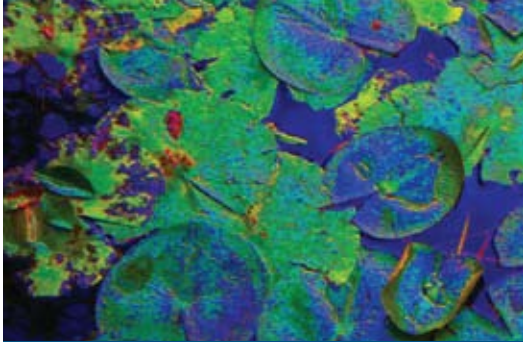
Annual Report 2009

Australian Safety and Efficacy Register of New Interventional Procedures — Surgical

Royal Australasian College of Surgeons

ASERNIP-S

Contents



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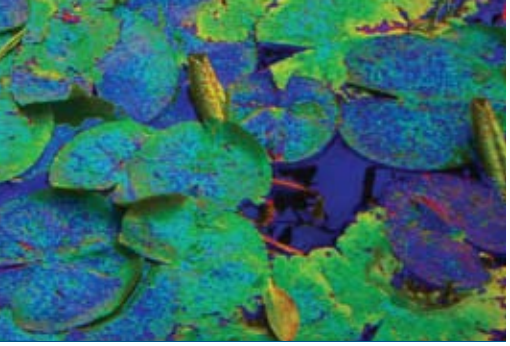
Photographs in this report provided courtesy of Vendra Severin, Bi-National Colorectal Cancer Audit Project Manager, Logbooks Manager and photographer



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, evidence essential reports 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

ASERNIP-S starts its twelfth year more relevant and needed than ever. The pace of technological change is increasing, and the need to assess and audit new surgical procedures, and advise surgeons, hospitals, government and patients of the outcomes, is vital.

Over the last eleven years ASERNIP-S has become the world authority on new surgical technology assessment. This has been due to high quality advice provided by Fellows and meticulous, dedicated staff who have analysed the available literature. The work has been published in the world's best surgical journals, and recent input of a trilogy of papers in *The Lancet* on assessment of surgical innovation was driven in part by the ASERNIP-S experience.

"The pace of technological change is increasing, and the need to assess and audit new surgical procedures, and advise surgeons, hospitals, government and patients of the outcomes, is vital."

While there are many individuals who have contributed to the development of the organisation, the vision of Colin McCrae, the College President who created ASERNIP-S, and the tireless energy of Dr Wendy Babidge, Director of Research, Audit and Academic Surgery, have been vital to its birth and growth.

Recently the College Council commenced a review of ASERNIP-S to guide the way forward. The findings of the review support my opening comments. They reaffirm the need for ASERNIP-S to be bound to the College and the University system; the organisation must also become more flexible with funds held over to develop new initiatives and cushion funding shortages. To date, ASERNIP-S has been almost no burden on College funds, obtaining over 98% of its funds externally. This principle should hold, but the College must help to maintain the function and capacity of ASERNIP-S, else others will, and their understanding of surgery, surgeons and the diseases we treat is likely to be less informed.

ASERNIP-S Reviews

- New assessments completed
- Assessments in progress
- Other commissioned projects
- Procedure nominations

Systematic reviews

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

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.

Evidence essentials

The evidence essentials report is designed to inform on the existence and findings of high-level evidence such as systematic reviews and health technology assessments. In this way it reduces duplication of endeavour and provides rapid and timely information to interested end-users, including those who have approached ASERNIP-S to investigate the given topic. The evidence essentials report provides a summary of a high-level evidence base, including an appraisal of the quality and appropriateness of the published evidence; a commentary on the appropriateness of the data to the Australian locality (if possible); and a summary of the overall conclusions of the published evidence.

New assessments completed

Systematic literature reviews

- Permanent and semi-permanent dermal fillers
  ASERNIP-S Report no. 55
- The effect of fatigue on surgeon performance and surgical outcomes
  ASERNIP-S Report no. 68

Evidence essentials

- Endoscopic thoracic sympathectomy
  ASERNIP-S Report no. 71
- Neoadjuvant radiochemotherapy for rectal cancer
  ASERNIP-S Report no. 72
- Radiofrequency ablation for the treatment of renal tumours
  ASERNIP-S Report no. 73

Reviews for other organisations

- A rapid review of robotic-assisted surgery for urological, cardiac and gynaecological procedures (Department of Human Services, Victoria)
- A brief review of fast-track surgery and enhanced recovery after surgery (ERAS) programs (Department of Human Services, Victoria)
- Sacral nerve stimulation for urinary indications (MSAC Application 1115)
- Computer-navigated total knee arthroplasty (MSAC Application 1123)

Permanent and semi-permanent dermal fillers

ASERNIP-S Report no. 55

Objective

Dermal fillers have become a popular means of addressing contour defects resulting from ageing, photo-damage, disease and scarification. The aim of this review was to assess the safety and efficacy of injectable semi-permanent and permanent dermal fillers in comparison with other injectable methods of facial augmentation for age-related wrinkle reduction, and for aesthetic improvement of human immunodeficiency virus (HIV)-associated facial lipoatrophy.

Methods

Search strategy: Studies were identified by searching EMBASE, CINAHL, PubMed, The Cochrane Library and Current Contents from inception to July 2008. The Clinical Trials Database (US), NHS Centre for Research and Dissemination Databases (UK), National Research Register (UK), Meta Register of Controlled Trials, and the Australian Clinical Trials Registry were also searched in July 2008. Additional articles were identified through reference sections of the retrieved studies.

Study selection: Systematic reviews, randomised controlled trials (RCTs), non-randomised comparative studies and case series of at least 40 patients reporting the use of injectable semipermanent and permanent dermal fillers for age-related lines and wrinkles, and for HIV-associated facial lipoatrophy were included for review. Efficacy outcomes included changes in skin thickness, observer ratings of appearance, success of treatment, patient/practitioner satisfaction and quality of life. Safety outcomes included mortality, allergic reactions, granuloma formation, palpable lumpiness, abscess formation and infections.

Data collection and analysis: Data from the included studies were extracted by an ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Statistical pooling was not appropriate due to the study heterogeneity.

Results

A total of 20 studies were included in this review: four RCTs, one pseudo-RCT, two non-randomised comparative studies and 13 case series. The comparator used in the studies was often a temporary filler, which by its nature does not last as long as a permanent or semipermanent filler and has a different mechanism of action. For age-related lines and wrinkles, and for HIV-associated facial lipoatrophy patients, permanent and semi-permanent dermal fillers increased skin thickness or improved subjective ratings of appearance and resulted in high patient satisfaction.

Long-term efficacy data were scarce, but appeared good in the few studies that reported it. There was great variation in the level of adverse event reporting for both interventions. In general, many adverse events were transient and mild in nature, with the majority being associated with the injection process and resolving within a matter of days. Lumps were reported in many of the studies included in the review but received little follow-up. Long-term safety was limited and hence could not be determined.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of injectable semi-permanent and permanent dermal fillers in comparison with other injectable methods of facial augmentation for age-related wrinkle reduction, and for aesthetic improvement of human immunodeficiency virus (HIV)-associated facial lipoatrophy:

Classifications

Evidence rating

The evidence base in this review for the use of permanent and semi-permanent dermal fillers for age-related lines and wrinkles is poor, and for HIV-associated lipoatrophy is average.

The review was limited by the lack of a valid comparator for long-term outcomes. The included studies were of variable quality, and did not employ similar study protocols. This variation prevented statistical pooling and limited the conclusions which could be drawn.

Safety

From the limited data included in this systematic review, permanent and semi-permanent dermal fillers appear at least as safe as temporary fillers in the short term in those studies that compared them. Long-term safety could not be determined.

Efficacy

The treatment of age-related lines and wrinkles, and the effects of HIV-associated lipoatrophy, is more efficacious with permanent and semi-permanent dermal fillers than with temporary fillers in those studies that compared them. Case series evidence suggests that permanent and semi-permanent dermal fillers achieve their objective, which is to

decrease the visible (objective or subjective) effects of age-related changes for HIV-associated facial lipoatrophy, with high patient satisfaction.

Clinical and research recommendations

It is recommended that further research be done on:

- long-term efficacy of permanent and semi-permanent dermal fillers
- long-term safety of permanent and semi-permanent dermal fillers, including the nature and outcomes of lumps
- facial changes around permanent and semi-permanent dermal fillers, and whether the face can adequately accommodate them long term
- potential gender differences in response to permanent and semi-permanent dermal fillers
- short- and long-term quality of life outcomes after permanent and semi-permanent dermal filler treatment
- the development, and/or validation of assessment tools for use in cosmetic intervention studies
- the development of training standards to aid physicians with injection techniques and product placement.

Review Group membership

Protocol Surgeon: Mr Rodney Cooter
Advisory Surgeon: Mr Keith Mutimer
Other Specialty Surgeon: Mr John Graham
ASERNIP-S Surgical Director: Professor Guy Maddern
ASERNIP-S Researcher: Ms Lana Sturm

THE EFFECT OF FATIGUE ON SURGEON PERFORMANCE AND SURGICAL OUTCOMES

ASERNIP-S Report no. 68

OBJECTIVE

Fatigue has been shown to adversely affect the performance of individuals in various situations. Fatigue has been widely studied in relation to poor performance outcomes in drivers, pilots and industrial workers. There is growing concern that fatigue and extended surgical working hours may contribute to poor performance in surgery. The objective of this review was to investigate the effect of fatigue on surgeons and surgical outcomes, and to investigate the impact of fatigue on the cost of surgery and surgical training, through a systematic review of the literature.

METHODS

Search strategy: Studies were identified by searching EMBASE, CINAHL, PubMed, The Cochrane Library and Current Contents from inception to June 2008. The Clinical Trials Database (US), NHS Centre for Research and Dissemination Databases (UK), National Research Register (UK), Meta Register of Controlled Trials, and the Australian Clinical Trials Registry were also searched in June 2008. Additional articles were identified through reference sections of the retrieved studies.

Study selection: Systematic reviews, randomised controlled trials (RCTs), non-randomised comparative studies and case series (pre-test/post-test outcomes) examining the effect of fatigue on clinical, academic, cognitive or psychomotor performance of surgeons or surgical trainees, and on the cost of surgery and surgical training, were included.

Data collection and analysis: Data from the included studies were extracted by an ASERNIP-S researcher using standardised data extraction tables developed a priori and checked by a second researcher. Statistical pooling was not appropriate due to the study heterogeneity.

RESULTS

A total of 20 studies were included for review: two RCTs, seven non-randomised comparative studies and 11 case series (pre-test/post-test outcomes). Studies were of variable quality and differed in study design. No economic evaluations were found.

Clinical performance (five studies): Three non-randomised comparative studies failed to demonstrate any significant clinical differences between the sleep-deprived and non sleep-deprived groups. One non-randomised comparative study found that when residents operated on a not on call day, complications were 45% more likely to occur when the resident had been on call than not on call the day before ($P<0.02$). A case series study found that being on call every other night was associated with significantly greater levels of fatigue ($P\leq0.05$) and stress ($P\leq0.05$), and less operating room participation (P value not reported) and overall satisfaction ($P\leq0.05$), when compared with the every fourth night with cross-cover schedule, but not with the frequency of reported errors.

Academic performance (two studies): Two non-randomised comparative studies demonstrated that being on call the night before the American Board of Surgery In Training Examination did not affect performance when compared with those not on call the night before the examination.

Cognitive performance (five studies): RCT evidence (one study) indicated that sleep deprivation had no effect on factual recall and concentration. One non-randomised comparative study reported no differences within or between residents in relation to clear thinking, judgment, memory and learning when residents were acutely fatigued. Evidence from three case series studies suggested that there were some variations in cognitive performance when participants were tired, but only for some variables in some studies, or only for certain individuals.

Psychomotor skill performance (11 studies): RCT evidence (two studies) reported no significant differences in psychomotor performance between rested and unrested groups. Non-randomised comparative studies (one study) and case series studies (eight studies) provided more mixed data: for performance time, hand movements and manual dexterity, approximately half of the studies found no significant differences or improvements between the rested and fatigued states post-call, while the other half reported decrements in performance when participants were fatigued. Errors were more likely to occur post-call. Surgical residents with less surgical training/experience appeared to be more affected by sleep deprivation than more senior residents.

SUMMARY

There is a paucity of evidence investigating the effects of sleep loss and fatigue on the performance of surgeons and subsequent clinical outcomes. The overall weight of (poor) evidence shows that clinical, academic and cognitive performance are not proven to be affected by sleep deprivation or fatigue and that psychomotor performance

may or may not be. Variations in results were in some cases attributable to the level of training of participants, and between-subject differences. Many studies used surrogate markers to measure performance, although the relationship between these markers to actual clinical performance is unclear. It appears that fatigue can be compensated for in the acute operating room setting, but it is unclear what impact it has on normal functions. The search strategy did not identify any economic evaluations, resulting in an inability to comment on the financial effect of fatigue on surgery and surgical training. We acknowledge that it would be beneficial to compare the results of this systematic review with data from professions other than the field of surgery. A systematic assessment of fatigue in other professions, such as aeronautics, transport, military and shift workers, was beyond the scope of this current assessment. Overall, these reports generally demonstrated similar findings to this review, although some individual reports written within these industries have suggested detrimental effects of fatigue on performance.

Conclusion

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classification and recommendations concerning the effect of fatigue on the performance of surgeons and surgery:

Classifications

Evidence rating

The evidence-base in this review is rated as poor. The studies included were of variable quality, differed in study design, and many used surrogate markers to assess performance, resulting in an inability to draw solid conclusions.

Clinical and research recommendations

It is recommended that further research be done into:

- the identification of surrogate markers, if any, to actual clinical performance, and the strength of the relationship between these surrogate markers (e.g. cognitive performance) and actual clinical performance
- the development of a clearer definition of fatigue and its relationship to sleep deprivation
- the development of common numerical values for acute and chronic sleep deprivation
- the effect of acute sleep deprivation on performance
- the effects of acute sleep deprivation on top of chronic partial sleep loss on performance
- comparison of sleep-deprived surgeons with those who have had at least one week of normal sleep
- comparison of performance at difference times of day to assess outcomes at different circadian points
- comparison of performance of inexperienced surgeons with experienced surgeons with respect to fatigue and sleep loss
- the determination of the impact of fatigue on the cost of surgery and surgical training.

Review Group membership

Advisory Panel members: Professor Drew Dawson, Professor Richard Vaughan, Mr Peter Hewett, Associate Professor Andrew Hill, Mr John Graham

ASERNIP-S Surgical Director: Professor Guy Maddern

ASERNIP-S Researcher: Ms Lana Sturm

Assessments in progress

Systematic literature reviews

- Autologous fat transfer for cosmetic and reconstructive breast augmentation ASERNIP-S Report no. 70

Other commissioned projects

Simulated Surgical Skills Program

The Simulated Surgical Skills Program (SSSP), 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 program will also develop a 'train the trainer' program to assess the best way to teach the use of the chosen surgical simulators.

Data collection for curriculum development is well underway in South Australia, Western Australia and Victoria; the Queensland site is planned to begin in early 2010. In New South Wales the SSSP will operate from two fixed sites by the end of 2009; in addition, a Mobile Simulation Unit containing laparoscopic simulators will travel to metropolitan and country SET trainees. This high-tech van will enable those training outside the city centres to have access to this innovative and valuable training program.

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
- endoscopic stapling of pharyngeal pouch
- 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
- single port laparoscopy
- 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

Data collection

- Bi-National Colorectal Cancer Audit
- National Breast Cancer Audit
- Australian and New Zealand Gastric & Oesophageal Surgeons Association Audit
- Audit for Endovascular Repair of Abdominal Aortic Aneurysms

Bi-National Colorectal Cancer Audit

The Bi-National Colorectal Cancer Audit (BCCA) is an important activity for the Colorectal Surgical Society of Australia and New Zealand (CSSANZ). In Australia, there are now over 3000 episodes entered into the database from across the regions, including Victoria, South Australia, Tasmania, New South Wales and Queensland. In New Zealand, surgeons have commenced data collection; the existing data collection processes will now incorporate the BCCA minimum dataset which will see electronic data capture occur. Data entry support is being offered to New Zealand surgeons by the project team at the College in South Australia, and will be facilitated through a number of initiatives. This support is extended to all CSSANZ members and non-members who wish to submit their data into the audit.

The BCCA is actively encouraging the use of the data through research projects. In June 2009 the Cancer Council launched a national advocacy campaign, Get Behind Bowel Screening, to encourage the Australian Government to expand the National Bowel Cancer Screening Program (NBCSP) to include biennial screening for all Australians 50 years and over. Central to the launch was the release of new data from the BCCA, which revealed that the NBCSP is finding twice the number of bowel cancers at stage A compared with those symptomatic cases discovered outside the program. This data provided the first specific evidence on the efficacy of the NBCSP, and added to the convincing body of research in favour of making bowel cancer screening accessible to everyone over 50.

The BCCA data has also been used in a Cancer Council advocacy document that will go to all federal members of parliament; this document has featured on the campaign website and has formed part of the Cancer Council's 2010 Budget Submission.

Through the audit the CSSANZ will continue to work towards the ultimate aim, which is to maintain and improve surgical practices for the purpose of quality assurance. This will continue to be facilitated through regular reporting and feedback to surgeons and hospitals, and will contribute to the identification of benchmarks, peer review and development of multi-centre research projects.

The BCCA wishes to acknowledge the continued financial support of Covidien and the Ludwig Institute for Cancer Research in 2009.

National Breast Cancer Audit

The main objective of the National Breast Cancer Audit (NBCA) is to improve the quality of care offered by surgeons to patients with early breast cancer in Australia and New Zealand. The audit data is used to compare a surgeon's practice against predetermined quality thresholds (benchmarks), with the aim of fostering a culture of quality improvement among the surgical community. In 2008/09, 257 surgeons reported data to the NBCA. Currently we have received around 8000 cases from 2008 and 3497 from 2009, although data will continue to be entered for these years.

NBCA in transition

The second half of 2009 has seen a transition period for NBCA; the recent funding agreement with National Breast and Ovarian Cancer Centre (NBOCC) ended in June 2009 and was not renewed. We continue to maintain this long-term relationship, however, through NBOCC's involvement with the Steering Committee and Evidence and Performance Subcommittee. Additionally, we hope to continue research collaborations between the two organisations.

In May 2009 at the College's Annual Scientific Congress the formation of the Breast Surgeons' Society of Australia and New Zealand (Breast SurgANZ) was announced. Breast SurgANZ will become the peak membership body for surgeons performing breast cancer surgery in Australia and New Zealand and will take over the responsibility of the NBCA. The College will continue to manage the project from its ASERNIP-S offices in Adelaide.

Australian Clinical Quality Registries Project

In October 2008, the NBCA was selected as one of six similar projects by the Australian Commission for Safety and Quality in Health Care to participate in the 12-month project Testing and Validating Draft Operating Principles and Technical Standards for Australian Clinical Quality Registries. This project allowed the NBCA to assess the audit against the draft principles and implement or flag a number of improvements. Feedback was provided to the Commission on these principles and standards based on our review over the past 12 months. For more information on this project visit http://www.health.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_CQRegistries or email the NBCA Help Desk.

Key progress areas for 2009

- The Minimum Dataset Online (MDS) was launched in March:
  - Surgeons can choose between the long and short forms, or switch between the two.
  - MDS appears as a single scrolling page allowing for fast and easy data entry.
  - New prompts remind surgeons to make sure their cases are complete.
  - Incomplete cases are shown with a red cross and a list can be downloaded to help with filling in missing data.
  - Since the implementation of the MDS online, over 50% of cases have been submitted using the new form and the lag time between surgery and data entry was improved by 2 months.
  - Completeness has also improved by 20%, which shows that the easier format and the reminder prompts are working well to improve data quality.

- A new generic institutional data uploading program has been developed which involves data from large hospitals being transformed in-house to match the NBCA dataset:
  - It is cheaper and more timely than outsourcing this work to IT consultants.
  - The bulk upload software developed by the programmers is generic, enabling its re-use for multiple datasets.
  - The new system has successfully uploaded a batch of about 1000 cases for Auckland surgeons so far.

- The Evidence and Performance Subcommittee has been considering two new key performance indicators as part of the process to improve care for all people with early breast cancer through the application of a full cycle of clinical audit. This involves:
  - referral for chest wall irradiation for high risk invasive cases after mastectomy
  - referral to a medical oncologist for moderate to high risk cases of invasive breast cancer.

- The switch to an opt-out patient consent process will improve data capture and reduce the burden on surgeons and patients. New patient information and opt-out consent forms are available from the website.

- A new online data entry manual for the website is available online. Please contact the NBCA Help Desk if you prefer a hard copy.

- The NBCA and Breast Cancer Network Australia (BCNA) continue their strong collaborative work. This year a link to our surgeon participation list was added to the BCNA website. We collaborated to prepare summaries of NBCA articles written in lay language which were also uploaded on the website.

Survival analysis

In 2008 the NBOCC sponsored a successful data linkage project between the NBCA and the Australian Institute of Health and Welfare's National Death Index. This allowed us to gain the patient outcome data for cases submitted to the audit. In 2010 the partnership will again look at this data for the analyses of several key interest areas relating to survival from early breast cancer and data collected by the NBCA.

For any further information regarding the National Breast Cancer Audit or to provide feedback on any issue please contact the Help Desk on: 61 8 8363 7513 or college.breast.audit@surgeons.org.

All National Breast Cancer Audit reports, research, forms and other materials are available from www.surgeons.org/nbca.

ANZGOSA Audit

ASERNIP-S will manage a new national database for the Australian and New Zealand Gastric & Oesophageal Surgeons Association (ANZGOSA). This will involve further development of a new web-enabled database, based on a previous dataset of the Sydney Upper Gastrointestinal Surgeons Society; the new database will be available to all ANZGOSA members.

For more information on the ANZGOSA Audit please contact Senior Research Officer, ASERNIP-S, Primali de Silva at primali.desilva@surgeons.org, or Executive Officer, ANZGOSA, Leanne Rogers at leanne.rogers@surgeons.org.

Audit for Endovascular Repair of Abdominal Aortic Aneurysms (EVAR)

In 2009 the final report of the EVAR Audit was prepared and released. The EVAR Audit began in 1999 and followed 961 patients who had the procedure. Up to 8 years of follow-up was obtained for surviving patients. The audit has resulted in permanent funding of two MBS item numbers for the procedure and the development of a predictive model. The predictive model was validated this year using data from the UK. ASERNIP-S gratefully acknowledges the funding provided by Cook Australia for the past two years, and the dedication of the surgeons involved in this audit who dutifully contributed data for many years. The final report, predictive model and St George's UK data report prepared by CSIRO are all available on the website at www.surgeons.org/asernip-s/audit.htm.

New and Emerging Techniques – Surgical (NET-S)

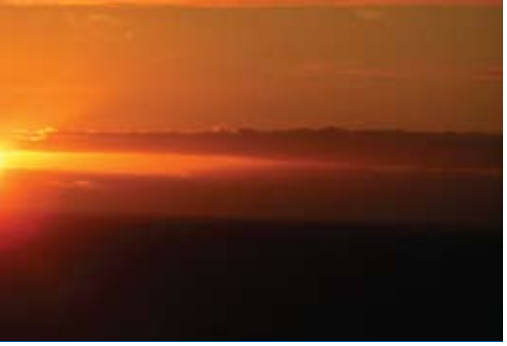
- Horizon scanning project
- NET-S on the web

NET-S 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 substantial impact on the Australian and New Zealand health systems in the near future. This 'early warning system' gives clinicians and policy makers access to unbiased, evidence-based recommendations on the safety and efficacy of these new technologies, thereby facilitating efficient resource allocation and better patient outcomes.

The majority of our 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 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 substantial 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 at the Euroscan website as well (http://www.euroscan.bham.ac.uk/index.htm).

The NET-S project works with the HealthPACT Committee of the ANZHSN, which is managed from the Department of Health and Ageing and continues to perform assessments on emerging technologies following the extension of our contract. NET-S continues to work with the New Zealand Accident Compensation Corporation and now covers a broader range of health topics beyond the area of surgery. In addition, our work with the American College of Surgeons continues to expand our areas of expertise.



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/device or comment on completed assessments.

Prioritising summaries prepared in 2009:

- EsophyX™ system for the treatment of symptomatic chronic gastro-oesophageal reflux disease
- Dermagold™ shock wave therapy for soft tissue wounds
- transoral robotic surgery for head and neck cancers
- percutaneous compression plate for intertrochanteric hip fractures
- autofluorescence imaging for colonoscopic adenoma detection
- totally endoscopic coronary artery bypass surgery (da Vinci System)
- tumour treating fields for glioblastoma multiforme
- dynamic wound closure
- single incision laparoscopic cholecystectomy
- minimally invasive robot-assisted unicompartmental knee arthroplasty
- intra-abdominal vagal blocking for the treatment of obesity
- percutaneous pulmonary valve implantation
- robot-assisted thyroidectomy
- transvaginal cholecystectomy
- total mesometrial resection.

Horizon scanning reports prepared in 2009:

- desensitisation protocols for human leukocyte antigen antibodies in renal transplantation
- filter-type embolic protection devices for carotid artery stenting
- image-guided intensity modulated radiotherapy.

Horizon scanning briefs prepared for the New Zealand Accident Compensation Corporation in 2009:

- diffusion tensor imaging and MR spectroscopic imaging for the detection of mild traumatic brain injury
- dynamic stabilisation devices
- targeted muscle reinnervation
- Cool-Cap® device for hypoxic-ischaemic encephalopathy
- diaphragm pacing system
- biomarkers for traumatic brain injury
- DEKA prosthetic arm
- bone morphogenic proteins
- collaborative wheelchair assistant
- tongue drive system for direction of powered wheelchairs
- telemedicine for falls prevention.

Horizon scanning assessments prepared for the American College of Surgeons in 2009:

- robot-assisted laparoscopic adrenalectomy
- robotic colorectal surgery
- sacral nerve stimulation for the treatment of constipation.

Project Activities

Project activities

- Consumer involvement
- New contracts
- Promotional activities
- Externally-commissioned projects
- ASERNIP-S website
- ASERNIP-S Advisory Committee
- Representation on external committees
- Students
- Personnel

Consumer involvement 2009

Consumers continue to be involved at all stages of the ASERNIP-S process, from nominating a procedure for assessment to preparing consumer information. This input ensures that our work is relevant for patients and carers, and accessible to the general public.

We receive expert advice from two consumer representatives on the ASERNIP-S Advisory Committee, Margaret Charlton from the Health Consumers' Alliance and Jane Doyle, professional communicator. Margaret and Jane focus on the systematic review process, and help us to write plain English consumer summaries which are posted on our website at http://www.surgeons.org/asernip-s/consumer.htm. Many consumers search our site for this type of information, which can be used when patients and doctors make decisions together on new treatments.

Consumers are also involved at various levels in the morbidity and mortality audits of the Division of Research, Audit and Academic Surgery, including the steering committees. The peak consumer group Breast Cancer Network Australia continues to provide invaluable input to the National Breast Cancer Audit, and has driven and funded specific reports. Consumer representatives work with the Australia and New Zealand Audit of Surgical Mortality (ANZASM) at both the national and regional levels.

This year we invited consumers who have provided input to the division to participate in a survey. The aim was to gain the consumer perspective on issues like the role of consumers in the research process and motivations for involvement. We presented the preliminary results at the Health Technology Assessment International (HTAi) conference in June in Singapore, and the full results should be available soon. We continued our work with a team to prepare the HTAi international glossary of medical terms, which was launched in 2009. We forged a collaborative relationship with the health technology assessment office of the Malaysian Department of Health, and have begun to exchange ideas on the preparation of consumer information. An ASERNIP-S staff member visited the department in December to continue these discussions.

ASERNIP-S values its membership of the peak consumer group Consumers' Health Forum (CHF) and provides input into information papers. This year CHF were very helpful in directing us to consumer advice on specific reviews. We thank all the consumers who worked with us this year for their excellent contribution.

New contracts

The Simulated Surgical Skills Program has been extended by an additional year under a Deed of Variation entered into with the Commonwealth. Contracts are being negotiated around the country with skills centres for the collection of data. Contracts with the University of Sydney and the University of Western Australia have been signed and negotiations are underway with a further hospital in New South Wales and with a skills centre in Queensland. We have also negotiated contracts for the purchase of equipment necessary for the completion of the project.

A contract has been negotiated for ASERNIP-S to further develop and manage a new national database for the Australian and New Zealand Gastric & Oesophageal Surgeons Association (ANZGOSA). The new web-enabled database will be based on a previous dataset of the Sydney Upper Gastrointestinal Surgeons Society, and will be available to all ANZGOSA members.

In addition to our work for the Medical Services Advisory Committee (MSAC) and the South Australian Department of Health, ASERNIP-S successfully tendered in December 2008 and again in May 2009 to provide research services to the Victorian Department of Health. ASERNIP-S has been awarded two research projects, one conducted in partnership with the Centre for Health Economics Research and Evaluation (CHERE), University of Technology, Sydney.

ASERNIP-S has been awarded an extension of its horizon scanning contract with the Commonwealth until 30 June 2010. The sub-consultancy agreement with Adelaide Research & Innovation will also be extended. We have successfully negotiated a further year's work for the American College of Surgeons to complete four larger reports in 2010. We hope to continue work for the New Zealand Accident Compensation Corporation following the pilot in 2009.

Promotional Activities 2008

Peer-reviewed publications 2009

Ananda S et al. Initial impact of Australia's national bowel cancer screening program. *Medical Journal of Australia* 2009; 191(7): 378-381

Barber C, Watt A, Pham C, Humphreys K, Penington A, Mutimer K, Edwards M, Maddern G. Influence of bioengineered skin substitutes on diabetic foot ulcer and venous leg ulcer outcomes. *Journal of Wound Care* 2008; 17(12): 517-527

Chen D, Barber C, McLoughlin P, Thavaneswaran P, Jamieson G, Maddern G. Systematic review of endoscopic treatments for gastro-oesophageal reflux disease. *British Journal of Surgery* 2009; 96: 128-136

Hoggan BL, Cameron AL, Maddern GJ. Systematic review of endovenous laser therapy versus surgery for the treatment of saphenous varicose veins. *Annals of Vascular Surgery* 2009; 23(2): 277-287

Humphreys K, Wormald P, Maddern GJ. Upper airway surgery for adult obstructive sleep apnoea: what is the evidence? *ANZ Journal of Surgery* 2009; 79(4): 223-224

Leopardi D, Hoggan BL, Fitridge RA, Woodruff PWH, Maddern GJ. Systematic review of treatments for varicose veins. *Annals of Vascular Surgery* 2009; 23(2): 264-276

Perera CL, Bridgewater FH, Thavaneswaran P, Jamieson GG, Maddern GJ. Nontherapeutic male circumcision: tackling the difficult issues. *Journal of Sexual Medicine* 2009, 6(8): 2237-2243

Perera CL, Bridgewater FHG, Thavaneswaran P, Maddern GJ. The safety and efficacy of non-therapeutic male circumcision: a systematic review. *Annals of Family Medicine* (in press)

Roder D, Wang J, Zorbas H, Kollias J, Maddern G. Survival from breast cancers managed by surgeons participating in the National Breast Cancer Audit of the Royal Australasian College of Surgeons. *ANZ Journal of Surgery* (in press)

Sturm LP, Cooter RD, Mutimer KL, Graham JC, Maddern GJ. A Systematic Review of Permanent and Semipermanent Dermal Fillers for HIV-Associated Facial Lipoatrophy. *AIDS PATIENT CARE and STDs* 2009; 23(9): 699-714

Wang J, Kollias J, Boult M, Babidge W, Zorbas H, Roder D, Maddern G. Pattern of surgical treatment for women with breast cancer in relation to age. *The Breast Journal* (in press)

Wang J, Marsh C, Maddern G, Kollias J. Are male breast cancer patients treated differently from female breast cancer patients in Australia and New Zealand? *The Breast* (in press)

Watt AM, Patkin M, Sinnott MJ , Black RJ, Maddern GJ. *Scalpel safety in the operative setting: A systematic review. Surgery* (in press)

Other publications 2009

Happy 10th anniversary ASERNIP-S! *Royal Australasian College of Surgical News,* November/December 2008; 9(10): 20-21

Appraising New Surgical Procedures. *HealthInsite,* September 2009; 6(6): 3

Bi-National Colorectal Cancer Audit. *Royal Australasian College of Surgeons Surgical News*, April 2009; 10(3): 12-13

Dermal Fillers. *Royal Australasian College of Surgeons Surgical News,* October 2009; 10(9): 16-17

Horizon Scanning Network. *Royal Australasian College of Surgeons Surgical News*, June 2009; 10(5): 8

New reviews from ASERNIP-S. *Royal Australasian College of Surgeons Surgical News*, January/February 2009; 10(1): 10

Simulated Surgical Skills Program. *Royal Australasian College of Surgeons Surgical News*, April 2009; 10(3): 10

Simulated Surgical Skills Program. *Royal Australasian College of Surgeons Surgical News*, August 2009; 10(7): P16

Pre entations

Maddern G. *What is optimal use of technology: the clinician's experience.* HTA for optimization of technology utilization, HTAi Policy Forum, San Francisco, USA, 9 February 2009

Maddern G. *Health technology assessment: the Australian experience.* International meeting for HTA-emerging countries, Ankara, Turkey, 5 March 2009

Maddern G. *Governance and health technology assessment*. International meeting for HTA-emerging countries, Ankara, Turkey, 5 March 2009

Maddern G. *Coordinating HTA practices worldwide.* International meeting for HTA-emerging countries, Ankara, Turkey, 5 March 2009

Maddern G. *Introduction to evidence based health care and HTA.* Health Technology Assessment Principles and Practices, Kuching, Malaysia, 7 April 2009

Maddern G. *Generalising and transferability of HTA.* Health Technology Assessment Principles and Practices, Kuching, Malaysia, 8 April 2009

Maddern G. *Knowledge transfer: challenges in putting HTA into practice.* Health Technology Assessment Principles and Practices, Kuching, Malaysia, 8 April 2009

Maddern G. *Health technology assessment in hospital and district general hospital settings.* Health Technology Assessment Principles and Practices, Kuching, Malaysia, 8 April 2009

Maddern G. *Model of implementation of HTA activities: the Australian experience.* Health Technology Assessment Principles and Practices, Kuching, Malaysia, 10 April 2009

Maddern G. *Meeting decision makers' needs.* Health Technology Assessment Principles and Practices, Kuching, Malaysia,10 April 2009

Maddern G. *How to present your work at a meeting and how to get your paper published,* Serdang Hospital, Malaysia, 13 April 2009

Maddern G. *Development and assessment of novel surgical technologies and their introduction into the Australian healthcare system.* Basil Hetzel Institute for Medical Research Seminar Series, The Queen Elizabeth Hospital, 28 April 2009

Maddern G. *Medical workforce solution: Delegation or substitution?* South Australian Nurse Practitioners Group, 17 June 2009

Maddern G. *Rapid HTA – Inventory of current methods and practice around the globe.* Medtronic Symposium, 6th Annual Meeting HTAi, Suntec Singapore International Convention & Exhibition Centre, Suntec City, Singapore, 22 June 2009

Thavaneswaran P, Maddern G. *Maximising health outcomes from surgical interventions.* Sixth Annual HTAi Meeting, Suntec Singapore International Convention & Exhibition Centre, Suntec City, Singapore, 22 June 2009

Ahern E, Charlton M, Doyle J, Cameron AL Thavaneswaran P, Marsh C, Cuncins-Hearn A, Babidge W, Maddern GJ. *Different roles played by consumers in one HTA organisation.* Poster presentation, Sixth Annual HTAi Meeting, Suntec Singapore International Convention & Exhibition Centre, Suntec City, Singapore, 23 June 2009.

Maddern G. *Coordination of HTA activities among established HTA agencies and programs.* Plenary Session, Sixth Annual HTAi Meeting, Suntec Singapore International Convention & Exhibition Centre, Suntec City, Singapore, 24 June 2009

Babidge W. *Patient reported outcomes.* Master of minimally invasive surgery, The Queen Elizabeth Hospital, Adelaide, 7th August 2009

Maddern G. Hypothetical: *Treating adolescents – A challenge in confidentiality and consent.* Medical Insurance Group Australia, Adelaide, 1 August 2009; Sydney, 22 August 2009; Melbourne, 12 September 2009; Barossa Valley, 10 October 2009; Adelaide, 21 November 2009; Coonawarra, 28 November 2009

Maddern G. *Stage 4 colon cancer: How much liver resection is too much?* International Surgical Week, Adelaide, 7 September 2009

Maddern G. *Audit and clinical governance satisfying the RACS CPD requirements in private practice.* 33rd Annual Australasian Society of Aesthetic Plastic Surgery Conference 2009, Westin Hotel, Sydney, 4 October 2009

Maddern G. *Multidisciplinary teamwork for safety.* (facilitator) The Australian Council of Healthcare Standards, Ballarat, 5 October 2009; Adelaide, 7 October 2009; Sydney, 2 November 2009; Gold Coast, 9 November 2009

Maddern G. *Working with consumers.* (facilitator) The Australian Council of Healthcare Standards, Ballarat, 5 October 2009; Adelaide, 7 October 2009; Sydney, 2 November 2009; Gold Coast, 9 November 2009

Ahern E, O'Callaghan M, Salisbury J, Stove K. *Precise and unambiguous: making sense of the words scientists use.* Panel session, 4th IPEd National Editors Conference, Adelaide Festival Centre, Adelaide, 9 October 2009

Maddern G. *The Australian solution. Surgical innovation: Issues around evaluation, education, accreditation and reimbursement.* American College of Surgeons 95th Annual Clinical Congress, Chicago, USA, 14 October 2009.

Externally-commissioned projects

ASERNIP-S is approved to provide consultancy services to:

- the Cancer Institute New South Wales
- the Therapeutic Goods Administration (TGA) product evaluation panel.

ASERNIP-S website

We started the year with a new look College website, with fresh colours and a more user-friendly layout. In the first eight months of 2009, the number of visitors to our homepage increased by almost 50 per cent compared to the same period the previous year.

The ASERNIP-S website, which may be accessed directly (http://www.surgeons.org/asernip-s/) or via links from the College homepage, provides detailed information on our activities. The full text of our reports can be downloaded free from the site. We include regular updates of new projects and a comprehensive archive of previous work. One of the recent additions to our publications page is the exciting Evidence Essentials reports. You can read more about these in the section on ASERNIP-S reviews in this annual report.

The web-interface database for the New and Emerging Techniques – Surgical (NET-S) horizon scanning project is linked via the ASERNIP-S homepage. The database is regularly updated with new reports and prioritising summaries. The increased number of visitors to this site in 2009 indicates that these reports continue 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. These accreditations help to reassure visitors to our website of the quality of the information presented.

ASERNIP-S Advisory Committee

The members of the ASERNIP-S Advisory Committee are:

Professor Ian Gough	*Chairman, and College President*
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)*

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
- 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
- International Network of Agencies for Health Technology Assessment (INAHTA) Board – Professor Guy Maddern, Ex officio
- International Network of Agencies for Health Technology Assessment (INAHTA) Board – Dr Wendy Babidge, Director
- International Network of Agencies for Health Technology Assessment (INAHTA), Impact of Health Technology Assessment subcommittee – Dr Wendy Babidge, Co-Chair.

Students

This year ASERNIP-S supervised research proposals for three fourth-year medical students from the University of Adelaide:

Arvind Rajagopalan has spent the past year undertaking a project with the Australian and New Zealand Audit of Surgical Mortality. The focus of Arvind's project was to look at ways of improving surgical practice through auditing surgical mortality. He was faced with the challenges of looking at both the Root Cause Analysis methodology and specifically the South Australian Audit of Peri-Operative Mortality to see if the same or similar outcome could be achieved using a similar case study.

Rebecca Holst worked with the National Breast Cancer Audit as part of her medical course in 2009. She developed a research proposal to evaluate the effect of tumour size, nuclear grade, the presence or absence of comedonecrosis, age of the patient and the margin width, on the recurrence of breast cancer after breast-conserving surgery with and without adjuvant radiotherapy for patients with ductal carcinoma in situ breast tumours.

The Simulated Surgical Skills Program supported Eamon Raith in his research proposal 'What length of rest period is necessary for restoration of optimal laparoscopic surgical skill following fatigue-related decline in operative function associated with on-call commitments in Australian surgical trainees?'

Personnel

During 2009 we welcomed:

- Peta Connor, Research Officer, Breast Audit
- Susan Dawe, Project Officer SSSP
- Dr Primali De Silva, Senior Research Officer, Breast Audit
- Jessica Gadsby, Project Data Officer, Colorectal Cancer Audit
- Stefanie Gurgacz, Research Officer
- Wendy Morros, Office Manager and PA to the Director, RAAS
- Michelle Ogilvy, Project Officer, Clinical Australian Quality Registries
- Christine Richardson, Research Officer
- Catherine Yap, Project Contracts Manager.

In 2009 we benefited from the expertise of the following consultancy groups:

- **Dr Ann Scott**

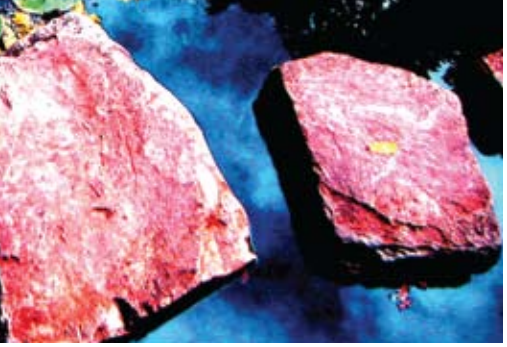
Ann Scott originally trained as an animal physiologist and gained her PhD in zoology from the University of NSW in Sydney. Ann spent three years working as a Senior Research Officer for ASERNIP-S before moving to Canada in June 2002 to join the HTA Unit at the Alberta Heritage Foundation for Medical 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**

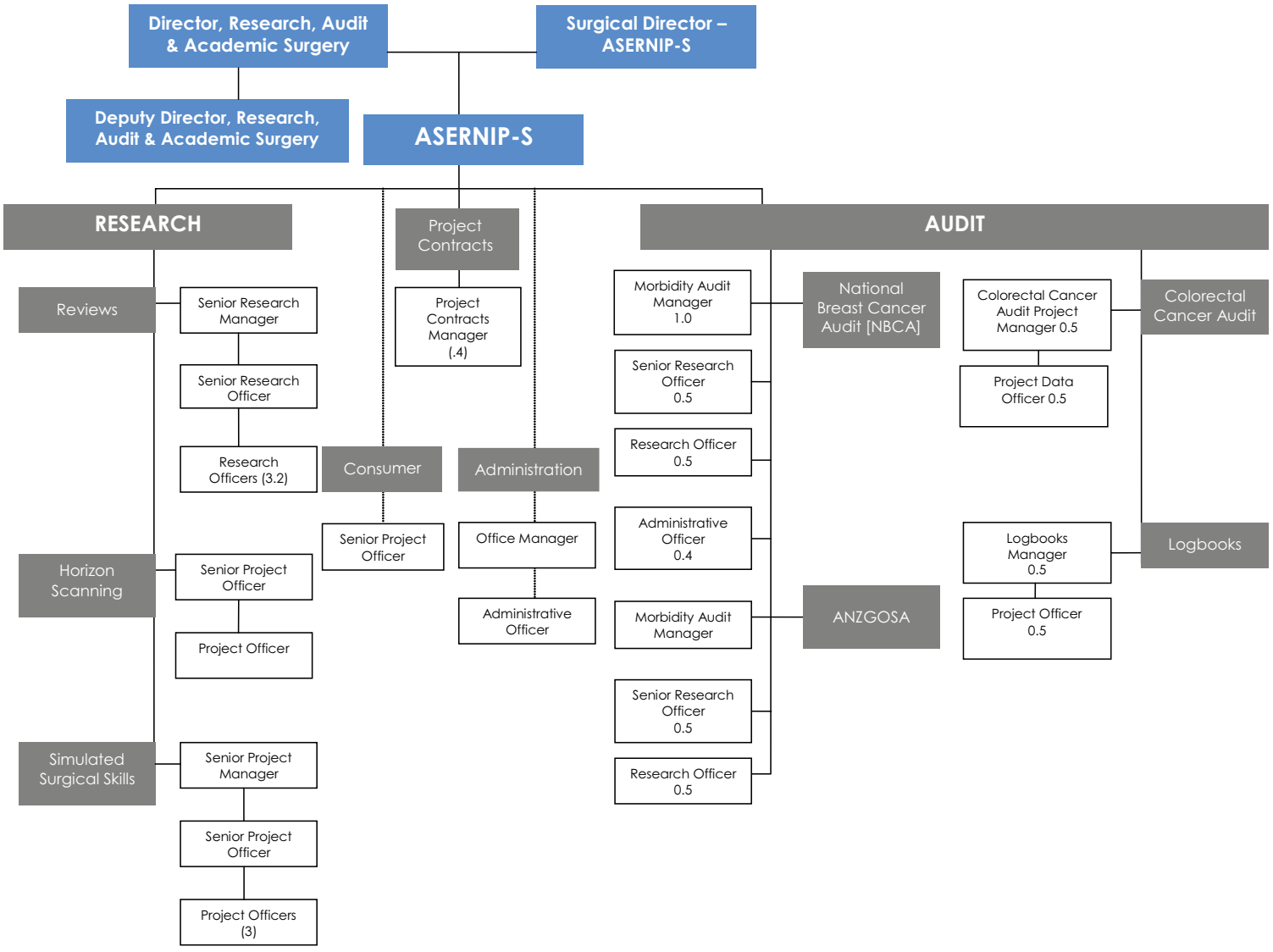
Since April 2007 ASERNIP-S has entered into a collaboration with the Centre for Health Economics Research and Evaluation (CHERE) for assistance with economic evaluation for our health technology assessments. CHERE is a joint initiative of the Faculties of Business and Nursing, Midwifery and Health at 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. They are also involved in state-funded reviews requiring economic evaluation.

STAFF

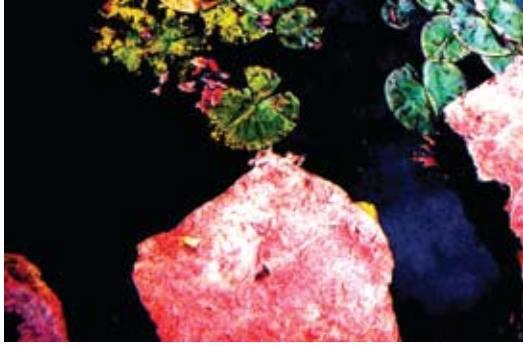
- Professor Guy Maddern
- Dr Wendy Babidge
- Nicola Robinson
- Dr Alun Cameron
- Dr Prema Thavaneswaran
- Eleanor Ahern
- Meryl Altree
- Peta Connor
- Susan Dawe
- Dr Primali De Silva
- Jane Franklin
- Jessica Gadsby
- Stephanie Gurgacz
- Karen Humphreys
- Louise Kennedy
- Irving Lee
- Deanne Leopardi
- Tania Margitich
- Nicholas Marlow
- Claire Marsh
- Wendy Morros
- Michelle Ogilvy
- Caryn Perera
- Christine Richardson
- Vendra Severin
- Jenna Turner
- Lana Sturm
- Dr Meegan Vanderpeer
- Catherine Yap
- Luis Zamora



Research, Audit and Academic Surgery Division – Royal Australasian College of Surgeons ASERNIP-S Organisational Chart



Management



Professor Guy Maddern

Dr Wendy Babidge

Nicola Robinson

Dr Alun Cameron

Meryl Altree

Claire Marsh

Wendy Morros

Vendra Severin

Catherine Yap

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

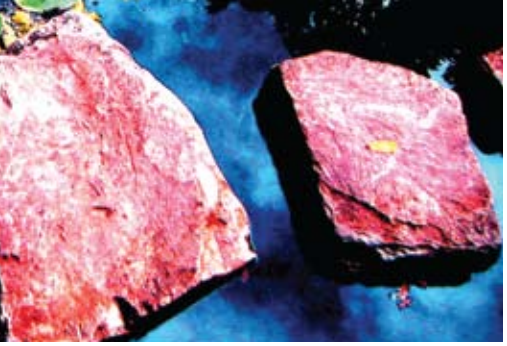
Dr Wendy Babidge

Dr Wendy Babidge is 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. In 2009 she was appointed as a Director to the International Network of Agencies for Health Technology Assessment Board.

Deputy Director, Research, Audit and Academic Surgery Division, Royal Australasian College of Surgeons

Nicola Robinson

Nicola Robinson is the Deputy Director of the Division of Research, Audit and Academic Surgery of the Royal Australasian College of Surgeons. Nicola oversees the College mortality audits, the provision of scholarships for surgical research and associated fundraising activities. She is also secretariat to the Section of Academic Surgery and the Board of Surgical Research. Nicola has extensive experience in management and marketing having worked in the financial sector as a product manager and as a director of a publishing firm. She has a Bachelor of Arts - Communication Studies 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 United Kingdom, prior to moving to Adelaide. At ASERNIP-S Dr Cameron has been mainly involved with managing Medical Services Advisory Committee 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 Project Manager - Simulated Surgical Skills Program

Meryl Altree

Meryl Altree 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. Prior to working with the College, she spent 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 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 for the National Breast Cancer Audit and the Audit for Endovascular Repair. In June 2008 she moved into the role of Morbidity Audits Manager, working across the National Breast Cancer Audit, the Audit for Endovascular Aneurysm Repair, and the Australian Clinical Quality Registries Project.

ASERNIP-S Officer Manager and PA to the Director, Research, Audit and Academic Surgery Division

Wendy Morros

Wendy Morros joined the Division in the role of Office Manager/Personal Assistant to the Director in November 2008. Wendy has a background in the Commonwealth Public Service including DEETYA, the Australian Taxation Office and Medicare Australia, as well as in the private sector. Wendy is responsible for overall office management and the provision of high level administrative support to the Director, Division and committees and working parties associated with the Division.

Bi-National Colorectal Cancer Audit Project Manager and Logbooks Manager

Vendra Severin

Vendra Severin joined ASERNIP-S in July 2007. She is the Bi-National Colorectal Cancer Audit (BCCA) Project Manager and Logbooks Manager. As BCCA Project Manager she is responsible for the establishment of the BCCA for the Colorectal Surgical Society of Australia and New Zealand (CSSANZ). As Logbooks Manager she is responsible for the continued support and development of a web-based Logbook application for Trainees and Fellows of the College. Her previous experience includes a diverse range of registry and audit environments, specialising in cancer data, more specifically colorectal and urological cancer data. She also has expertise and knowledge in the development of IT systems and applications. She has a Graduate Certificate in Health (Health Service Management), Flinders University South Australia. She is the South Australian convenor for the Australasian Health and Research Data Managers Association (AHRDMA).

ASERNIP-S Project Contracts Manager

Catherine Yap

Catherine Yap joined the Royal Australasian College of Surgeons as Project Contracts Manager in March 2009. She is responsible for all contract related matters for the Research, Audit & Academic Surgery Division. Catherine has a Bachelor of Laws from the University of Adelaide and Bachelor degrees in Economics and Arts (Legal Studies) from Flinders University as well as a Graduate Diploma in Legal Practice. Practising as a legal practitioner for the past decade, Catherine has gained extensive experience in contract negotiation and drafting. She was employed as a Senior Associate in Sydney at a leading national law firm for 6 years before moving to Adelaide.

Appendices

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 2007-2008

Appendix A
Hierarchy of evidence

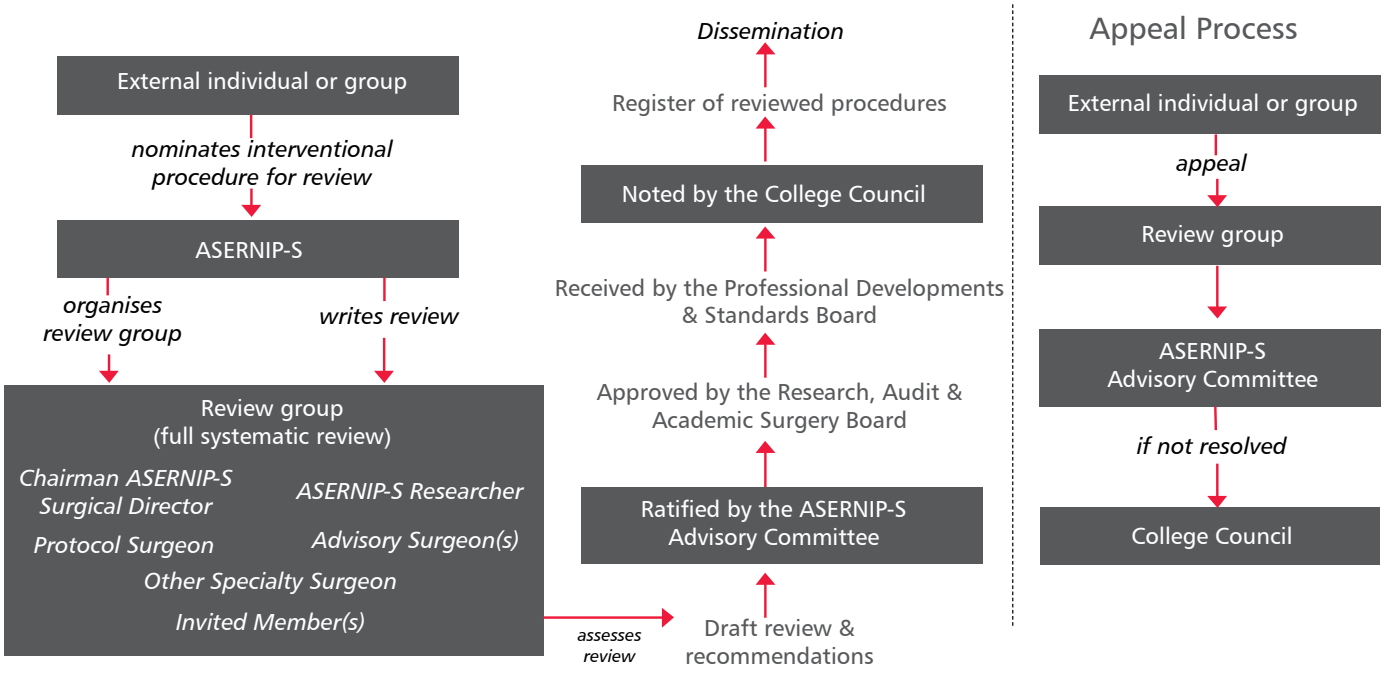
Designation of levels of evidence[1]

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 Scientifi 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 2007-2008

2008

ASERNIP-S Report no. 63
Clinical treatments for wrist ganglia (rapid review), October 2008

ASERNIP-S Report no. 64
Diagnostic arthroscopy for conditions of the knee (rapid review), October 2008

ASERNIP-S Report no. 65
Non-therapeutic male circumcision (rapid review), October 2008

ASERNIP-S Report no. 66
Treatments for varicose veins (rapid review), October 2008

ASERNIP-S Report no. 67
Upper airway surgery for the treatment of adult obstructive sleep apnoea (rapid review), October 2008

ASERNIP-S Report no. 69
Treatments for varicose veins, October 2008

Barnes M, Boult M, Maddern G, Fitridge 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 translumenal endoscopic surgery™ (NOTES™) for intra-abdominal surgery: applicability to the clinical setting. *Annals of Surgery* 2008; 247(4): 583-602

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

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Appendices

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

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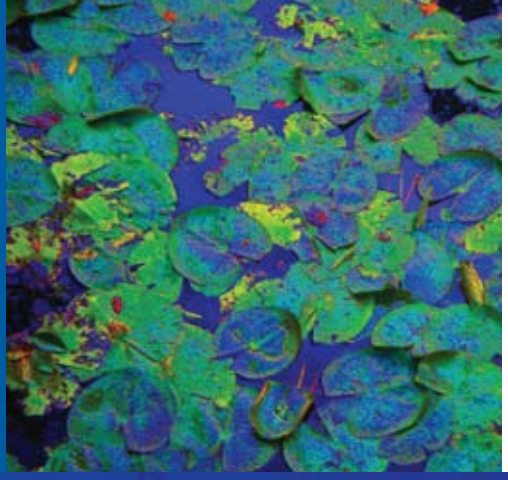
The nomination of procedures for assessment by ASERNIP-S should be made to the ASERNIP-S office on the appropriate form. The continued participation of surgeons in procedure review groups and the submission of data on procedures under audit by ASERNIP-S are encouraged. For further information on either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



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