as highly relevant. ASERNIP-S reviews are also valued as a locally applicable independent evaluation of new surgical techniques and technologies. In the first pie chart it can be seen that over 60% of respondents described ways in which notifications are useful, while only 34% reported that the reviews are not relevant to their surgical practice, and of these, 30% reported that they are still useful for keeping up-to-date.
The issue of relevance also impacts on the usefulness of reviews for decision-making. On average, respondents did not report that reviews were useful for decision-making in their hospitals. However, for 32% of respondents the review topics were not relevant to surgical practice in their hospitals and could not be expected to impact on decision-making. For hospitals where notifications were relevant to practice, over 70% found the notifications useful for decision-making and only 24% reported that they were not useful for decision-making.

Nearly 40% of respondents reported that notifications have changed practice in the hospital. The second pie chart shows how notifications have been used to change practice. Around half of respondents reported that notifications have been used in planning the implementation of new procedures, for credentialling and application of privileges. In 26% of cases ASERNIP-S notifications have been used to allow or disallow the use of a new procedure.

Respondents were enthusiastic about the possibility of being notified of the work of the NET-S horizon scanning project. It was thought that notifications of new and emerging techniques and technologies could be circulated to staff to increase awareness of new procedures, and would assist in monitoring the introduction of new techniques, for credentialling purposes, and for negotiating with health funds. It was also expected that notifications of NET-S procedure briefs could be useful for negotiating with medical device companies or surgeons wanting to try new procedures.

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Terms of Reference of
ASERNIP-S Management Committee

- To meet on a regular basis.
- Agree on programme schedules, plans and tasks required to meet programme objectives.
- To provide leadership and guidance to the programme — to focus on strategy to meet programme objectives.
- Responsible for identifying resource requirements and, wherever possible, organising provision of these resources.
- To exercise direction over programmes 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 number of staff (particularly new research officers) have attended generalist evidence-based medicine courses such as those offered by the Australian Centre for Evidence-Based Practice at Flinders University. Since more intensive and advanced courses are rarely available locally, a staff member will participate in a new Canadian distance learning course on health technology assessment from early 2004.

Few staff join ASERNIP-S with indepth knowledge of health technology assessment. In-house training and mentoring has therefore become more structured this year, with further development of the operations manual, the introduction of a specialised orientation manual, and specific training sessions for new staff. The fortnightly journal club for all research and audit staff continues to be a valuable education activity.

Medical students
In 2003, the structure of fourth year research placements changed from a six week placement to attendance for a half day each week over the academic year; and students were required to prepare a proposal for a research project rather than carry out a piece of research. Two students were based at ASERNIP-S during the year and both prepared protocols for systematic reviews (one on robotic cardiac surgery and one on carotid stenting).

External training provided by ASERNIP-S
Philippa Middleton led a seminar on evidence-based medicine and critical appraisal for South Australian orthopaedic registrars, and Wendy Babidge, Rebecca Tooper and Philippa Middleton led a workshop on critical appraisal at the national conference of the Australasian Health and Research Data Managers Association.

Personnel

During 2003 Mr Andrew Chapman, Dr Marie Andrew and Dr Leanne Sutherland left ASERNIP-S. We welcomed new Research Officers Dr Susan Hazel, Mr Michael Duffield and Research Assistants Ms Rebecca Morgan, Dr Afsha Chughtai and Mr Paul O’Donnell.
ASERNIP-S
Staff Profiles

Professor Guy Maddern
Dr Wendy Babidge
Eleanor Ahern
Dr Marie Andrew
Maggi Boult
Andrew Chapman
Dr Afsha Chughtai
Astrid Cuncins-Hearn
Michael Duffield
Claire Dunstall
Mariëlle Esplin

Jane Franklin
Dr Tabatha Griffin
Dr Susan Hazel
Louise Kennedy
Philippa Middleton
Rebecca Morgan
Paul O’Donnell
Clarabelle Pham
Elen Shute
Dr Bronni Simpson
Dr Leanne Sutherland
Dr Rebecca Tocher
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, is 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 manages the ASERNIP-S programme which currently has 20 staff members. 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 Research Assistant  
Eleanor Ahern  
Eleanor Ahern has a Master of Arts Degree in politics and is currently completing an Advanced Diploma in Professional Writing at Adelaide TAFE. She has a background in medical studies. Eleanor has worked as a freelance editor and is now writing the consumer summaries of reviews conducted by ASERNIP-S.
ASERNIP-S Research Officer
Dr Marie Andrew
Dr Marie Andrew joined ASERNIP-S in January 2003. She has a Bachelor of Arts degree and Honours in Psychology. She has considerable research experience in the field of cardiothoracic surgery and has recently completed her PhD investigating psychosocial outcomes following cardiac surgery. At ASERNIP-S Marie conducts systematic reviews.

ASERNIP-S Senior Research Officer (Data Manager)
Maggi Boult
Maggi Boult 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 Senior Research Officer
Andrew Chapman
Andrew Chapman has an Honours degree in Psychology from the University of Adelaide. As a researcher, he has worked for the SA Health Commission and as a private consultant. At ASERNIP-S he conducts systematic literature reviews and administers the ASERNIP-S computer network.

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 supports researchers in conducting systematic reviews and prepares horizon scanning summaries and reports.

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 specializing 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.

ASERNIP-S Administrative Assistant
Claire Dunstall
Claire Dunstall joined ASERNIP-S in December 2002, on a part-time (casual) basis. She is currently studying a Bachelor of Commerce at Adelaide University. At ASERNIP-S, Claire provides administrative assistance, data entry and clerical support to research and administration staff.

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 assists with the NET-S horizon scanning project and supports researchers in conducting systematic literature reviews. She also provides assistance with website and computer administration.
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.

ASERNIP-S Research Officer  
Dr Susan Hazel  
Dr Susan Hazel joined ASERNIP-S in September 2003 to conduct systematic reviews. She graduated as a veterinary surgeon and worked for three years in private practice in Australia and the UK, before completing a PhD in 1994 at the Child Health Research Institute, Adelaide. Her PhD project involved the role of growth factors in chronic renal failure. She held post-doctoral positions in Stockholm and Sydney, and has most recently been working in the field of cancer research in Adelaide, involving the commercialisation of an assay that she developed.

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 Research Assistant  
Rebecca Morgan  
Rebecca Morgan joined ASERNIP-S in September 2003 as a Research Assistant. She has a Bachelor of Science degree majoring in Biochemistry and Anatomical Sciences, and an Honours Degree in Anatomical Sciences from the University of Adelaide. Prior to joining ASERNIP-S, Rebecca worked in the UK in microbiology and biochemistry. At ASERNIP-S, Rebecca assists with the NET-S horizon scanning project and supports researchers in conducting systematic reviews.

ASERNIP-S Research Assistant  
Paul O’Donnell  
Paul O’Donnell joined ASERNIP-S in October 2003 as a Research Assistant. He has a Bachelor of Engineering (Electronic and Electrical) Degree from the University of Strathclyde, Scotland, UK. At ASERNIP-S, Paul assists with computer administration and other programme activities.

ASERNIP-S Research Assistant  
Clarabelle Pham  
Clarabelle Pham joined ASERNIP-S in January 2003, as a Research Assistant. Her academic qualifications include a degree in Science, 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, Clarabelle conducts rapid reviews and supports researchers in conducting systematic literature reviews.

ASERNIP-S Administrative Officer  
Elen Shute  
Elen Shute joined ASERNIP-S in April 2003 as a Research Assistant. She holds a Bachelor of Arts degree from Flinders University, with majors in Biology, Environmental Studies and Public Policy. Elen completed an Honours Degree in Environmental Studies in 2002, in the area of bird conservation. At ASERNIP-S, Elen supports researchers in conducting systematic reviews.
ASERNIP-S Research Officer
Dr Bronni Simpson
Dr Bronni Simpson joined ASERNIP-S in October 2001. Bronni has a degree in science, honours 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 conducts systematic literature reviews. She is also involved in developing the New and Emerging Techniques - Surgical (NET-S) horizon scanning project, preparing guidelines for systematic reviews and website administration.

ASERNIP-S Research Officer
Dr Leanne Sutherland
Dr Leanne Sutherland joined ASERNIP-S in May 2001. Leanne has a Degree in Science, majoring in Genetics and Molecular Biology, and Honours in Biochemistry from the Flinders University of South Australia and a PhD from the University of Adelaide. At ASERNIP-S she conducts systematic literature reviews.

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) focussed 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 has recently joined ASERNIP-S as a researcher after four years operating the RACS Breast Audit as a separate project. 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
Appendices

Appendix A
Hierarchy of Evidence

Designation of levels of evidence

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials.</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial.</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).</td>
</tr>
<tr>
<td>III-2</td>
<td>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.</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case-series, either post-test or pre-test/post-test.</td>
</tr>
</tbody>
</table>

Appendix B
ASERNIP-S Review Process

- External Individual or Group
  - Nominates interventional procedure for review
- ASERNIP-S
  - organises review group
  - writes review

Review Group
- Chairman ASERNIP-S
- Surgical Director
- Protocol Surgeon
- ASERNIP-S Researcher
- Advisory Surgeon
- Other Specialty Surgeon
- Invited Member(s)

Dissemination
- Register of reviewed procedures
- RACS Council

Ratification of Procedure Classification
- Ratification of the Review
- Management Committee (ASERNIP-S)

Appeal Process
- External Individual or Group
  - appeal
- Review Group
- Management Committee (ASERNIP-S)
  - if not resolved
- RACS Council

Draft Review and Recommendations

Assesses Review
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(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(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(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(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

1998

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

2000
ASERNIP-S Report No 5
Percutaneous Endoscopic Laser Disectomy: Update & Re-appraisal, February 2000

ASERNIP-S Report No 6

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

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


Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI), May 2000
2001
ASERNIP-S Report No 11
Tension-Free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-Free Vaginal Tape procedures, February 2001

ASERNIP-S Report No 12
Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis, June 2001

ASERNIP-S Report No 14
Minimally Invasive Parathyroid Surgery: Update & Re-appraisal, June 2001

ASERNIP-S Report No 19
Dynamic Graciloplasty for the Treatment of Faecal Incontinence, June 2001

ASERNIP-S Report No 25
Off-pump Coronary Artery By-Pass Surgery, September 2001 — MSAC

ASERNIP-S Report No 26
Minimally Invasive Direct Coronary Artery By-Pass Surgery, September 2001 — MSAC

ASERNIP-S Report No 13
Methods Used to Establish Laparoscopic Pneumoperitoneum, October 2001

ASERNIP-S Report No 20
Off-Pump Coronary Artery Bypass Surgery with the Aid of Octopus Tissue Stabilizer: Update & Re-appraisal, October 2001


2002

ASERNIP-S Report No. 21
Autologous Fat Transfer for Breast Augmentation, February 2002

ASERNIP-S Report No. 24
Stapled Haemorrhoidectomy, February 2002

ASERNIP-S Report No. 31
Laparoscopic Adjustable Gastric Banding for the Treatment of Obesity — Update & Re-appraisal, June 2002

ASERNIP-S Report No. 27
Intraoperative Radiotherapy for Early Stage Breast Cancer, October 2002

ASERNIP-S Report No. 28
Radiofrequency Ablation of Liver Tumours, October 2002


General guidelines for Assessing, Approving & Introducing New Procedures into a Hospital or Health Service, ASERNIP-S/RACS 2002


2003
See Promotional Activities, page 22.
ASERNIP-S wish to thank the Fellows of the Royal Australasian College of Surgeons, the Australian Government Department of Health and Ageing, the Department of Surgery at the Queen Elizabeth Hospital and other members of the health care industry who have participated in and contributed to the programme throughout 2003.

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Richard Wolf GmbH, Germany

The nomination of procedures for assessment by ASERNIP-S should be made to the ASERNIP-S office on the appropriate form. The continued participation of surgeons in procedure Review Groups and the submission of data on procedures under audit by ASERNIP-S are encouraged. For further information on either of these aspects or any other areas, please contact ASERNIP-S.