

ANNUAL REPORT 2008

AUSTRALIAN SAFETY AND EFFICACY REGISTER OF NEW INTERVENTIONAL PROCEDURES — SURGICAL
ROYAL AUSTRALASIAN COLLEGE OF SURGEONS





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Images of glass sculptures in this report provided courtesy of Mr Randall Sach, surgeon-artist.



MISSION STATEMENT

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

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

SURGICAL DIRECTOR'S REPORT

GUY MADDERN
SURGICAL DIRECTOR

In 2008 the role of ASERNIP-S continued to broaden, and some of its early work on evidence was translated into practical research agendas. This year work was completed for the Australian Government looking at technologies and surgical interventions that may have become less relevant. Work began with the government to define how a technology or a procedure is handled as alternatives become more available or information regarding its efficacy becomes clearer. This important work will need to be continued over the coming years.

Following some early ASERNIP-S reports on surgical simulation and its transfer into the operating room, the Australian Government is now supporting a research proposal to test some of the important questions regarding simulation. The government granted \$5 million to the Royal Australasian College of Surgeons to work on this important and difficult project, which is well underway. It is managed by a Steering Committee and a strong Scientific Committee with a proven track record in laparoscopic surgery. The challenges of this research project involve assessing not only high fidelity and low fidelity surgical simulation, but also the skill of trainers required to impart basic skills, the effect of fatigue and the ability to deliver simulated environments to more remote areas within Australia. This work will take place over the next 2–3 years, with important milestones being reported both to the College and in the scientific literature during that time.

The role of ASERNIP-S in the international health technology assessment community continues to increase, with the positions of Chair of INAHTA (International Network of Agencies for Health Technology Assessment) and Secretary of the HTAi (Health Technology Assessment International) being held by Professor Guy Maddern until the middle of 2009.

There have been considerable efforts to advise and input into South East Asian health technology assessment, with ASERNIP-S representatives attending important meetings in Malaysia and China. A closer cooperation with the World Health Organization and its pursuit of essential health technologies has also been developed and this will have important implications for the College in the future.

While at a scientific and developmental level ASERNIP-S continues to progress strongly, there are considerable challenges in maintaining a funding base for its many activities. This has involved representation from the College and ASERNIP-S to the new Australian Government in an effort to secure an ongoing and sustainable base for our work, particularly to look at new surgical interventions that do not necessarily involve new devices or government review, the ability to develop appropriate audits and oversight of surgical procedures and interventions.

As is always the case in such organisations, our staff members are our strongest asset and ASERNIP-S has worked hard to maintain its high quality workforce. This should equip the organisation well for the challenges that are on the horizon.



“The role of ASERNIP-S in the international health technology assessment community continues to increase”



REVIEWS

NEW ASSESSMENTS COMPLETED

SYSTEMATIC LITERATURE REVIEWS

- Treatments for varicose veins
ASERNIP-S Report no. 69

RAPID REVIEWS

- Clinical treatments for wrist ganglia
ASERNIP-S Report no. 63
- Diagnostic arthroscopy for conditions of the knee
ASERNIP-S Report no. 64
- Non-therapeutic male circumcision
ASERNIP-S Report no. 65
- Treatments for varicose veins
ASERNIP-S Report no. 66 (A systematic review was conducted after the rapid review. Please see report no. 69 under Systematic literature reviews.)
- Upper airway surgery for the treatment of adult obstructive sleep apnoea
ASERNIP-S Report no. 67

OTHER PROJECTS

- Maximising health outcomes from government investment in surgical interventions

SYSTEMATIC REVIEWS FOR OTHER ORGANISATIONS

- Endoscopic argon plasma coagulation of gastrointestinal bleeding and oesophageal stents (MSAC Application 1106)
- Deep brain stimulation for essential tremor and dystonia (MSAC Application 1109)
- Endovenous laser therapy (ELT) for varicose veins (MSAC Application 1113)

SYSTEMATIC REVIEWS

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

RAPID REVIEWS

A rapid systematic review is an evidence-based assessment in which the methodology has been limited in one or more areas to shorten the timeline for its completion. Modifications can be made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality and data analysis. These limits are made possible primarily by restricting the specific clinical questions that the review is trying to answer. It is considered that these amendments would not significantly alter the overall findings of the rapid review when compared to a full systematic review.

TECHNOLOGY OVERVIEWS

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

ASSESSMENTS IN PROGRESS

PROCEDURE NOMINATIONS

NEW ASSESSMENTS COMPLETED

SYSTEMATIC LITERATURE REVIEWS

TREATMENTS FOR VARICOSE VEINS

ASERNIP-S Report no. 69

AIM AND SCOPE

This systematic review aimed to assess the safety and effectiveness of current treatment options for varicose veins. The treatment options assessed include surgery, phlebectomy, sclerotherapy, endovenous laser therapy (ELT), radiofrequency ablation (RFA) and conservative therapies, including the use of compression hosiery.

Studies eligible for inclusion were those reporting on human patients with varicose veins of the legs, both superficial and complicated. Included studies reported on the use of one or more intervention for the treatment of varicose veins and compared at least one of the included interventions with another included treatment modality.

METHODS

The search strategy identified articles published between January 1988 and February 2008 in the English language. The following databases were searched: BMJ Clinical Evidence, The York (UK) Centre for Reviews and Dissemination (CRD), Cochrane Database of Systematic Reviews, PubMed and EMBASE. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data, and pearling references from retrieved articles were not undertaken. Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

KEY RESULTS AND CONCLUSIONS

Seventeen studies, all published between 2003 and 2007, were identified as eligible for inclusion in this systematic review. Of these, four publications were systematic reviews of existing literature, 10 were randomised controlled trials (RCTs), and three were nonrandomised comparative studies. Of the included randomised controlled trials, three were reported in one or more of the included systematic reviews in some detail, and were also reported independently in full. The remaining seven RCTs were published after the systematic reviews. Conclusions based on the results of the review are summarised below:

- Ligation with stripping plus avulsion is generally regarded as the 'gold standard' treatment for primary long saphenous veins, with good long-term effectiveness (≥ 12 months).

- Compression stockings are often used as a first-line treatment for varicose veins; however, evidence suggests they are a less effective treatment measure than sclerotherapy or surgery involving ligation with stripping.
- There appears to be a place for both surgery and sclerotherapy in the management of varicose veins. Sclerotherapy shows better early outcomes and faster patient recovery, but surgery produces more durable long-term outcomes (≥ 12 months).
- Sclerotherapy and phlebectomy may be best suited to patients with minor superficial varicose veins not related to reflux in the saphenous system, or as a post-treatment or adjunctive procedure to other treatments.
- Endovenous varicose vein treatments (ELT and RFA) appear to be safe procedures, and at least as safe as conventional surgery (junction ligation and vein stripping). Both can be regarded as effective for treating saphenous varicose veins and may provide a valid alternative to surgery, with better quality of life in the short term (\leq one week for RFA and ≤ 12 weeks for ELT) and faster recovery. While both endovenous treatments were generally found to be as clinically effective as surgery, authors of at least one study regarded clinical results after RFA to be poorer than after surgery. More long-term studies (≤ 12 months) are required before the clinical effectiveness of ELT relative to surgery can be stated definitively.

While comparative evidence was available on a wide range of treatments for varicose veins, much of it was of mediocre quality, making definitive judgments regarding the relative safety and effectiveness of treatments for varicose veins difficult. It is also unclear from the evidence retrieved whether some treatments are more or less effective in particular patient subgroups, dependent on the aetiology of the varicose veins. More high-quality comparative studies (such as well-designed RCTs) with appropriate statistical comparisons are needed before newer varicose vein treatments and surgery (ligation plus stripping) can be definitively compared. The extent of varicose veins should govern the intervention of choice, with no single treatment universally employed.

RAPID REVIEWS

CLINICAL TREATMENTS FOR WRIST GANGLIA

ASERNIP-S Report no. 63

AIM AND SCOPE

This rapid review aimed to assess the safety and effectiveness of clinical treatments for wrist ganglia compared with simple reassurance. Eligible studies compared clinical treatment options for wrist ganglia to simple reassurance. Clinical treatment options included both surgical (excision) and non-surgical (aspiration, puncture etc.) techniques. Simple reassurance includes educating the patient about the nature of wrist ganglia and informing them that the masses are not cancerous and may resolve spontaneously. Studies were restricted to those conducted in adult (≥ 18 years) patients who had no previous treatment for wrist ganglia.

METHODS

The search strategy identified original articles published from January 1980 onwards. Databases searched included: BMJ Clinical Evidence, the York Centre for Reviews and Dissemination, Cochrane Database of Systematic Reviews, PubMed and EMBASE. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data, and pearling references from retrieved articles were not undertaken. Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

KEY RESULTS AND CONCLUSIONS

From the search strategy, 276 potentially relevant articles were identified of which 33 were retrieved. A total of seven studies, including two randomised controlled trials (RCTs), three pseudorandomised controlled trials and two nonrandomised comparative studies, were included for appraisal and inclusion in this rapid review. None of the RCTs or pseudorandomised controlled trials included reassurance as a comparator, and only the nonrandomised comparative studies fulfilled the initial objective of comparing clinical wrist ganglia treatments to simple reassurance.

The findings and conclusions made based on the included evidence were as follows:

- There is discrepancy with regards to the relative recurrence rates after various treatments in the included studies. There is some evidence that surgical excision may be no better than aspiration or reassurance in preventing recurrence. However, several trials indicated that surgical excision appears to be significantly more effective in preventing ganglia recurrence compared to aspiration, at least in the short term (<6 months).
- Patients treated with surgical excision were significantly more satisfied compared to those who received aspiration or reassurance, despite the fact that resolution of symptoms was lowest compared to aspiration and reassurance. Patient satisfaction appeared to be related to the extent of intervention and speed of resolution of the mass instead of symptom improvement.
- Surgical excision is associated with higher complication rates and may cause more severe complications compared to aspiration and reassurance.
- Surgical excision is associated with longer time off work.
- Limitations of the current evidence base include lack of studies including reassurance as a comparator, short follow-up durations, small patient numbers and insufficient measures of effectiveness. The best evidence currently available on the treatment of wrist ganglia are nonrandomised comparative studies. The published randomised and pseudorandomised trials lack methodological detail and sufficient outcome measures, and are not suitable to determine the relative effectiveness of clinical treatment against simple reassurance.
- Based on the available evidence, wrist ganglia should be treated only if symptomatic. Surgical excision should be used as a last resort in view of the relatively high complication rates and the possibility that it does not confer enough benefit to warrant the higher risk. Due to the apparent patient value placed on intervention, aspiration may be considered as the preferred clinical treatment due to its lower complication rates and lower cost relative to excision.



DIAGNOSTIC ARTHROSCOPY FOR CONDITIONS OF THE KNEE

ASERNIP-S Report no. 64

AIM AND SCOPE

This rapid review aimed to assess the safety and effectiveness of arthroscopy for diagnosing knee conditions, compared with magnetic resonance imaging (MRI) and ultrasound. Studies eligible for inclusion were those with an independent, blinded comparison of the index and reference test among consecutive or non-consecutive patients.

METHODS

Studies were identified by searching BMJ Clinical Evidence, the York (UK) Centre for Reviews and Dissemination (CRD), the Cochrane Library, PubMed and EMBASE from January 1977 to March 2008. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data, and pearling references from retrieved articles were not undertaken. Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

KEY RESULTS AND CONCLUSIONS

From the search strategy, 1140 potentially relevant articles were identified of which 21 articles were retrieved. Two systematic reviews, both published in 2007, were eligible for inclusion. Both of the included reviews compared the results of MRI to that of standard arthroscopy. One review focused on the diagnosis of meniscal lesions and anterior cruciate ligament (ACL) tears, while the other study focused primarily on meniscal tears. Conclusions based on the two included reviews are summarised below.

- For meniscal lesions and ACL tears, MRI is an effective diagnostic tool when compared with diagnostic arthroscopy. In particular, MRI has a high specificity and negative predictive value, suggesting that screening MRI studies can effectively rule out the presence of meniscal lesions and ACL tears and reduce the number of unnecessary diagnostic arthroscopies performed. MRI is useful when the results of a clinical examination are uncertain, and it is the most appropriate diagnostic screening tool to use before therapeutic arthroscopy.
- Arthroscopy should be reserved for patients with a lesion that is treatable by arthroscopic methods.
- Safety outcomes were not reported in any of the included systematic reviews or in the primary studies included in these reviews; thus, it was not possible to assess the safety of arthroscopy for diagnosing knee conditions in comparison with other diagnostic procedures. As with all surgical procedures, diagnostic arthroscopy may be associated with certain adverse events, including anaesthetic complications. Therefore, where reliable and accurate diagnosis of knee pathologies can be achieved using non-invasive procedures, diagnostic arthroscopy should be avoided.

NON-THERAPEUTIC MALE CIRCUMCISION

ASERNIP-S Report no. 65

AIM AND SCOPE

The objective of this rapid review was to assess the safety and effectiveness of non-therapeutic male circumcision (NTMC) in comparison with no circumcision. Therapeutic male circumcision is performed to treat an underlying pathological process whereas non-therapeutic male circumcision may be performed for prophylactic, religious, cultural or social reasons. Eligible studies were those reporting on circumcision in a hospital setting in males of any age with no contraindications to, or medical indications for, circumcision. The main comparator for circumcision was no circumcision (intact genitalia).

METHODS

The search strategy identified articles published between January 1997 and February 2008 in the English language. The following databases were searched: BMJ Clinical Evidence, The York (UK) Centre for Reviews and Dissemination (CRD), The Cochrane Library, PubMed and EMBASE. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data, and pearling references from retrieved articles were not undertaken. Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

KEY RESULTS AND CONCLUSIONS

A total of six systematic reviews and six randomised controlled trials (RCTs) were eligible for appraisal and inclusion in this rapid review. No systematic reviews or RCTs were identified on the religious, cultural and social issues surrounding circumcision, so the researcher undertook to find key recent literature reviews summarising current knowledge on these topics. The following findings and conclusions were made:

- One systematic review reported that the prevalence of complications ranged from 0% to 50.1% in a series of haemophiliacs. Two RCTs reported on adverse events relating to circumcision and found that these were generally mild or moderate in severity and included postoperative bleeding and infections, wound disruptions, delayed healing, pain, damage to the penis, haematoma, insufficient skin removal, problems with appearance, swelling at the incision site, anaesthetic-related events and erectile dysfunction.
- One systematic review found insufficient evidence to conclude that male circumcision as a preventative strategy for human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) does more good than harm. Three subsequent RCTs showed that circumcision is effective in preventing HIV/AIDS infection in the sub-Saharan African population (fixed effects OR 0.44, 95% CI 0.32-0.59, $P < 0.00001$). These RCTs were stopped by their data and safety monitoring boards before their designed completion because of significant reductions in HIV incidence in the circumcision groups.



- Two systematic reviews and one RCT found that:
 - Circumcised men may be at higher risk of sexually transmitted urethritis and genital discharge syndrome (GDS) and chlamydial infection.
 - Uncircumcised men may be at higher risk of developing genital ulcerative disease (GUD) and syphilis.
 - There was a minimal association between circumcision status and gonococcal urethritis or chancroid. Circumcised men were found to have a lower risk of herpes simplex virus type 2 (HSV-2) infection; however, this was not statistically significant.
 - One systematic review found that circumcision prevented urinary tract infection (UTI) in children, although the benefit of circumcision only outweighed the risk of the procedure in boys who have had UTI previously and have a predisposition to repeated UTI. This systematic review did not support the routine circumcision of normal boys with standard risk in order to prevent UTI, but suggested that circumcision of boys with higher than normal risk of UTI should be considered.
 - One systematic review found that the literature does not support an association between the prevalence of genital human papillomavirus (HPV) and circumcision status when strict criteria for diagnosis of HPV are applied.
 - One RCT found that of the 1333 circumcised men interviewed three days post-surgery, all those who were employed reported that they had resumed working, and 1287 (96%) reported having returned to normal activities by this time. By eight days post-surgery, all but one person had returned to normal activities.
 - One RCT reported that 1274 (99.5%) individuals were 'very satisfied' and six (0.5%) were 'somewhat satisfied' with their circumcision, while another RCT reported that 98.5% of men who were circumcised were 'very satisfied' with the result of their circumcision at three months post-surgery.
 - One RCT found that although uncircumcised men reported statistically significant higher sexual satisfaction than circumcised men, adult male circumcision did not adversely affect sexual satisfaction or clinically significant function.
 - One RCT suggested pain control after circumcision to promote neonatal comfort and improve mother-infant interaction. Another RCT concluded that circumcised infants showed a stronger pain response to subsequent routine vaccination than uncircumcised infants, and recommended analgesia for circumcision pain.
- In conclusion, there is strong evidence that NTMC can prevent HIV/AIDS acquisition in sub-Saharan African men, but it is unclear whether these findings can be extrapolated to male populations in other countries. While NTMC may prevent childhood UTI, the role of the procedure in preventing other conditions is unclear. As high quality RCTs have not assessed the efficacy of neonatal NTMC for preventing these conditions it would be inappropriate to recommend widespread neonatal circumcision for these purposes.



UPPER AIRWAY SURGERY FOR THE TREATMENT OF ADULT OBSTRUCTIVE SLEEP APNOEA

ASERNIP-S Report no. 67

AIM AND SCOPE

This rapid review aimed to evaluate the safety and effectiveness of upper airway surgery for treating obstructive sleep apnoea (OSA) in adults, in comparison with conservative therapy, treatment with devices (continuous positive airway pressure [CPAP] and oral appliances) and no treatment/placebo.

METHODS

Studies were identified by searching BMJ Clinical Evidence, the York (UK) Centre for Reviews and Dissemination (CRD), the Cochrane Library, PubMed and EMBASE from inception to March 2008. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data, and pearling references from retrieved articles were not undertaken. Data from the included studies were extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

KEY RESULTS AND CONCLUSIONS

From the search strategy, 1016 potentially relevant articles were identified of which 35 articles were retrieved. Four systematic reviews, published between 1996 and 2007, were eligible for inclusion. The reviews evaluated a range of procedures, and included four relevant randomised controlled trials (RCTs) that examined the upper airway surgical procedures of uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP) and temperature-controlled radiofrequency tissue ablation (TCRFTA). An additional RCT on another upper airway surgical procedure (palatal implants) which was published too recently to be included in any systematic review was also included in this rapid review. High-level evidence was not available for any other procedures. Conclusions based on the five included studies are summarised below.

- There was insufficient evidence to determine the effect of upper airway surgery on polysomnography results. From limited short-term evidence, UPPP and TCRFTA do not present significant benefits in mean polysomnography outcomes compared with conservative management or placebo, although one UPPP study reported a higher success rate in UPPP compared with conservative management.

One RCT of LAUP and one RCT of palatal implants found some benefit in surgery compared with no treatment/placebo in the short-term. Use of devices (oral appliance therapy and CPAP) produced better polysomnographic outcomes than surgery in the short-term; however, unlike surgery, any device has the additional issue of compliance. Surgical success rates varied depending on the procedure, the patient population, and the definition of success. It is unclear from the evidence whether any surgical procedure is superior, and the long-term effectiveness of the procedures cannot be established.

- There was insufficient evidence to determine the effect of upper airway surgery on daytime sleepiness, snoring or quality of life. When compared with conservative management or no treatment/placebo, two RCTs suggested some benefit for UPPP and palatal implants for daytime sleepiness and snoring, while two other RCTs found no benefit for LAUP and TCRFTA for daytime sleepiness. For quality of life measures, one RCT found no benefit for LAUP, while two others reported possible benefit after TCRFTA and palatal implant compared with no treatment/placebo. There was no difference between surgery and use of devices for these outcomes.
- There was insufficient evidence to determine levels of patient satisfaction, or to make long-term survival comparisons between upper airway surgery and alternative treatments.
- From limited safety evidence, it would appear that UPPP had more adverse effects than the less invasive procedures of TCRFTA and palatal implants. LAUP had similar adverse effects to UPPP, at similar rates of occurrence. Long-term safety data were not available from the included studies.

From the reviewed literature, upper airway surgery for OSA does not provide significant benefit over conservative treatment or treatment with devices. Following failed conservative treatment or treatment with devices, selected patient groups with specific anatomical features, body mass index and OSA severity may benefit from certain upper airway surgical techniques. However, at present, there is insufficient high-level evidence on the effectiveness of any surgical procedure, regardless of patient characteristics.

OTHER PROJECTS

MAXIMISING HEALTH OUTCOMES FROM GOVERNMENT INVESTMENT IN SURGICAL INTERVENTIONS

The aim of this project was to strengthen the evidence base for assessing the effectiveness of certain surgical interventions. As part of this project a Key Stakeholder Advisory Group was established, comprising representatives from the following organisations:

- Royal Australasian College of Surgeons
- Australian Commission on Safety and Quality in Health Care
- Australian Health Insurance Association
- Consumers' Health Forum of Australia
- National Health and Medical Research Council
- National Institute of Clinical Studies
- Medical Services Advisory Committee
- Medicare Australia
- Department of Health and Ageing
- Australian Medical Association
- Australian Association of Surgeons
- Adelaide Health Technology Assessment, University of Adelaide.

Initially, a systematic search of the peer-reviewed literature was conducted to identify:

- criteria that have been used both nationally and internationally to identify surgical procedures which may be of questionable clinical benefit
- processes that have been used to change clinical practice in relation to these procedures.

It was agreed that it is important to keep both practitioners and consumers informed about changes to best practice based on current evidence. One of the challenges which emerged during discussions with key stakeholders was how to produce up-to-date clinical guidance on existing surgical procedures that is accessible for both audiences. It was suggested that future work could focus on the development of guidance for clinicians and patients in relation to services under review.

SYSTEMATIC REVIEWS FOR OTHER ORGANISATIONS

- Endoscopic argon plasma coagulation of gastrointestinal bleeding and oesophageal stents (MSAC Application 1106)
- Deep brain stimulation for essential tremor and dystonia (MSAC Application 1109)
- Endovenous laser therapy (ELT) for varicose veins (MSAC Application 1113)

ASSESSMENTS IN PROGRESS

SYSTEMATIC LITERATURE REVIEWS

- Permanent and semi-permanent dermal fillers
ASERNIP-S Report no. 55
- The effect of fatigue on surgeon performance
ASERNIP-S Report no. 68
- Autologous fat transfer for breast augmentation
(update) ASERNIP-S Report no. 70
- Percutaneous endoscopic laser discectomy (update)
ASERNIP-S Report no. 71

OTHER COMMISSIONED PROJECTS

- Simulated Surgical Skills Program

ASERNIP-S commenced work late last year on the Simulated Surgical Skills Program (SSSP). This program, funded by the Australian Government through the Department of Health and Ageing, is charged with the development, implementation and assessment of a new laparoscopic surgical skills training curriculum. This curriculum will incorporate the use

of laparoscopic simulators alongside traditional training techniques to provide a new mode of surgical skills training in Australia.

The SSSP has five core aims:

- to produce a report examining international laparoscopic surgical simulation training and its implications in Australia
- to develop a training and assessment program suited to the Australian education and healthcare systems
- to implement this curriculum
- to assess this curriculum
- to develop a 'train the trainer' program to assess the best way to teach the use of the chosen surgical simulators.

This program will build on current international developments in laparoscopic surgical training to produce a new and innovative curriculum for the provision of surgical education. A pre-trial assessment of this curriculum will be performed in South Australia in late 2008, followed by the national implementation in early to mid 2009.



PROCEDURE NOMINATIONS

The following nominations have been received by the ASERNIP-S Advisory Committee but are currently unfunded:

- Asymptomatic gallstones
- Computer-assisted cardiac surgery
- Delivery of conscious sedation
- Downstaging of rectal cancer using neoadjuvant radiochemotherapy
- Endoscopic stapling of pharyngeal pouch
- Endoscopic thoracic sympathectomy
- Folate fortification of flour in Australia
- Injectable silicone for incontinence, reflux and other indications
- Intramedullary bone lengthening with fitbone device
- Laparoscopic adhesion division
- Laparoscopic hemi-hepatectomy
- Palatal procedures for snoring
- Provision of emergency surgical services in Australia
- Radiofrequency ablation of tumours (not liver)
- Refractive keratoplasty
- Small vessel angioplasty
- Spinal endoscopy
- Spinal fusion apparatus
- The evidence for safe surgical working hours
- Thermal capsular shrinkage (for shoulder ligament laxity)
- Trans-oral laser resection for laryngeal cancer
- Transpupillary thermotherapy
- Trauma systems
- 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/publications.htm>



DATA COLLECTION

- Audit of endovascular aneurysm repair
- Bi-National Colorectal Cancer Audit
- National Breast Cancer Audit

AUDIT OF ENDOVASCULAR REPAIR OF ABDOMINAL AORTIC ANEURYSMS

The Audit of endovascular repair of abdominal aortic aneurysms was established in 1999 in response to recommendations by the Medical Services Advisory Committee (MSAC) to assess the mid- to long-term safety and efficacy of endovascular grafts as an alternative to open surgery for aneurysm repair.

The endovascular aneurysm repair (EVAR) procedure was granted temporary funding pending the mid-term results of the ASERNIP-S audit and was assigned two interim numbers on the Medical Benefits Schedule. On 4 June 2007 the Minister for Health and Ageing, the Hon Tony Abbott, endorsed the recommendation of MSAC to support permanent funding for EVAR following consideration of the audit report on procedures with 5-year follow-up.

Of the 961 patients enrolled in the audit, around 60% survived to 5 years. We are now analysing 7- and 8-year follow-up data. Results of the audit have so far shown EVAR provides patients and physicians with a possibility of abdominal aortic aneurysm repair that is less invasive, has fewer risks and faster recovery, and is an option for patients unsuitable for open repair.

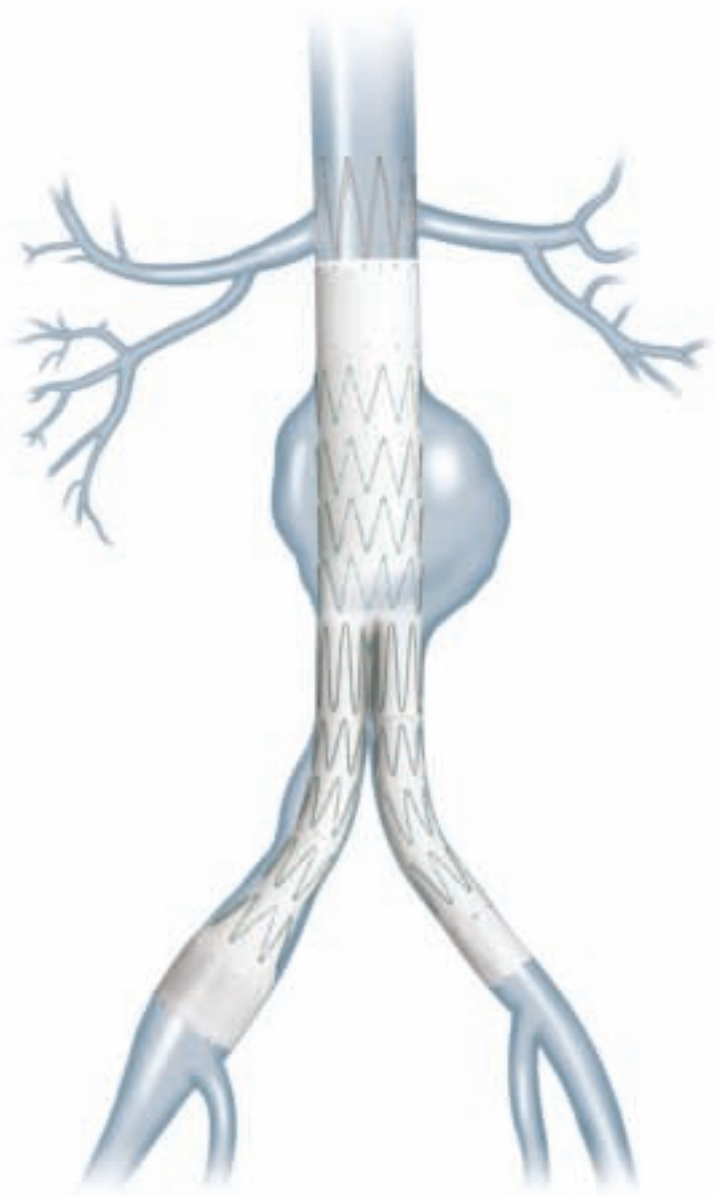
While EVAR has these benefits over open repair, it requires ongoing surveillance. Evidence of long-term outcomes is limited and despite improvements in graft devices late onset complications such as endoleaks and aneurysm enlargement may occur in the long-term. In some cases a reintervention may be needed. The audit found almost a quarter of patients undergoing EVAR with a Zenith graft required a secondary endovascular procedure at the time of their initial procedure, although the need for additional open procedures at this time is comparably much lower. Additionally, 11% of patients required a secondary procedure for their aneurysm in the mid- to long-term follow-up period; the majority of these procedures were endovascular procedures (72%). Only 3.6% of patients required more than one reintervention for their aneurysm, and these additional procedures were generally successful.

A predictive model was developed using the audit data, which can project a patient's likelihood of success with EVAR based on various patient and aneurysm parameters. This is currently available as an Excel Workbook downloadable from the ASERNIP-S website for surgeons to use when considering EVAR. The audit will be conducting further analyses to validate the predictive model using data from the United Kingdom late in 2008.

The EVAR audit will complete follow-up data collection in 2008 for the current cohort. A successful NHMRC application now means that research in this area will be continuing.

We would like to acknowledge the efforts of those surgeons who originally contributed operative data and those who continued to contribute follow-up data; a participation list has been added to the ASERNIP-S page on the Royal Australasian College of Surgeons website.

Reports and documents pertaining to the audit can also be found on the ASERNIP-S website: www.surgeons.org/asernip-s/audit.htm.



BI-NATIONAL COLORECTAL CANCER AUDIT

Through a collaboration between the Colorectal Surgical Society of Australia and New Zealand (CSSANZ), the Research, Audit & Academic Surgery Division (RAAS) of the College and the BioGrid Australia (formerly Bio21:MMIM) project, the Bi-National Colorectal Cancer Audit has been established.

In Victoria, colorectal cancer data is being collected in public and private hospitals. Collection commenced at Western Hospital in 1999; Austin Hospital, Royal Melbourne Hospital and Melbourne Private in 2003; and Box Hill Hospital, Epworth Eastern, Knox Private Hospital and Peter MacCallum Cancer Centre in 2006, all using the ACCORD (Australian Comprehensive Cancer and Research Database) clinical database. Cabrini/Monash/Alfred Hospitals have developed a database which will commence collection by the end of 2008.

The initial phase of the audit included gauging the interest of surgeons across Australia and New Zealand and obtaining approval for the audit, development of a minimum dataset (MDS), set up of data collection processes and establishment of the Colorectal Cancer Audit Committee and the Research Subcommittee.

Once data collection processes had been established, approval was sought from ethics committees so that the activity could be undertaken in the first instance at the major metropolitan hospitals and some private hospitals within South Australia. These hospitals included the Royal Adelaide Hospital, the Queen Elizabeth Hospital, Lyell McEwin Health Services, Flinders Medical Centre, Repatriation General Hospital, Flinders Private, Ashford Private and St Andrews Private. Data collection commenced on 1 July 2007.

Data is entered onto a database housed at the RAAS Division of the College. With the establishment of the audit in South Australia well underway participation has increased, and data is now collected and entered into the College database from Queensland and Tasmania. Recently surgeons in New South Wales and Western Australia gained approval to contribute data at some institutions. Since data collection commenced on 1 July 2007, almost 1000 cases have been entered onto the College server and 500 were entered directly into the BioGrid Australia database in Victoria.

The College also approved the audit activity under the Continuing Professional Development Program (Category One: Surgical Audit and Peer Review). Formal notification was received in October 2007 that the audit has been declared under the Australian Government, Commonwealth Qualified Privilege Scheme.

The audit aims to reduce duplication of data entry. Some surgeons who wish to continue to use their own existing databases have agreed to use the MDS. These surgeons were provided with assistance to submit the appropriate ethics applications and have since received approval from their local ethics committees to participate and commence data collection using the MDS.

The audit has been working towards the establishment of a web-based data entry system. This is expected to be available for use in 2009. A reporting suite will also be available and will utilise the data entered into the audit through a number of standard reports which are currently under development.

The Colorectal Cancer Audit Committee has continued to meet on a monthly basis. These meetings have facilitated discussion in all aspects of the project, including establishment issues, funding, management and research. The committee has provided strategic direction, consistency and dedication, which have enabled the audit to progress. This committee has been well supported by the Research Subcommittee whose focus has been implementation of research projects. They have also overseen the utilisation of the data collected within the CSSANZ audit and other data collected as part of the BioGrid Australia collaboration. Other priorities for the committee are to seek additional funding opportunities and to lead the way in initiating research projects using the prospective data.

The Colorectal Cancer Audit Committee and the Research Subcommittee have recently collaborated to develop the Colorectal Cancer Audit, Data Access and Authorship Guidelines. These guidelines will be revised over time. They have recently been circulated to the CSSANZ membership for consideration and feedback.

Ultimately, the aim of the audit is to maintain and improve surgical practices for the purpose of quality assurance. Regular reporting and feedback to surgeons and hospitals continues, and will contribute to the identification of benchmarks, peer review and development of multicentre research projects. Through the collaborative efforts of CSSANZ, the College and BioGrid Australia, the Colorectal Cancer Audit is continuing to work towards achieving these goals.

NATIONAL BREAST CANCER AUDIT

The main objective of the audit is to improve the quality of care offered by surgeons to patients with early breast cancer in Australia and New Zealand. The audit collects patient and hospital demographics as well as information on the diagnostic, surgical and adjuvant management of early breast cancer including pathology results. The audit data is used to compare a surgeon's practice against predetermined quality thresholds (benchmarks), which informs both the surgeon's self-auditing practices and the full clinical audit cycle. The aim is to foster a culture of quality improvement among the surgical community.

This year the NBCA has focused on improving the audit's resources to make contributing data more user-friendly, and providing more benefits to surgeons. In response to concerns from some users that the full length audit was time-consuming and complex to complete, the NBCA has developed a minimum dataset (MDS) comprising only the items most pertinent to assessing performance against the thresholds. The MDS is available on a one-page paper form for invasive cancer cases and ductal carcinoma in-situ cases. The online data entry system is also about to launch a new facility for entering this short form online, streamlining the data submission process even more. NBCA users maintain the option to submit their data using either the full dataset or the minimum dataset.

Other efforts to make the audit more user-friendly include improving the format of the Excel spreadsheet downloaded by surgeons for self-audit or research purposes. The audit's Data Dictionary was also updated with more user-oriented definitions and explanations on how to answer items. Definitions in the Data Dictionary were reviewed and aligned with the newly released guidelines for pathology reporting of early breast cancer prepared by National Breast and Ovarian Cancer Centre (NBOCC).

Following work to assess and improve the data quality and completeness, the NBCA conducted a pilot study of the Standard's Assessment Process through funding from Breast Cancer Network Australia (BCNA). A report was produced showing de-identified surgeons' results against the quality thresholds. The report showed that overall surgeon performance was very good, but that reliable results were harder to obtain for surgeons with a small number of cases.

The NBCA continues to work with institutions such as large hospitals to attempt to capture breast cancer data collected in institutional databases through specialised data linkages, increasing the audit's patient and surgeon coverage.

The audit also continues to produce research based on audit data. Results have been prepared for publication in peer-reviewed journals and presented at relevant healthcare conferences. Information recently published or under preparation includes results on surgeons' involvement with multidisciplinary care teams and breast care nurses, the trend of surgical and adjuvant treatment, and the uptake of key recommendations as an indication of surgeon performance.

A general overview of the audit data by way of a public health report summarising 2007 data is being finalised and will soon be available to the public on the College and NBOCC websites.

DIRECTIONS FOR 2009

The NBCA was selected by the Australian Commission for Safety and Quality in Healthcare to participate in a pilot study assessing proposed guidelines for Australian Clinical Registries. We expect this work will create more improvements for the audit over the coming year.

We will also focus on increasing the profile of the audit and improving surgeon participation. A working party will address issues around increasing the number of surgeons performing breast surgery who participate in the audit, and increasing the number of cases captured by the audit overall. This work will align closely with the Australian Clinical Registries project.

We also aim to increase information materials for surgeons and administrative staff involved in data submission by developing a training manual/information pack for users.

The NBCA continues to build strong relationships with breast cancer groups, BCNA, NBOCC and National Breast Cancer Foundation (NBCF), as well as maintaining our commitment to the surgeons for whom the audit was conceived through our ties with the College's Section of Breast Surgery.

The NBCA gratefully acknowledges NBOCC and NBCF for their continued funding of the NBCA. The current funding arrangement was initiated in 2006 and continues through to June 2009. We also thank the BCNA for their additional funding.



NEW AND EMERGING TECHNIQUES – SURGICAL (NET-S)

- Horizon scanning project
- NET-S on the web

HORIZON SCANNING PROJECT

As medical technologies continue to evolve, the identification of emerging technologies and procedures is becoming increasingly important. Established in 1999, the New and Emerging Techniques - Surgical (NET-S) project aims to identify and assess advances in surgery that are likely to cause a significant impact on the Australian and New Zealand health systems in the near future.

Assessments are presented in the form of prioritising summaries or horizon scanning reports. Prioritising summaries are concise documents that provide the reader with some background of the technology and present the evidence available pertaining to the safety and efficacy of the technology or procedure. Horizon scanning reports are more detailed assessments typically reserved for procedures or technologies that are deemed to be of high impact and have a considerable evidence base. Both prioritising summaries and horizon scanning reports are available on the NET-S website (<http://www.surgeons.org/asernip-s/nets.htm>) and the Australia and New Zealand Horizon Scanning Network (ANZHSN) website (<http://www.horizonscanning.gov.au/>). As a member of Euroscan, all NET-S prioritising summaries are uploaded to the EuroScan database and can be viewed on the Euroscan website (<http://www.euroscan.bham.ac.uk/index.htm>).

This year, NET-S was contracted to conduct horizon scanning assessments by the American College of Surgeons, with a specific focus on general surgery. In addition, the New Zealand Accident Compensation Commission has approached NET-S to conduct horizon scanning on new and emerging treatments related to serious injury as a result of traumatic accidents.

NET-S ON THE WEB

All summaries and horizon scanning reports are available for download on the NET-S website (<http://www.surgeons.org/asernip-s/nets.htm>) and the ANZHSN website (<http://www.horizonscanning.gov.au/>). Contact details are provided for readers who wish to nominate a new technique or comment on completed summaries or reports.

The following is a list of prioritising summaries prepared in 2008:

- Allogenic pancreatic islet cell transplantation
- APACHE-AAA scoring system
- Autofluorescence imaging for colonoscopic adenoma detection
- Autologous fat injection for breast reconstruction
- Balloon-based, circumferential, endoscopic radiofrequency ablation of Barrett's oesophagus
- Bioprosthetic anal fistula plugs
- Circumferential pulmonary vein ablation for atrial fibrillation
- Computed tomography assessment for suspected large bowel obstruction
- Filterwire embolic protection system
- GORE TAG
- Heartmate II ventricular assist device
- Implantable baroreflex stimulation in the treatment of hypertension
- Implantable device for control of pulmonary blood flow
- Kidney transplantation using incompatible blood group donors
- Microdebrider intracapsular tonsillectomy
- Microwave ablation for hepatic tumours
- Mini-cardiopulmonary bypass system
- Minimal incision hip arthroplasty
- Minimally invasive treatment of atrial fibrillation
- Nerve stimulation in thyroid surgery
- Paracor HeartNet cardiac restraint device
- Pediguard pedicle screw placement
- Percutaneous compression plate
- Percutaneous endoscopic colostomy
- Piezosurgery
- Pulsed electron avalanche knife (PEAK-fc)
- Serial transverse enteroplasty
- Wearable defibrillator.

There are two new horizon scanning reports available:

- ABO incompatible kidney transplantation
- Continuous flow ventricular assist devices.



PROJECT ACTIVITIES

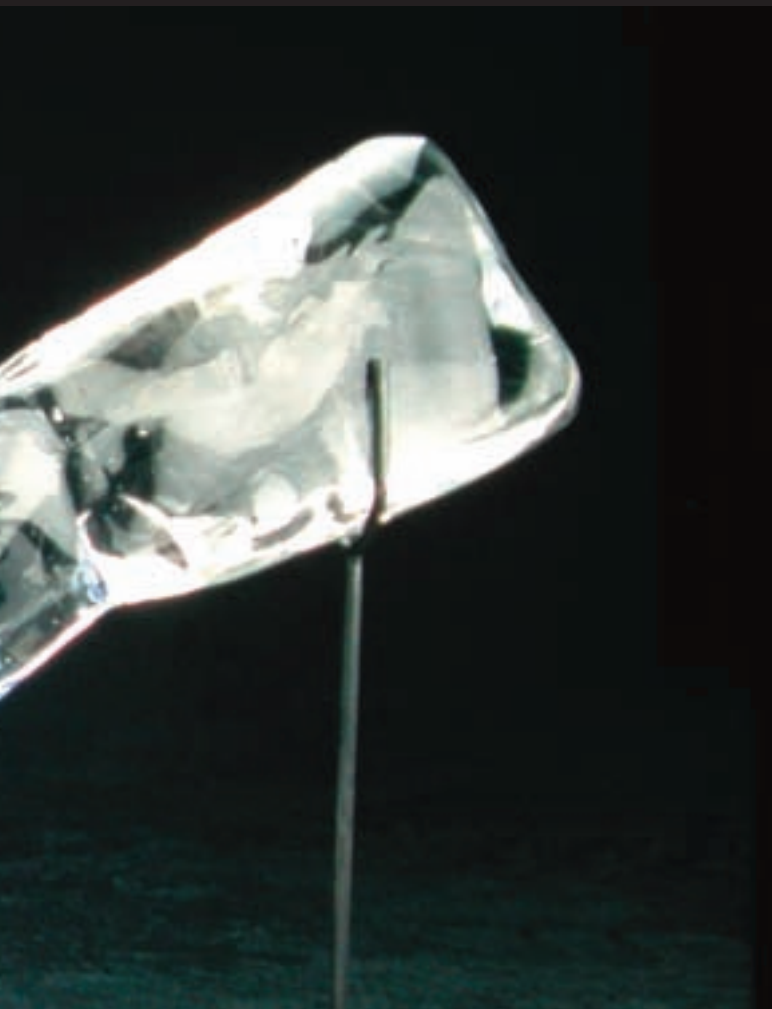
- Consumer involvement
- New contracts
- Promotional activities
- ASERNIP-S website
- ASERNIP-S Advisory Committee
- Representation on external committees
- Education and training
- Personnel

CONSUMER INVOLVEMENT

Consumer involvement in the work of ASERNIP-S ensures that our research is relevant to the needs of patients.

Consumers can provide input on our systematic reviews from the moment a new procedure is nominated for assessment until the final stages of the research process. We thank the two consumer representatives on the ASERNIP-S Advisory Committee, Margaret Charlton from the Health Consumers' Alliance and Jane Doyle, professional communicator, for their excellent contribution. Margaret and Jane comment on our systematic reviews, and work with researchers and surgeons to prepare short summaries, written in easy-to-read language for consumers and posted on our website at <http://www.surgeons.org/asernip-s/consumer.htm>. This year we prepared a consumer summary on the systematic review of permanent and semi-permanent dermal fillers. We continue to have interest from consumers, as gauged by visits to the consumer information page of our website.

We welcome consumer feedback on our consumer summaries via email at asernipsconsumer@surgeons.org. This year a web-based survey was attached to the summaries. In addition we encourage queries from patients on new surgeries, which are responded to by the College's Executive Director of Surgical Affairs.



The National Breast Cancer Audit involves consumers in many aspects of its work. It has been supported by a peak consumer group, the Breast Cancer Network Australia, aimed at improving the quality of healthcare for breast cancer patients through a better adherence to established evidence for best practice.

With the help of our consumer representatives, we establish links with consumer organisations; these contacts help us to disseminate our research findings and learn more about the needs of consumers. This year the College, through ASERNIP-S, has become an organisational member of the Consumers' Health Forum, which has led to a fruitful exchange of ideas. Consumer representatives are also invited to participate in the systematic reviews conducted on behalf of the Medical Services Advisory Committee. We continue to work with a sub-group of Health Technology Assessment International on patient/public participation in this area, which keeps us in touch with the work of similar organisations worldwide. We helped prepare the first draft of an international glossary of medical terms for consumers.

ASERNIP-S greatly values the involvement of consumers in all aspects of the research process. We look forward to increasing the role played by consumers in the future.

NEW CONTRACTS

In June we were successful in extending our work for the Medical Services Advisory Committee (MSAC), in partnership with the Centre for Health Economics Research and Evaluation (CHERE), University of Technology, Sydney. We now have a contract of work for MSAC until June 2011.

The South Australian Department of Health has shown a real commitment to evidence-based medicine in providing us with a contract for provision of research services for a further 3 years.

ASERNIP-S has also been extending its horizon scanning capability with work being conducted for both the American College of Surgeons and the New Zealand Accident Compensation Corporation. ASERNIP-S considers these international efforts to be key in progressing our work and we hope that these two programs will lead to further opportunities.

In October, following a successful tender submission, the National Breast Cancer Audit (NBCA) was selected by the Australian Government's Commission for Safety and Quality in Healthcare to be part of a pilot project assessing the feasibility of proposed operating guidelines for Australian Clinical Quality Registries.

The NBCA has also had other short-term contracts throughout 2008, including a data linkage project in partnership with the National Breast and Ovarian Cancer Centre, a pilot study of surgeon performance against the audit's thresholds for Breast Cancer Network Australia and the provision of some statistical analyses for the Urological Society of Australia and New Zealand.

PROMOTIONAL ACTIVITIES 2008

PEER-REVIEWED PUBLICATIONS

Barnes M, Boulton M, Maddern G, Frittridge R. A model to predict outcomes for endovascular aneurysm repair using preoperative variables. *European Journal of Vascular and Endovascular Surgery* 2008; 35: 571-579

Della Flora E, Wilson T, Martin I, O'Rourke N, Maddern G J. A review of natural orifice transluminal endoscopic surgery™ (NOTES™) for intra-abdominal surgery: applicability to the clinical setting. *Annals of Surgery* 2008; 247(4): 583-602

Maddern G, Boulton M, Ahern E, Babidge W. ASERNIP-S: International trend setting. *ANZ Journal of Surgery* 2008; 78: 853-858

Marsh C, Boulton M, Wang J, Maddern G, Roder D, Kollias J. National breast cancer audit: the use of multidisciplinary care teams by breast surgeons in Australia and New Zealand. *Medical Journal of Australia* 2008; 188(7): 385-388

Pham C, Perera C, Watkin S, Maddern G. Laparoscopic ventral hernia repair: a systematic review. *Surgical Endoscopy* 2008, DOI 10.1007/s00464-008-0182-8

Sturm L, Windsor J, Cosman P, Cregan P, Hewett P, Maddern G. A systematic review of skills transfer after surgical simulation training. *Annals of Surgery* 2008; 248(2): 166-179

Wang J, Boulton M, Roder D, Babidge W, Kollias J, Maddern G. Commentary: How surgical audits can be used to promote the update of surgical evidence. *ANZ Journal of Surgery* 2008; 78: 437-438

Wang J, Boulton M, Tyson S, Babidge W, Zorbas H, Kollias J, Roder D, Maddern G. Trends in surgical treatment of younger patients with breast cancer in Australia and New Zealand. *ANZ Journal of Surgery* 2008; 78: 665-669

Watt A, Cameron A, Sturm L, Lathlean T, Babidge W, Blamey S, Facey K, Hailey D, Norderhaug I, Maddern G. Rapid reviews versus full systematic reviews: An inventory of current methods and practice in health technology assessment. *International Journal of Technology Assessment in Health Care* 2008; 24(2): 133-139

Watt A, Cameron A, Sturm L, Lathlean T, Babidge W, Facey K, Blamey S, Hailey D, Norderhaug I, Maddern G. Rapid versus fully systematic reviews – methods. *International Journal of Technology Assessment in Healthcare* (in press)

Watt A, Patkin M, Sinnott M, Black R, Maddern G. Scalpel injuries in the operating theatre. *British Medical Journal* 2008; 336: 1031

Windsor J, Sturm L, Cosman P, Cregan P, Hewett P, Maddern G. RE: A systematic review of skills transfer after surgical simulation training. *Annals of Surgery* 2008; 248(4): 690-691

OTHER PUBLICATIONS

Simulated Surgical Skills Program. *Royal Australasian College of Surgeons Surgical News*, January / February 2008; 9(1): 35

The National Breast Cancer Audit. *Royal Australasian College of Surgeons Surgical News*, April 2008; 9(3): 6

PRESENTATIONS

Maddern G. *Mortality audits - update and involvement of all specialties and regions*. Surgical Leaders' Forum. Royal Australasian College of Surgeons, Melbourne, 27 February 2008

Maddern G. *Simulation project - is it relevant to all of surgery?* Surgical Leaders' Forum. Royal Australasian College of Surgeons, Melbourne, 27 February 2008

Maddern G. *Research challenges and opportunities in simulation*. International Conference on Surgical Education & Training. Royal Australasian College of Surgeons, Melbourne, 5 March 2008

Maddern G. *Audit/Credentiaing* Younger Fellows Forum. Royal Australasian College of Surgeons Combined Annual Scientific Congress Aberdeen, Hong Kong, 10 May 2008

Maddern G. *National registration and accreditation*. Meeting of Councillors, Specialist Society Presidents, National and Regional Board Chairs. Royal Australasian College of Surgeons Combined Annual Scientific Congress Convention and Exhibition Centre, Hong Kong, 12 May 2008

Maddern G. *BPFET*. Meeting of Councillors, Specialist Society Presidents, National and Regional Board Chairs. Royal Australasian College of Surgeons Combined Annual Scientific Congress Convention and Exhibition Centre, Hong Kong, 12 May 2008

Maddern G. *Focal ablative techniques for CRC metastases*. HPB & UGI Session: Optimising treatment of colorectal cancer metastases. Royal Australasian College of Surgeons Combined Annual Scientific Congress Convention and Exhibition Centre, Hong Kong, 13 May 2008

Maddern G. *Who should be responsible for this - government, industry, the College?* Plenary: Credentialling the surgeon for new technology Royal Australasian College of Surgeons Combined Annual Scientific Congress Convention and Exhibition Centre, Hong Kong, 15 May 2008

Watt A, Patkin M, Sinnott M, Black R, Maddern G. *Scalpel safety in the operative setting*. ACORN, Queensland, 22 May 2008

Single A, Ahern E, Stafinski T. *HTAi consumer glossary*. 5th Annual HTAi meeting, Montreal, Canada, 6 July 2008.

Maddern G. *Rapid reviews or full health technology assessments - what are the needs in decision making?* Parallel Panel Session: HTA products - Roles and functions Fifth Annual HTAi Meeting, Fairmont The Queen Elizabeth Hotel, Montreal, Canada, 7 July 2008

Maddern G. *South Australian Health Technology Advisory Group (HTAG): Policy and procedural guidelines for the introduction of new health technology into the South Australian public hospital system*. Plenary Session: HTA in Hospitals, Fifth Annual HTAi Meeting, Fairmont The Queen Elizabeth Hotel, Montreal, Canada 9 July 2008

Maddern G. *Surgeons - Is procedural credentialling enough*. Credentialling and Health Care Seminar, Royal Adelaide Hospital, Adelaide, 15 August 2008

Maddern G. *Surgical Simulation: do we have the evidence?* SimTect Health 2008, Brisbane, 10 September 2008

Maddern G. *New technology in surgery: how do we know it works?* Vascular 2008 Conference, Adelaide Convention Centre, 14 September 2008

Maddern G. *Surgical simulation – or clinical trial and error*. Vascular 2008 Conference, Adelaide Convention Centre, 14 September 2008

Babidge W. *The National Breast Cancer Audit – Current research and development*. Royal Melbourne Hospital, Melbourne, 30 September 2008

Maddern G. *Adapting health technology assessment to changing health care and social context*. National Health Technology Assessment Seminar: From Evidence to Policy, Kuala Lumpur, Malaysia, 9 October 2008

Maddern G. *Developing assessment system for new health technologies*. National Health Technology Assessment Seminar: From Evidence to Policy, Kuala Lumpur, Malaysia, 9 October 2008

Maddern G. *Health Technology Assessment agencies: the Australian experience*. National Health Technology Assessment Seminar: From Evidence to Policy, Kuala Lumpur, Malaysia, 10 October 2008

Maddern G. *HTA – strategy for the future*. National Health Technology Assessment Seminar: From Evidence to Policy, Kuala Lumpur, Malaysia, 10 October 2008

Maddern G. *Australian experience with HTA for medical devices*. Asia-Pacific Health Policy Summit, J&J Medical Asia-Pacific, Westin Bund Centre, Shanghai, 13 October 2008

Maddern G. *Public-private partnerships/Stakeholder-Industry participation in reimbursement decision making and risk-sharing – Break Out Session*. Asia-Pacific Health Policy Summit, J&J Medical Asia-Pacific, Westin Bund Centre, Shanghai, 13 October 2008

EXTERNALLY-COMMISSIONED PROJECTS

ASERNIP-S has been commissioned to work on:

- the provision of research consultancy services for the Cancer Institute New South Wales
- the Therapeutic Goods Administration (TGA) product evaluation panel.

ASERNIP-S WEBSITE

The ASERNIP-S website (<http://www.surgeons.org/asernip-s/>) has continued to provide site users with detailed information regarding our work. The website, which is accessible directly or via links from the College homepage, provides regular updates on the activities of ASERNIP-S. The full text of our reports can be downloaded free from the site. A comprehensive archive of previous work is also maintained.

Additionally, the web-interface database for the New and Emerging Techniques – Surgical (NET-S) horizon scanning project is linked via the homepage and continues to be regularly updated with new reports and prioritising summaries. Full access to this work via the site continues to be useful to healthcare professionals, policy makers and consumers.

ASERNIP-S remains accredited by HealthInsite, the Australian Government portal website for health information, and HONcode, the international standard for quality health information.

The College is currently restructuring the website for ease of navigation, so we hope to have an improved new look next year.



ASERNIP-S ADVISORY COMMITTEE 2008

The members of the ASERNIP-S Advisory Committee are:

Professor Ian Gough	Chairman, and College President (from June 2008)
Dr Andrew Sutherland	Chairman, and College President (to May 2008)
Ms Margaret Charlton	Consumer Representative, Health Consumers Alliance
Ms Jane Doyle	Consumer Representative
Professor Kingsley Faulkner	College Fellow
Dr David Hailey	Health Technology Assessment Expert
Dr David Hillis	College Chief Executive Officer
Mr Brian Johnston	Chief Executive, Australian Council on Healthcare Standards
Professor Brendon Kearney	MSAC Representative
Professor Guy Maddern	ASERNIP-S Surgical Director
Dr Denise O'Connor	Australasian Cochrane Centre Representative
Dr John Quinn	College Executive Director for Surgical Affairs (Australia)

In May 2008 Dr Andrew Sutherland resigned from the committee due to the completion of his term as College President. We thank him for his valuable contribution while Chairman of the committee.

REPRESENTATION ON EXTERNAL COMMITTEES

ASERNIP-S staff members were represented on the following committees:

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

EDUCATION AND TRAINING

STUDENTS

This year ASERNIP-S supervised research proposal development for four 4th year medical students from the University of Adelaide:

- Geraldine Connolly has spent the past year undertaking a project with the Australian and New Zealand Audit of Surgical Mortality. The focus of Geraldine's project was to quantify the value of peer review with regards to the assessment of surgical performance. The unique challenges of conducting randomised controlled trials in surgery were also investigated.
- Timothy Chan developed a research proposal for further study in the field of surgical simulation. His research proposal was designed to investigate the impact of educational and surgical experience on laparoscopic surgical training outcomes. The successful completion of this research proposal is a requirement of Mr Chan's medical degree; however, it is hoped that this research proposal may also be initiated to complement the findings of the Simulated Surgical Skills program.
- Bianca Djurdjevic worked with the Breast Audit. As part of her medical course this year she developed a research proposal to evaluate the extent of patients' refusal of recommended treatment and its impact on the surgeons' performance level. She determined the proportion of patients who contravene treatment recommendations and the factors relating to the refusal.
- Brittannie Bierteron also worked with the Breast Audit. She developed a research proposal to assess the link between the levels of evidence behind a few selected recommendations in clinical guidelines for breast cancer treatment and their uptake. She also considered the rate of adherence to these recommendations based on data reported by breast surgeons to the National Breast Cancer Audit. This proposal is to test the hypothesis that health professionals are more likely to accept and adhere to recommendations based on a high level of evidence than on lower levels of evidence.

TRAINING OPPORTUNITIES FOR STAFF

Courses and conferences attended by staff members in 2008 included:

- Principles of Questionnaire Design, Australian Bureau of Statistics, Adelaide, March
- Australian College of Operating Room Nurses (ACORN) 13th National Conference, Queensland, May
- Conjoint Annual Scientific Congress of the Royal Australasian College of Surgeons, Hong Kong, May
- Australian Centre for Evidence Based Clinical Practice – Evidence-based clinical practice workshop, Adelaide, June
- Joanna Briggs Institute – Comprehensive systematic review training program, Adelaide, July
- PRINCE-2, Dimension Data Learning Solutions, Adelaide, July
- Time management, Royal Australasian College of Surgeons, Melbourne, July
- Management leadership course, Royal Australasian College of Surgeons, Melbourne, August, September
- Australasian Cochrane Centre workshop - Cochrane protocol and analysis workshop, Adelaide, September
- Health Services Research Association of Australia and New Zealand Workshop - A Fresh Perspective on Health Services Research in South Australia, Adelaide, September.



PERSONNEL

During 2008 we welcomed new Research Officers, Catherine Spirat and Dr Meegan VandePeer. Meryl Altree joined us as Senior Project Manager for the Simulated Surgical Skills Program, Tania Margitich as Project Officer and Julia Cooper as Administrative Officer. The following staff left ASERNIP-S: Maggi Boulton, Ben Hoggan, Julia Cooper, Kate Sloan, Tim Lathlean, Catherine Spirat and Joanne Chesson.

In 2008 we benefited from the expertise of one consultant and a consultancy group:

- **Dr Ann Scott**

Ann Scott originally trained as an animal physiologist and gained her PhD in zoology from the University of NSW in Sydney. Ann spent three years working as a Senior Research Officer for ASERNIP-S before moving to Canada in June 2002 to join the HTA Unit at the Alberta Heritage Foundation for Medical Research. Ann has written numerous systematic reviews and journal articles encompassing such varied fields as surgery, diagnostic imaging, chronic pain management and guideline development. As an active member of the Cochrane Collaboration, Ann continues to develop her skills in systematic review methods and is a member of the Advisory Board for the Cochrane Back Review Group. In January 2006 Ann established a Canadian-based freelance consultancy in HTA and provides external scientific review for various ASERNIP-S reports and projects.

- **CHERE**

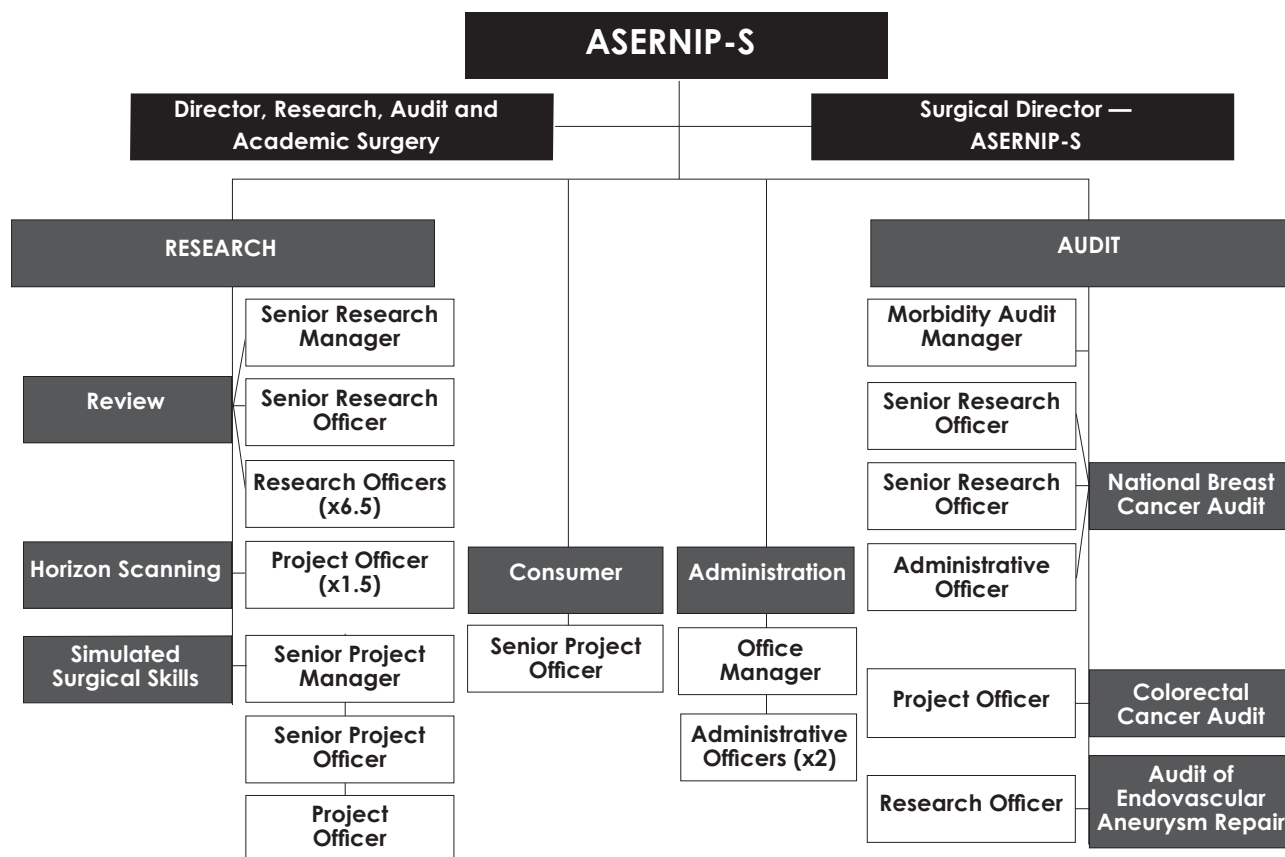
Since April 2007 ASERNIP-S has entered into a collaboration with the Centre for Health Economics Research and Evaluation (CHERE) for assistance with economic evaluation for our health technology assessments. CHERE is a joint initiative of the Faculties of Business and Nursing, Midwifery and Health at the University of Technology, Sydney, in collaboration with Sydney South West Area Health Service. Professor Jane Hall (Director), Associate Professor Marion Haas, Dr Stephen Goodall, Dr Richard Norman and Dr Gisselle Gallego have been assisting with numerous Medical Services Advisory Committee reports in order to provide economic evaluation of procedures under consideration for Medicare funding.

The background of the page features three abstract glass sculptures of human figures. The figures are rendered in a variety of colors including dark green, black, gold, and red. They have a smooth, glossy finish and are positioned in a way that suggests movement or interaction. The central figure is slightly behind the other two, creating a sense of depth. The overall aesthetic is modern and artistic.

STAFF PROFILES

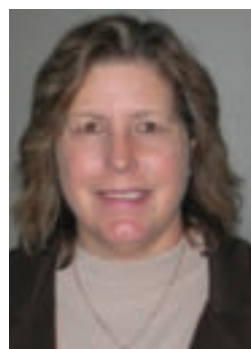
- Professor Guy Maddern
- Dr Wendy Babidge
- Dr Alun Cameron
- Dr Prema Thavaneswaran
- Eleanor Ahern
- Meryl Altree
- Maggi Boulton
- Joanne Chesson
- Deborah Clapp
- Julia Cooper
- Dr Michael Duffield
- Jane Franklin
- Ben Hoggan
- Karen Humphreys
- Louise Kennedy
- Tim Lathlean
- Irving Lee
- Deanne Leopardi
- Tania Margitich
- Nicholas Marlow
- Claire Marsh
- Caryn Perera
- Vendra Severin
- Kate Sloan
- Catherine Spirat
- Lana Sturm
- Belinda Tarca
- Dr Meegan Vanderpeer
- Dr Jim Wang
- Amber Watt
- Luis Zamora

RESEARCH, AUDIT AND ACADEMIC SURGERY DIVISION – ROYAL AUSTRALASIAN COLLEGE OF SURGEONS ASERNIP-S ORGANISATIONAL CHART



ASERNIP-S SURGICAL DIRECTOR PROFESSOR GUY MADDERN

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



DIRECTOR, RESEARCH, AUDIT AND ACADEMIC SURGERY DIVISION, ROYAL AUSTRALASIAN COLLEGE OF SURGEONS DR WENDY BABIDGE

Dr Wendy Babidge is the Director of the Division of Research, Audit and Academic Surgery of the Royal Australasian College of Surgeons. This Division currently supports close to 50 staff members across Australia. As well as directing the ASERNIP-S program, Wendy oversees the College morbidity and mortality audits, the provision of scholarships for surgical research and the fundraising activities associated with this. Another major focus of the Division is to establish a secure web-based system at the College for the purpose of training. Wendy has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business.



ASERNIP-S SENIOR RESEARCH MANAGER

DR ALUN CAMERON

Dr Alun Cameron joined ASERNIP-S in August 2005. He has a Bachelor of Science in Biochemistry (with Medical Biochemistry), and studied cell signaling mechanisms in African trypanosomes during his PhD. Since then he has worked in the field of connective tissue research at Manchester University in the UK, prior to moving to Adelaide. At ASERNIP-S Dr Cameron has been mainly involved with managing MSAC projects and has written or assisted with numerous reports. He now assumes a more senior role in managing the ASERNIP-S research program.

ASERNIP-S SENIOR RESEARCH OFFICER

DR PREMA THAVANESWARAN

Dr Prema Thavaneswaran joined ASERNIP-S in January 2005. She has a Bachelor of Science degree with Honours from the University of Adelaide. Prema has recently completed a PhD investigating the prenatal programming of the Insulin Resistance Syndrome in the aged guinea pig. She is currently undertaking post-graduate studies in public health. At ASERNIP-S Prema conducts systematic reviews and assists other researchers with projects, being a deputy to Dr Cameron.

ASERNIP-S SENIOR PROJECT OFFICER - CONSUMER ELEANOR AHERN

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

ASERNIP-S SENIOR PROJECT MANAGER - SIMULATED SURGICAL SKILLS PROGRAM

MERYL ALTREE

Meryl Aintree joined ASERNIP-S in September 2008. Meryl is a Registered Nurse and holds a Diploma of Applied Science and a Bachelor of Nursing. She has extensive experience in both clinical nursing and management in the South Australian Public Health Sector. She has spent the last 12 years running research trials for the South Australian Clinical Genetics Service, Familial Cancer Unit based at the Women's and Children's Hospital.

ASERNIP-S MORBIDITY AUDIT MANAGER

MAGGI BOULT

Maggi Boulton has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. She joined ASERNIP-S in 1998 and during her tenure developed and managed surgical audits for the College and for the Federal Government. Maggi was also the ASERNIP-S Privacy Officer. Maggi left ASERNIP-S in July.

ASERNIP-S RESEARCH OFFICER

JOANNE CHESSON

Joanne joined ASERNIP-S in August 2008. She has a Bachelor of Biomedical Science Honours degree from The University of Melbourne and majored in Immunology and Microbiology. Her honours thesis focussed on how the early stages of Plasmodium falciparum Malaria induce immune responses in humans. She then worked on international cohort studies on Malaria at The Walter and Eliza Hall Institute of Medical Research for four years. At ASERNIP-S Joanne is involved in the National Breast Cancer Audit.

ASERNIP-S ADMINISTRATIVE OFFICER

DEBORAH CLAPP

Deborah Clapp joined ASERNIP-S in August 2006 to provide additional administrative support to the program. She has a background in administration in the health sector (cosmetic surgery industry), a Bachelor of Arts Degree majoring in English, and certificates in Medical Computing, Medical Terminology and Business Administration.

ASERNIP-S ADMINISTRATIVE OFFICER

JULIA COOPER

Julia Cooper joined ASERNIP-S in April 2008 as an Administrative Officer to provide administrative support primarily to the Simulated Surgical Skills Program, the Scholarships Program and Logbooks. Julia has extensive administrative experience having previously worked in both the Human Resources and Medical Industry. She also holds a Certificate IV in Business (Frontline Management). Julia left ASERNIP-S in July.



ASERNIP-S RESEARCH OFFICER

DR MICHAEL DUFFIELD

Dr 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 has completed his PhD, which involved a molecular biological and electrophysiological investigation of ion channel gating. In 2005 Michael commenced studies in medicine at Flinders University, but he still works at ASERNIP-S on a part-time basis.

ASERNIP-S ADMINISTRATIVE OFFICER

JANE FRANKLIN

Jane Franklin joined ASERNIP-S in January 2001 to provide administrative and reception support to the program. Jane has a background in banking and customer service and a Certificate II in Business (Office Administration). Jane liaises with INAHTA, providing information on projects and publications for international databases. She is also responsible for maintaining specific areas of the ASERNIP-S website.

ASERNIP-S RESEARCH OFFICER

BEN HOGGAN

Ben Hoggan joined ASERNIP-S in January 2007. He has a Bachelor of Science (Psychology) degree from The University of Melbourne and a Bachelor of Psychology (Honours) degree from the University of South Australia. Ben spent the previous two years with the Spencer Gulf Rural Health School conducting research into the propensity for rural secondary students to study medicine, and at ASERNIP-S conducts systematic literature reviews. Ben left ASERNIP-S in June.

ASERNIP-S RESEARCH OFFICER

KAREN HUMPHREYS

Karen Humphreys joined ASERNIP-S in November 2007 to conduct systematic literature reviews. She has a Bachelor of Medical Science (specialising in microbiology) and a Bachelor of Nutrition and Dietetics (with First Class Honours). Her Honours project investigated the nutritional status of patients with chronic obstructive pulmonary disease.

ASERNIP-S ADMINISTRATIVE OFFICER

LOUISE KENNEDY

Louise Kennedy joined ASERNIP-S in December 2002. 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 OFFICER

TIM LATHLEAN

As an undergraduate Tim studied a Bachelor of Behavioural Science, focusing on Psychology and Health Science. Following this, he completed a Bachelor of Science (Honours) through the Flinders University School of Medicine. His honours thesis focused on comparing Chronic Condition Self-Management, involving Pulmonary Rehabilitation and was based at the Flinders Human Behaviour and Health Research Unit (FHBHRU) and also at the Repatriation General Hospital. Tim has spent a number of years in the Australian Army Reserves and currently holds the rank of Lieutenant at 10/27 Battalion Royal South Australia Regiment. He holds a Diploma of Governmental, Operations and Personnel Management, which he has attained through his time as an Officer. Tim left ASERNIP-S in June.

ASERNIP-S PROJECT OFFICER – HORIZON REPORTING

IRVING LEE

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



**ASERNIP-S RESEARCH OFFICER
DEANNE LEOPARDI**

Deanne Leopardi graduated in June 2007 from Flinders University with a Bachelor of Science, specialising in Microbiology. Deanne joined ASERNIP-S in October 2007 as a Research Officer to carry out systematic literature reviews.

**ASERNIP-S PROJECT OFFICER -
SIMULATED SURGICAL SKILLS PROGRAM
TANIA MARGITCH**

Tania has almost completed a Masters of Psychology (Organisational and Human Factors) at the University of Adelaide. Her undergraduate degree was a Bachelor of Health Sciences, including the study of psychology, physiology and public health. At ASERNIP-S, Tania is the Project Officer for the Simulated Surgical Skills Program.

**ASERNIP-S SENIOR PROJECT OFFICER –
SIMULATED SURGICAL SKILLS PROGRAM
NICHOLAS MARLOW**

Nicholas Marlow joined ASERNIP-S in late 2005, and until early 2008 worked in the research division performing systematic reviews. Since 2008 Nicholas has been working on the Simulated Surgical Skills Program as a senior project officer providing clinical design, development and implementation direction for this project.

**ASERNIP-S MORBIDITY MANAGER
CLAIRE MARSH**

Claire Marsh joined ASERNIP-S in August 2005. She has a Bachelor of Health Sciences Honours degree from the University of Adelaide, and majored in public health and psychology throughout her undergraduate course. At ASERNIP-S Claire has worked as a research officer across the National Breast Cancer Audit and the Audit for Endovascular Repair and has now moved into the role of Morbidity Audits Manager working across the National Breast Cancer Audit and the Audit for Endovascular Aneurysm Repair.

**ASERNIP-S RESEARCH OFFICER
CARYN PERERA**

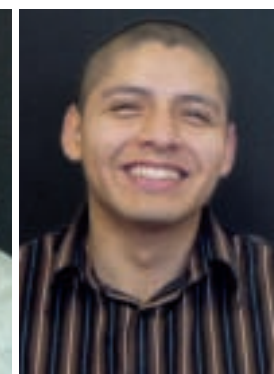
Caryn Perera joined ASERNIP-S in September 2007. She has a Bachelor of Arts degree (Library and Information Management) from the University of South Australia and a Graduate Certificate in Evidence Based Practice from Monash University. Caryn has eight years of experience as a medical librarian with particular interests in literature searching and teaching clinicians how to access evidence. At ASERNIP-S she conducts systematic literature reviews.

**COLORECTAL CANCER AUDIT PROJECT OFFICER
AND LOGBOOKS MANAGER
VENDRA SEVERIN**

Vendra Severin joined ASERNIP-S in July 2007. She is the Colorectal Cancer Audit Project Officer (commenced July 2007) and the Logbooks Manager (commenced February 2008). Previously she has worked in a diverse range of registry/audit environments, specialising in cancer data, more specifically colorectal. She has a Graduate Certificate in Health (Health Service Management), Flinders University South Australia. She is also working in collaboration with other Clinical Research Professionals to establish a Research and Audit Group (established as part of the Clinical Research Professionals Group, affiliated with the Clinical Oncological Society of Australia (COSA)).

**ASERNIP-S SENIOR PROJECT MANAGER –
SIMULATED SURGICAL SKILLS PROGRAM
KATE SLOAN**

Kate joined ASERNIP-S in January 2008. She holds a Bachelor of Behavioural Science and a Master of Gerontology. Kate spent five years living and working in London and returned to Adelaide in late 2007. In London, she worked as a Project Manager at both Guy's and St Thomas' Hospitals and Lambeth Primary Care Trust. At ASERNIP-S, Kate was the Senior Project Manager for the Simulated Surgical Skills Program (SSSP). Kate left ASERNIP-S in August.



**ASERNIP-S RESEARCH OFFICER
CATHERINE SPIRAT**

Catherine Spirat joined ASERNIP-S in March 2008 as a Research Officer. She has a Bachelor of Health Sciences specialising in Health Promotion and Public Health from Flinders University. Prior to joining ASERNIP-S Catherine worked with the Flinders Human Behaviour and Health Research Unit (FHB&HRU) compiling NH&MRC grant applications and ethics protocols. Catherine left ASERNIP-S in October.

**ASERNIP-S RESEARCH OFFICER
LANA STURM**

Lana joined ASERNIP-S in May 2006. She has a Bachelor of Applied Science (Env Hlth) and a Bachelor of Science (Hons) from Flinders University. She has a Grad Dip Comms (PR) from Uni SA. Lana spent the last five years working as an Environmental Health Officer in local government. At ASERNIP-S she conducts systematic literature reviews.

ASERNIP-S OFFICE MANAGER AND PA TO THE DIRECTOR, RESEARCH, AUDIT AND ACADEMIC SURGERY DIVISION

BELINDA TARCA

Belinda Tarca joined ASERNIP-S in September 2006, having most recently worked at the Flinders Medical Centre. Belinda has had extensive administrative experience, working for many years in the State Government. At ASERNIP-S Belinda is the Office Manager and Personal Assistant to the Director, Research, Audit and Academic Surgery Division. Belinda left ASERNIP-S in November.

**ASERNIP-S RESEARCH OFFICER
DR MEEGAN VANDERPEER**

Dr Meegan Vandeppeer joined ASERNIP-S in 2008 to conduct systematic reviews. Over the past eleven years Meegan has been employed in the field of marine research specialising in the nutrition of aquatic animals. She conducted her Honours and PhD projects whilst working at the South Australian

Research and Development Institute Aquatic Sciences Centre (SARDI) in conjunction with Flinders University. After nine years of employment with SARDI, Meegan joined Barneveld Nutrition Pty Ltd, a small private company based in Brisbane, as a consultant animal nutritionist.

**ASERNIP-S RESEARCH OFFICER
DR JIM WANG**

Dr Jim Wang joined ASERNIP-S in January 2006. He has a Bachelor of Science in Agriculture and a Master of Public Health from University of Adelaide. Jim has worked extensively in research environments. At ASERNIP-S he has been involved in conducting systematic literature reviews and other research projects. In November 2006 he moved to the National Breast Cancer Audit. He is interested in analysing the audit data and using this data to assess the utilisation of available evidence in clinical practice.

**ASERNIP-S RESEARCH OFFICER
AMBER WATT**

Amber Watt joined ASERNIP-S in August 2005. She holds a Bachelor of Medical Science from Flinders University, with majors in Physiology and Neuroscience, and has completed a Graduate Diploma of Public Health at The University of Adelaide. At ASERNIP-S, Amber conducts systematic literature reviews, provides support to the South Australian Health Technology Advisory Group (SA-HTAG) and undertakes a variety of other project work.

**ASERNIP-S PROJECT OFFICER – HORIZON REPORTING
LUIS ZAMORA**

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

A detailed glass skull model, likely made of clear or slightly tinted glass, is mounted on a black stand. The skull is shown in profile, facing left. The glass is highly reflective, showing highlights and shadows that define the anatomical features of the skull, including the eye sockets, nasal cavity, and jaw. The background is a neutral, light-colored wall.

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 2003-2007

APPENDIX A HIERARCHY OF EVIDENCE

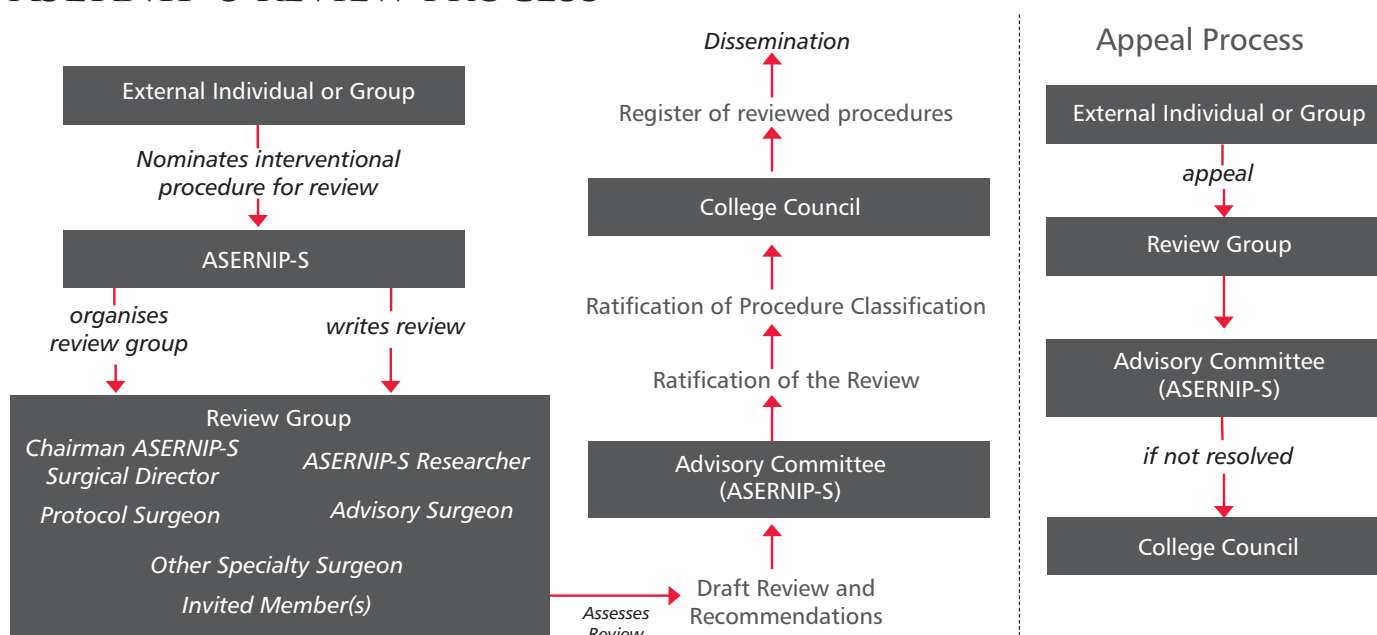
DESIGNATION OF LEVELS OF EVIDENCE¹

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

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

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

APPENDIX B ASERNIP-S REVIEW PROCESS



APPENDIX C

ASERNIP-S CLASSIFICATION SYSTEM

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

EVIDENCE RATING

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

GOOD

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

AVERAGE

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

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

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

ASERNIP-S REPORTS AND PUBLICATIONS 2003 – 2007

2007

ASERNIP-S Report no. 57

Centralisation of selected surgical procedures: implications for Australia, July 2007

ASERNIP-S Report no. 58

A review of policies and processes for the introduction of new interventional procedures, July 2007

ASERNIP-S Report no. 59

Scalpel safety in the operative setting, July 2007

ASERNIP-S Report no. 60

Rapid versus full systematic reviews: an inventory of current methods and practice in Health Technology Assessment, July 2007

ASERNIP-S Report no. 61

Surgical simulation for training: skills transfer to the operating room, July 2007

ASERNIP-S Report no. 62

Natural orifice transluminal endoscopic surgery (NOTES)™ for intra-abdominal surgery, July 2007

Boult M, Maddern G. Clinical Audits: Why and for Whom. *ANZ Journal of Surgery* 2007; 77: 572-578

Boult M, Maddern G, Barnes M, Fitridge R. Factors affecting survival after endovascular aneurysm repair: results from a population based audit. *European Journal of Vascular and Endovascular Surgery* 2007; 34: 156-162

Cuncins-Hearn A, Boult M, Babidge W, Zorbas H, Villanueva E, Evans A, Oliver D, Kollias J, Reeve T, Maddern G. National breast cancer audit: ductal carcinoma in situ management in Australia and New Zealand. *ANZ Journal of Surgery* 2007; 77: 64-68

Colledge J, Parr A, Boult M, Maddern G, Fitridge R. The outcome of endovascular repair of small abdominal aortic aneurysms. *Annals of Surgery* 2007; 245 (2): 326-333

Griffin T, Rowden N, Morgan D, Atkinson R, Woodruff P, Maddern G. Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis: a systematic study. *ANZ Journal of Surgery* 2007; 77: 214-221

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Maddern G. Assuring quality in HPB surgery – efficacy and safety. *HPB* 2007; 9(5): 335-338

Pham C, Greenwood J, Cleland H, Woodruff P, Maddern G. Bioengineered skin substitutes for the management of burns: a systematic review. *Burns* 2007; 33(8): 946-957

Wang J, Smith J, Babidge W, Maddern G. Silver dressings versus other dressings for chronic wounds in a community care setting. *Journal of Wound Care* 2007; 16(8): 352-356

Watt A, Faragher I, Griffin T, Rieger N, Maddern G. Self-expanding metallic stents for relieving malignant colorectal obstruction: a systematic review. *Annals of Surgery* 2007; 246(1): 24-30

Patient Information. *Royal Australasian College of Surgeons Surgical News January* 2007; 8(1): 12-13

Endoscopic treatments for gastroesophageal reflux disease. *Royal Australasian College of Surgeons Surgical News April* 2007; 8(3): 16-17

New Surgery, Centralisation, Safe Surgery – What next from ASERNIP-S. *Royal Australasian College of Surgeons Surgical News May* 2007; 8(4): 24

Robotic surgery: will it be evidence-based or just 'toys for boys'. *Royal Australasian College of Surgeons Surgical News May* 2007; 8(4): 20-21

Radiofrequency ablation for the treatment of liver tumours. *Royal Australasian College of Surgeons Surgical News June* 2007; 8(5): 40-41

ASERNIP-S Update. *Royal Australasian College of Surgeons Surgical News September* 2007; 8(8): 35

Surgery in the abdominal cavity through natural openings. *Royal Australasian College of Surgeons Surgical News September* 2007; 8(8): 36-37

New reviews of surgical procedures. *HealthInsite News*, 30 October 2007

ASERNIP-S update. *General Surgeons Australia Newsletter*, November 2007

Surgical simulation training: skills transfer to the clinical setting. *Royal Australasian College of Surgeons Surgical News November-December* 2007; 8(10): 12

Seamless surgery. *Science Show on ABC Radio National December* 2007. Maddern G interviewed.

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ASERNIP-S Report No. 46

Bioengineered skin substitutes for the management of burns, August 2006

ASERNIP-S Report No. 49

Self-expanding metallic stents for relieving malignant colorectal obstruction, August 2006

ASERNIP-S Report No. 52

Bioengineered skin substitutes for the management of wounds, August 2006

ASERNIP-S Report No. 53

Surgical simulation (update), August 2006

ASERNIP-S Report No. 54

Endoscopic treatments for gastro-oesophageal reflux disease: an accelerated systematic review, August 2006

ASERNIP-S Report No. 56

Radiofrequency ablation for the treatment of liver tumours (update), August 2006

Boult M, Babidge W, Maddern G, Barnes M, Fitridge R on behalf of the Audit Reference Group. Predictors of success following endovascular aneurysm repair: mid-term results. *European Journal of Vascular and Endovascular Surgery* 2006; 31: 123-129

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ASERNIP-S update. *General Surgeons Australia Newsletter*, December 2006; pp.5-6

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ASERNIP-S Report No. 30

Sentinel Lymph Node Biopsy in Breast Cancer – Diagnostic (MSAC), March 2005

ASERNIP-S Report No. 40

Carotid Percutaneous Transluminal Angioplasty with Stenting (MSAC), March 2005

ASERNIP-S Report No. 44

Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis, June 2005

ASERNIP-S Report No. 48

Laparoscopic radical prostatectomy, June 2005

ASERNIP-S Report No. 50

Sentinel Lymph Node Biopsy in Breast Cancer – Safety and efficacy (MSAC), March 2005

ASERNIP-S Report No. 51

Lung volume reduction surgery for emphysema: systematic review of studies comparing different procedures (CCOHTA), August 2005

Boult M, Cuncins-Hearn A, Tyson S, Kollias J, Babidge W, Maddern G. National Breast Cancer Audit: establishing a web-based data system. *Australia and New Zealand Journal of Surgery* October 2005; 75(10): 844-847

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Intraoperative Ablation for the Treatment of Atrial Fibrillation, July 2004

ASERNIP-S Report No. 41
Laparoscopic Ventral Hernia Repair: An Accelerated Systematic Review, July 2004

ASERNIP-S Report No. 45
Da Vinci Surgical Robotic System: A Technology Overview, July 2004

ASERNIP-S Report No. 22
Live-Donor Liver Transplantation – Adult Donor Outcomes, October 2004

ASERNIP-S Report No. 34
Live-Donor Liver Transplantation – Adult Recipient Outcomes, October 2004

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Comparison of lung volume reduction surgery with medical management of emphysema (CCOHTA), December 2004

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NET-S horizon scanning project values your input. *RACS Surgical News* August 2004; 5(7): 19

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) assess new surgeries. *Australian Health Review* September 2004; 28(1): 143-144

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ASERNIP-S Report No. 32
Transanal Endoscopic Microsurgery (MSAC), March 2003

ASERNIP-S Report No. 36
Radiofrequency Ablation of Liver Tumours (MSAC), May 2003

ASERNIP-S Report No. 42
Implantable Spinal Infusion Devices for Chronic Pain and Spasticity: Accelerated systematic review, May 2003

ASERNIP-S Report No. 23
Holmium Laser Prostatectomy for Benign Prostatic Hyperplasia, June 2003

ASERNIP-S Report No. 35
Laparoscopic Live-donor Nephrectomy: Second update and re-appraisal, June 2003

ASERNIP-S Report No. 43
Spinal Cord Stimulation/Neurostimulation: Accelerated systematic review, June 2003

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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.

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