

Australian Safety and Efficacy  
Register of New Interventional Procedures — Surgical

Royal Australasian College of Surgeons

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# Mission statement

The mission of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) 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**

At the beginning of 2010 the Commonwealth Review into Health Technology Assessment (HTA) was released. ASERNIP-S and the College had strongly advocated the need for a more comprehensive mechanism of HTA, particularly as it related to not only devices but also procedures. Many procedures do not require a new device but may carry with them great benefits, or potentially great harms if not introduced in a carefully controlled and monitored fashion. This advice gained some credence from the Review Committee, and as we move forward to implement the HTA review recommendations it can only be hoped that surgery and the craft, as well as the science, are appropriately reviewed and assessed.

During the year there has been an increased success in tenders made to the Commonwealth Government with respect to review of the Medicare Benefits Schedule (MBS). Tenderers are being asked to put together processes by which areas of activity currently funded by the MBS are reviewed and maintained, both now and into the future. This is a valuable function for ASERNIP-S to be fulfilling, and enables us to be aware of the processes that the government is enacting as well as to provide informed and balanced input to them. The project continues to provide advice to the Medical Services Advisory Committee, although during the last twelve months requests for work have not been as regular as the group would have liked.

The American College of Surgeons continues to use our input, particularly into horizon scanning activities; in addition, HealthPACT, an initiative of the Australian Government, contracts ASERNIP-S to provide input into the horizon scanning work, particularly as it relates to medical devices.

Audits of colorectal, upper gastro-intestinal and breast surgery continue to grow, with increasing complexity and sophistication being required. These audits not only need substantial IT input but also a complex maze of ethical approvals in order for them to progress. In the Australian context the latter is extremely complicated, taking a significant amount of time. The National Health and Medical Research Council and state jurisdictions are looking at ways of streamlining the process, but very little of a practical nature has actually changed so far.



The Simulated Surgical Skills Program continues to advance rapidly and will be drawing to a conclusion over the next twelve months. The most impressive development over 2010 was the development of the surgical simulation van which was designed to serve not only the inner Sydney region but also remote rural venues. The van is now being used to collect data, and the results should be available towards the middle of 2011.

The resource ASERNIP-S provides to the Royal Australasian College of Surgeons is substantial. In all, there are almost 50 individuals employed in the Research, Audit and Academic Surgery Division of the College who provide very specialised skills in research, audit and health technology assessment. This capability needs to be protected, and at present is done with little or no College financial underpinning. Indeed, many of the activities help support the College's infrastructure. We continue to explore ways of providing financial stability to ASERNIP-S so that it can continue its important work.



# ASERNIP-S reviews

- New assessments completed
- 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

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

### Evidence essentials

- Veress needle laparoscopic entry technique  
ASERNIP-S Report no. 76

### Reviews for other organisations

- Second generation contrast agents  
(MSAC Application 1129)
- Middle ear implant for sensorineural, conductive and mixed hearing losses  
(MSAC Application 1137)
- Percutaneous sclerotherapy for vascular malformations  
(Department of Health, Victoria)
- Evaluation for the Therapeutics Goods Administration (Federal Department of Health and Ageing)
- MBS Quality Framework  
(Federal Department of Health and Ageing)

## ASERNIP-S reviews

### Autologous fat transfer for cosmetic and reconstructive breast augmentation

ASERNIP-S Report no. 70

#### Objective

To assess, through a systematic review of the literature, the safety and efficacy of autologous fat transfer for:

- cosmetic breast augmentation in comparison with saline and cohesive silicone gel implants
- reconstructive breast augmentation in comparison with autologous tissue transfer and tissue expanders with breast implants.

#### Methods

**Search strategy:** Studies were identified by searches of Current Contents, The York Centre for Reviews and Dissemination, The Cochrane Library, Entrez-PubMed and Ovid EMBASE from January 2001 to January 2009. Date limitations were necessary to obtain literature published since the original ASERNIP-S systematic review of autologous fat transfer for cosmetic breast augmentation was conducted in 2002.

**Study selection:** Included in the review were case series studies and single-arm data obtained from randomised controlled trials of comparator procedures. The outcomes examined included complication rates, durability of enhancement, reoperation rates and patient satisfaction.

**Data collection and analysis:** Data from the included studies were extracted by an ASERNIP-S researcher using standardised extraction tables created a priori and checked by a second researcher. Overall complication rates were calculated as a means of indirectly comparing the safety of autologous fat transfer with the nominated comparator procedures.

#### Results

Thirty five studies were included in this systematic review. Nine studies were randomised controlled trials from which data from 12 single arms were extracted, and 26 were case series studies, 11 of which reported outcomes for autologous fat transfer. Overall, the literature available for inclusion in this review was of poor quality. In particular, the complete lack of comparative evidence necessitated indirect comparisons to be made which made the findings of this review less reliable. It was also difficult to draw comparisons between autologous fat transfer and its cosmetic and reconstructive comparator procedures

given the differences in volume achievable using prostheses or autologous tissue transfers compared with fat injections alone.

Fat necrosis, calcification and cysts were the most commonly reported complications associated with autologous fat transfer; however, these complications only occurred in a small proportion of patients. There were no data linking the presence of these complications with long-term mammographic and cancer-related outcomes; therefore, the safety of autologous fat transfer in regard to interference with cancer detection could not be determined by this review. Complications, such as skin/flap necrosis, occurred at a similar frequency in patients undergoing breast reconstruction with gluteal and abdominal flaps. In addition, there were a variety of serious complications related to some of the comparator procedures that were not associated with autologous fat transfer (including hernia and capsular contracture).

The efficacy of autologous fat transfer could not be compared with that of prostheses augmentation procedures or breast reconstruction using autologous tissue due to the variability of outcomes reported in these studies. Patient satisfaction following autologous fat transfer, as well as reconstructions using tissue expanders with breast implants and abdominal flaps, was high. However, patient satisfaction with breast reconstruction using gluteal flaps and latissimus dorsi flaps was generally higher than that of autologous fat transfer. For autologous fat transfer the limited breast volume increase was the main complaint associated with the procedure. Where patients desire a moderate to large increase in breast volume, the use of autologous fat transfer as an adjunct to prostheses or autologous tissue transfer is feasible. Results suggest that autologous fat transfer can be safely and effectively used in conjunction with other augmentative procedures.

Fat reabsorption occurred following autologous fat transfer to varying degrees, usually in the short-term (12-month) follow-up period. As a result, additional fat transfer procedures were often necessary to obtain the desired outcome. Flap loss occurred following autologous tissue reconstruction in some cases, but it was uncommon.

#### Classifications

##### Evidence rating

The evidence base in this review is rated as poor, limited by the quality of the available evidence. Specific limitations of the evidence include absence of studies comparing autologous fat transfer to the nominated comparator procedures, as well as a lack of standardised reporting of outcomes.

### Safety

Autologous fat transfer for cosmetic and reconstructive breast augmentation is considered to be at least as safe as the nominated comparator procedures. It is important to note that this rating is based on indirect comparisons that have been made using overall complication rates. Important safety data examining the effect of microcalcifications following autologous fat transfer on subsequent breast cancer detection were not reported in the studies included in this review; therefore, safety in regard to this outcome cannot be determined.

### Efficacy

The efficacy of autologous fat transfer cannot be determined from the literature included in this review. Efficacy outcomes reported in the included autologous fat transfer studies varied from those reported for the nominated comparator procedures; therefore, it was not possible to compare efficacy. However, the inability of autologous fat transfer to achieve a volume increase comparable to that of prostheses or autologous tissue augmentation suggests that it is less efficacious than these comparator procedures.

### Clinical and research recommendations

There is a need for controlled trials (ideally randomised), assessing the effects of microcalcifications following autologous fat transfer on immediate and long-term breast cancer detection, to be conducted. Studies to determine the maximal breast volume increase reliably achieved by autologous fat transfer would also be useful in order to define the patient population who would benefit most from the procedure, as well as which breast indications should be treated using autologous fat transfer.

### Review Group membership

**Protocol Surgeon:** Mr Norman Olbourne

**Advisory Surgeon:** Mr Keith Mutimer

**ASERNIP-S Surgical Director:** Professor Guy Maddern

**ASERNIP-S Researcher:** Ms Deanne Forel



## 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, and provide a new mode of surgical skills training in Australia. SSSP 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 nearing completion throughout Australia. In New South Wales the SSSP is currently assessing the use of a Mobile Simulation Unit containing laparoscopic simulators which travels to metropolitan and country SET trainees. This high-tech van enables those trainees located 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
- delivery of conscious sedation
- endoscopic stapling of pharyngeal pouch
- folate fortification of flour in Australia
- injectable silicone for reflux and other indications
- intramedullary bone lengthening with fitbone device
- laparoscopic adhesion division
- laparoscopic hemi-hepatectomy
- provision of emergency surgical services in Australia
- radiofrequency ablation of tumours (not liver or renal)
- 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

- Bi-National Colorectal Cancer Audit
- National Breast Cancer Audit
- Australian and New Zealand Gastric & Oesophageal Surgical Association Audit

# Bi-National colorectal cancer audit

Since 2008 the Bi-National Colorectal Cancer Audit (BCCA) has become an important activity for the Colorectal Surgical Society of Australia and New Zealand (CSSANZ). This has been ratified by the successful securing of funding from corporate sponsorship ensuring the short-term future sustainability of the audit.

There has been much collaboration, and we thank all of those who have shown their support and dedication. It is important to recognise that the audit can only continue to evolve with the support and contribution of all CSSANZ members. This is facilitated by their participation in the audit and through the provision of analysis and reporting to contributors.

This continued focus on reporting has resulted in the distribution of individual data contributor reports as part of a pilot to determine the reporting structure. It is envisaged that individual data contributors will receive six-monthly reports as well as an annual report with aggregated collaborative results.

Australian and New Zealand surgeons have now contributed over 3962 episodes which are registered in the CSSANZ database.

In New Zealand, surgeons have commenced data collection using the existing data collection processes, which includes the Otago Surgical Audit we reviewed to ensure that it contained all the fields within the CSSANZ minimum dataset (MDS). This work will continue and will result in surgeons contributing their data electronically to the audit. However, in the interim, data entry support is being offered by the project team located in South Australia at the College providing New Zealand surgeons with an opportunity to participate in the BCCA.

The audit has also seen submission of its first annual report to the Ministry of Health, New Zealand, regarding the continuing coverage of the audit as a Protected Quality Assurance Activity.

The CSSANZ has been approached on a number of occasions with requests from organisations seeking colorectal cancer data and/or information, and the BCCA has been recognised as being able to provide this. In June 2009 Cancer Council launched a national advocacy campaign, *Get Behind Bowel Screening*, to emphasise the importance to the Australian Government of expanding 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 audit which revealed the NBCSP is identifying twice the number of bowel cancers at stage A, compared with those discovered outside the program and after presentation of symptoms. This data provided the first specific evidence on the efficacy of the NBCSP, and added to the convincing body of evidence in favour of making bowel cancer screening accessible to everyone over 50 years of age.

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

Quality improvement is a focus for the audit. Two versions of the MDS, Australian and New Zealand, were developed to ensure that the collection, collation and analysis of data are approached with consistency. We encourage participants to review their own quality assurance activities; this would include ensuring that current versions of forms are used, and that all forms are completed with all requested information, resulting in a collection of valid and consistent data for reporting purposes.



# National Breast Cancer Audit

The National Breast Cancer Audit (NBCA) has been in operation for over 10 years. It was developed as a self-assessment tool for surgeons with the aim of improving and maintaining the quality of surgical care offered to patients with early breast cancer in Australia and New Zealand. In 2010, the NBCA has continued to strive for this quality through improving coverage of cases collected, increasing feedback to surgeons and providing valuable output for research.

## Data collection

The NBCA has been working on various strategies for increasing participation in the audit throughout 2009 and 2010. The focus has been on promoting the audit as a valuable activity to potential participants, as well as keeping existing participants engaged. The institutional uploads program, which involves gaining data from large institutional databases, transforming into NBCA format and uploading into the audit database, has hit its stride in 2010 with over 6,500 cases expected to be uploaded by the end of the year. With the success of this program, the NBCA is hopeful that data submissions for the year may be as high as 15,000 cases.

## Feedback and assessment

A new Key Performance Indicator will be implemented in late 2010: At least 85% of patients with high risk of recurrence after mastectomy should be referred to a radiation oncologist. Surgeons will then be able to assess their practice against five Key Performance Indicators through the case summary screen on the data entry portal. This screen is to be given an upgrade to make it more user-friendly and to ensure the calculations are both accurate and easy to understand.

## Output and partnerships

- The NBCA continues to provide data and analyses for peer-reviewed publications, with two articles published in 2010 and more in progress.
- Collaboration with the National Breast and Ovarian Cancer Centre (NBOCC) in Australia on a project examining survival from breast cancer according to age and provider characteristics has resulted in two research papers which are currently in development.
- Also in collaboration with the NBOCC, the NBCA produced the *Public Health Monitoring Report* using data on Australian patients diagnosed in 2008. This is the third in the series, with previous reports concerning 2007 and 2006 diagnoses.

- For the first time in 2010, the NCBA produced a report focusing on New Zealand patients comparing BreastScreen diagnosed patients with patients diagnosed via other means. This was made possible due to funding from BreastScreen Aotearoa and uses data on patients diagnosed in 2008. Further reports are also to be produced on 2009 and 2010 diagnoses.
- A new feature of the NBCA College webpage is a section for easy-to-read summaries of NBCA research for breast cancer patients. These are being promoted through the Breast Cancer Network Australia.

## Future directions

The Breast Surgeons of Australia and New Zealand (BreastSurgANZ) have informed the College of their intention to take over responsibility for the audit. The Research, Audit & Academic Surgery Division of the College will continue to manage the day-to-day running of the audit; however, a new governance structure will be formed in the coming months, determined by BreastSurgANZ.

**For further information or feedback regarding the National Breast Cancer Audit please see our website at <http://www.surgeons.org/nbca> or contact the Helpdesk at [college.breast.audit@surgeons.org](mailto:college.breast.audit@surgeons.org) or +61 8 8219 0900.**



# ANZGOSA Audit

An audit has been designed for the Australian and New Zealand Gastric and Oesophageal Surgical Association (ANZGOSA) as a self-assessment tool for their members. It has been set up to collect and store clinical and pathological details of patients undergoing surgery for oesophago-gastric cancer or gastrointestinal stromal tumour in Australia and New Zealand. Surgeons submit data through an online portal via secure log-in. This portal was officially launched on 31 August 2010 and is accessible from the ANZGOSA website ([www.anzgosa.org](http://www.anzgosa.org)).

## Future directions

A reporting function is currently being designed whereby surgeons will be able to assess their practice against aggregated peer results using automated reports on various elements of surgical care. Surgeons will also be able to export their data for personal analysis.

**For further information on the data collected or on how to become part of this initiative, see the ANZGOSA Audit webpage ([www.surgeons.org/anzgosa](http://www.surgeons.org/anzgosa)) or contact the audit helpdesk at [anzgosa.audit@surgeons.org](mailto:anzgosa.audit@surgeons.org) or +61 8 8219 0900.**



# New and Emerging Techniques – Surgical (NET-S)

- Horizon scanning project
- NET-S on the web

## Horizon scanning project

The New and Emerging Techniques – Surgical (NET-S) project was established in 1999 with the aim of identifying and assessing advances in surgery that are on the horizon of introduction into Australian and New Zealand healthcare systems - to act as an 'early warning system' for clinicians and policy makers. To do this, NET-S generates concise, unbiased, evidence-based recommendations on the safety and efficacy of these new procedures with the intention of facilitating efficient resource allocation and better patient outcomes.

The majority of NET-S assessments are presented in the form of prioritising summaries or horizon scanning reports. Prioritising summaries are short documents designed to provide readers with background on a particular technology and present the evidence available pertaining to the safety and efficacy of that technology. When a procedure or technology is considered to be of substantial impact and have a considerable evidence base, a more detailed assessment, in the form of a horizon scanning report, will be undertaken. All summaries and horizon scanning reports are available for download from the:

- NET-S website (<http://www.surgeons.org/asernip-s/nets.htm>)
- Australia and New Zealand Horizon Scanning Network (ANZHSN) website (<http://www.horizonscanning.gov.au/>).

As a member of Euroscan through HealthPACT, all NET-S prioritising summaries are also uploaded to the EuroScan database (<http://www.euroscan.bham.ac.uk/index.htm>), where they are available for viewing.

The NET-S project continues to work with the HealthPACT, Committee of the ANZHSN, which is managed by the Department of Health and Ageing, and the American College of Surgeons.

# 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 2010:

- Diaphragm pacing system
- Axial lumbar interbody fusion (AxiaLIF)
- ReCell therapy
- Scandinavian Total Ankle Replacement (STAR) system
- Emblocker: ultrasonic embolic protection device
- Stomaphyx for revision bariatric surgery
- Single incision laparoscopic surgery (SILS) for appendectomy and nephrectomy
- Cryotherapy for oesophageal cancer
- Multielectrode basket catheter
- StatScan critical imaging system
- Microwave ablation for lung cancer
- Laser lead extraction systems
- EndoBarrier gastrointestinal liner for obesity
- Carillon mitral contour system for mitral regurgitation
- SpyGlass direct visualisation system
- Transoral gastropasty (TOGA system) for obesity
- Watchman left atrial appendage occlusion device
- BodyTite LipoTite Liposuction (Radiofrequency-Assisted Liposuction)
- SpineAssist® Surgical Robot
- Stapled transanal rectal resection (STARR) for obstructed defecation syndrome (ODS)
- Inert liquid-to-solid gels for prostate-rectum separation

- Cerecyte (bioactive) Coils for the treatment of intracranial aneurysm
- RhinoChill intra-nasal cooling system
- GORE TAG® (update)
- Shock wave therapy for wound healing (update)
- Serial transverse enteroplasty (update)
- Esophyx system for gastro-esophageal reflux (update)
- Microwave ablation for hepatic tumours (update)
- Anal fistula plugs (update)
- Single-incision laparoscopic cholecystectomy (update)
- Percutaneous mitral valve repair utilising MitraClip (update)
- Robot-assisted endoscopic thyroidectomy (update)
- Natural orifice transluminal endoscopic surgery (NOTES): cholecystectomy (update)

Horizon scanning reports prepared in 2010:

- Laser prostatectomy
- Pumpless extracorporeal lung assist device.

Horizon scanning assessments (American College of Surgeons) prepared in 2010:

- Sentinel lymph node mapping for colorectal cancer
- Endoluminal treatments for obesity.



# Project activities

- Consumer involvement
- New contracts
- Promotional activities
- ASERNIP-S website
- South Australian Health Technology Advisory Group
- ASERNIP-S Advisory Committee
- Representation on external committees
- Personnel
- Students

## Consumer involvement

Consumer involvement is a vital part of health technology assessment and audit at ASERNIP-S. Consumers can provide input at any stage of the review process, from the nomination of a procedure for assessment to preparing consumer information. The mortality audits benefit from the advice of consumers on their management committees around Australia. The National Breast Cancer Audit works closely with the peak consumer group Breast Cancer Network Australia. We receive expert advice from two consumer representatives on our Advisory Committee, Margaret Charlton from the Health Consumers' Alliance and Jane Doyle, professional communicator. We are an active member of Consumers Health Forum.

This year a consumer information group prepared a consumer summary of the systematic review on autologous fat transfer for breast augmentation. Four consumer summaries of reports were prepared for the National Breast Cancer Audit website.

We continued to provide input to the subgroup of Health Technology Assessment International (HTAi) on patient/public participation. We reviewed a number of consumer abstracts for the HTAi 2010 Conference, and have offered our help for next year as well.

A paper entitled 'Consumer perspectives in surgical research and audit' was finalised and submitted to an international journal for publication. This reported on our 2009 survey of consumers who had provided input to the division; consumers were asked via questionnaires and interviews to give their perspective on working with the organisation, and consumer involvement in HTA in general.

Our collaborative relationship with the HTA office of the Malaysian Department of Health Technology Assessment (MaHTAS) has continued after the workshop we gave last December in Kuala Lumpur on preparing consumer information. Matron Sin Lian Thye from MaHTAS was attached to our office in Adelaide for two weeks in September of this year to learn more about the ASERNIP-S process.

We thank all the consumers and organisations who have been involved in the work of ASERNIP-S over the past year.

# New contracts

It has been a busy year for contract management and negotiation within the Division.

The Australian and New Zealand Audit of Surgical Mortality (ANZASM) added the Australian Capital Territory and the Northern Territory to the audits of surgical mortality in February and April respectively. In addition, the contracts supporting the audits in Tasmania, South Australia, Victoria, Queensland and Western Australia have all been successfully renewed. A number of these contracts have been extended up to mid 2013. The continual development of these audits has enabled the preparation of a national report and these audits are now a significant event in the health services arena. A contract was also successfully negotiated with the Victorian Institute of Forensic Medicine for access to the National Coroners Information System which further strengthens the data collection for ANZASM.

ASERNIP-S was offered an extension on the Deed of Standing Offer with the Therapeutic Goods Administration and a contract for evaluation services followed. Three new contracts were negotiated in the second half of the year following the successful tendering by ASERNIP-S for work on Health Services Evaluation for the Australian Government. A new Master Agreement was also successfully negotiated with the South Australian Department of Health, which continues to support ASERNIP-S ongoing work with the Health Technology Advisory Group.

ASERNIP-S also received further extensions by Deeds of Variation to the Consultancy Contract for Horizon Scanning services with a corresponding extension to the sub-consultancy agreement with Adelaide Research & Innovation.

The Simulated Surgical Skills Program successfully negotiated contracts with both a New South Wales hospital and a Queensland skills centre to further develop the data collection which will feed into this report, due in the second half of 2011.

The contract management staff member has negotiated the prospective lease of premises adjacent to the College's South Australian regional office. This will present the Division with exciting opportunities both immediate and for the future.



# Promotional activities

## Peer-reviewed publications 2010

Della Flora E, Perera C, Cameron A, Maddern G. Deep brain stimulation for essential tremor: a systematic review. *Movement Disorders* 2010; 25(11): 1550-1559

Lauder C, Marlow N, Maddern G, Barraclough B, Collier N, Dickinson I, Fawcett J, Graham J. Systematic review of the impact of volume of oesophagectomy on patient outcome. *ANZ Journal of Surgery* 2010; 80(5): 317-323

Maddern G, Marlow N. The current state of Australian laparoscopic surgical skills training. *ANZ Journal of Surgery* 2010; 80(10): 673-675

Marlow N, Barraclough B, Collier N, Dickinson I, Fawcett J, Graham J, Maddern G. Effect of hospital and surgeon volume on patient outcomes following treatment of abdominal aortic aneurysms: a systematic review. *European Journal of Vascular and Endovascular Surgery* (in press)

Marlow N, Barraclough B, Collier N, Dickinson I, Fawcett J, Graham J, Maddern G. Centralization and the relationship between volume and outcome in knee arthroplasty procedures. *ANZ Journal of Surgery* 2010; 80(4): 234-241

Marsh C, Wang J, Kollias J, Boulton M, Rice J, Maddern G. Disparities in access to breast care nurses for breast surgeons: A national breast cancer audit survey. *The Breast* 2010; 19: 142-146

Perera C, Bridgewater F, Thavaneswaran P, Maddern G. Safety and efficacy of nontherapeutic male circumcision: a systematic review. *Annals of Family Medicine* 2010; 8(1): 64-72

Sturm L, Cooter R, Mutimer K, Graham J, Maddern G. A systematic review of dermal fillers for age-related lines and wrinkles. *ANZ Journal of Surgery* (in press)

Thavaneswaran P, Maddern G. Maximising health outcomes from government investment in surgical interventions. *ANZ Journal of Surgery* 2010; 80(5): 308-309

Thavaneswaran P, Rukin G, Cooter R, Moyes D, Perera C, Maddern G. Paravertebral block for anesthesia: a systematic review. *Anesthesia and Analgesia* 2010; 110(6): 1740-1744

Wang J, Kollias J, Boulton M, Babidge W, Zorbas H, Roder D, Maddern G. Patterns of surgical treatment for women with breast cancer in relation to age. *The Breast Journal* 2010; 16 (1): 60-65

Watt AM, Patkin M, Sinnott MJ, Black RJ, Maddern GJ. Scalpel safety in the operative setting: a systematic review. *Surgery* 2010; 147: 98-106

Wilson A, Marlow N, Maddern G, Barraclough B, Collier N, Dickinson I, Fawcett J, Graham J. Radical prostatectomy: a systematic review of the impact of hospital and surgeon volume on patient outcome. *ANZ Journal of Surgery* 2010; 80(1-2): 24-29

## Presentations 2010

Maddern GJ. New surgical technologies: how should they be assessed? Grand Round, University Hospital, Zurich, 12 January 2010

Zille M, Severin V. Logbooks Application. The Board of General Surgery, Royal Australasian College of Surgeons, Melbourne, 31 Jan 2010

Perera CL, Bridgewater FHG, Thavaneswaran P, Maddern GJ. The clinical and social implications of nontherapeutic male circumcision. Adelaide RAH/QEH Surgical Research Society meeting, 10 February 2010

Maddern GJ. Hypothetical: Treating adolescents – A challenge in confidentiality and consent. Medical Insurance Group Australia, Brisbane, 13 February 2010; Sydney, 6 March 2010

Maddern GJ. Day surgery in the 21st century. Plenary session, 1st Malaysian Day Surgery Congress, Subang Jaya, Malaysia, 17 April 2010

Maddern GJ. 23 hour day surgery. 1st Malaysian Day Surgery Congress, Subang Jaya, Malaysia, 18 April 2010

Maddern GJ. How should new technology be assessed? Younger Fellows' Forum, Royal Australasian College of Surgeons Annual Scientific Meeting, Perth Convention Exhibition Centre, 2 May 2010

Maddern GJ. Why every surgeon can and should be an academic surgeon. Developing a Career in Academic Surgery Course, Royal Australasian College of Surgeons Annual Scientific Meeting, Perth Convention Exhibition Centre, 3 May 2010

Maddern GJ. Skill transfer from lab to operating room. Simulation in Surgical Training 2, 2nd International Conference on Surgical Education and Training, Royal College of Surgeons in Ireland, Dublin, 14 May 2010

Maddern G. National Audit – ANZASM preliminary findings. Annual Scientific Congress of the Royal Australasian College of Surgeons, Perth, May 2010

Kollias J, De Silva P, Marsh C, Turner J. Management patterns of ductal carcinoma in situ according to the Van Nuys Prognostic Index-results from the National Breast Cancer Audit. Annual Scientific Congress of the Royal Australasian College of Surgeons, Perth, May 2010

Whitfield R, Kollias J, De Silva P, Oglivvy M. The use of Trastuzumab in Australia and New Zealand - results from the National Breast Cancer Audit. Poster presentation, Annual Scientific Congress of the Royal Australasian College of Surgeons, Perth, May 2010

Maddern G, Cameron A. Rapid versus full systematic reviews: Finding the balance. Plenary Session, 7th Annual HTAi Meeting, Dublin, 7 June 2010

Maddern GJ. Rapid versus full systematic reviews: finding the balance. Plenary Session 2 – Maximising the value in conducting HTAs, 7th Annual HTAi meeting, Dublin, 8 June 2010

Maddern GJ. Health technology assessment of new interventional procedures: Australia. Panel Session – Health technology assessment of new interventional procedures in different countries: maximising the potential for mutual learning and international collaborations, 7th Annual HTAi meeting, Dublin, 8 June 2010

Babidge W. Impact of HTA from the perspective of healthcare professionals. 18th Annual Meeting of INAHTA, Dublin, 10 June 2010

Maddern GJ, Leopardi D, Thavaneswaran P, Olbourne NA, Mutimer K. Systematic review of autologous fat transfer for cosmetic and reconstructive breast reconstruction. Poster presentation, 7th Annual HTAi Meeting, Dublin, June 2010

Babidge W, Sturm L, Cameron AL. Enhanced recovery after surgery or fast-track surgery– what is the evidence? Poster presentation, 7th Annual HTAi Meeting, Dublin, June 2010

Maddern GJ. Hypothetical: Good medicine requires good notes – Poor notes = a poor defence. Medical Insurance Group Australia, Melbourne, 31 July 2010; Sydney, 21 August 2010; Adelaide, 11 September 2010; Barossa Valley,

18 September 2010; Adelaide, 6 November 2010; Coonawarra, 13 November 2010; Adelaide, 27 November 2010

Maddern GJ. The importance of research for a career in surgery. Adelaide University Surgical Society Career Series Lecture, Robson Lecture Theatre, Royal Adelaide Hospital, 3 August 2010

Maddern GJ. Is surgical technology out of control? St Mark's College, Adelaide, 16 August 2010

Maddern GJ. An overview of the current state of evidence around the acquisition and retention of surgical skills both in the clinical and simulated setting. SimTecT Health 2010, Hilton on the Park, Melbourne, 30 August 2010

Altree M. Mobile Surgical Simulation Unit. SimTect Health, Melbourne, 31 August 2010

Maddern GJ. Innovative medical technologies for a sustainable healthcare system. Panel member, Medical Technology Association of Australia Annual Conference Star City, Sydney, 15 September 2010

Maddern GJ. The future of medical registries. Medical Technology Association of Australia Annual Conference, Star City, Sydney, 16 September 2010

Maddern GJ. Who in their right mind would become an academic surgeon? Flinders University Surgical Society, Surgical Careers Night, Hilton Hotel, Adelaide, 22 September 2010

Maddern GJ. Innovative surgical technology: how do we know if it works? Ministry of Health, Singapore, 5 October 2010

Maddern GJ. Models of implementation of HTA activities. Ministry of Health, Singapore, 5 October 2010

Maddern GJ. An introduction to HTA. How, when and why? Workshop, Healthcare Quality Improvement Conference, Suntec Convention & Exhibition Centre, Singapore, 6 October 2010

Maddern GJ. HTA: a practical solution to cost and quality? Plenary Healthcare Quality Improvement Conference, Suntec Convention & Exhibition Centre, Singapore, 7 October 2010

Maddern GJ. What is Health Technology Assessment? International Society for Quality in Health Care, Paris, France, 11 October 2010

## Project activities

Maddern GJ. How to encourage surgical enthusiasm and keep the public safe. National Forum on Safety and Quality in Health Care, Canberra, 27 October 2010

Maddern GJ. The Australian experience in surgical mortality and audit. Scientific Forum: Research and Innovation in the Brazilian Hospital Sector, Belo Horizonte, Brazil, 8 November 2010

Maddern GJ. Masters in Minimally Invasive Surgery. Royal Australasian College of Surgeons Section of Academic Surgery, Adelaide, 18 November 2010

Maddern GJ. What the universities have to offer. Royal Australasian College of Surgeons Section of Academic Surgery, Adelaide, 18 November 2010

Maddern GJ. Surgeon Scientist program and universities. Royal Australasian College of Surgeons Section of Academic Surgery, Adelaide, 18 November 2010

Maddern GJ. Experiences and future direction in surgical simulation. Surgical Simulation Leadership Forum, Hilton, Orlando, USA, 1 December 2010

## Other publications 2010

The National Breast Cancer Audit. *Royal Australasian College of Surgeons Surgical News*, January/February 2010; 11(1): 18

ASERNIP-S Review 'An independent review of ASERNIP-S compliments its productivity and suggests structural changes'. *Royal Australasian College of Surgeons Surgical News*, January/February 2010; 11(1): 34

The Mobile Surgical Simulation Unit. *Royal Australasian College of Surgeons Surgical News*, April 2010; 11(3): 38

ASERNIP-S Review 'Enhanced recovery after surgery – what is the evidence?' *Royal Australian College of Surgeons Surgical News*, July 2010; 11(6): 12

Consumer information. *Royal Australasian College of Surgeons Surgical News*, September 2010; 11(8): 18

Autologous fat transfer for breast augmentation. *Royal Australasian College of Surgeons Surgical News*, November/December; 11(10): 26-27

## ASERNIP-S website

All our reports are available from the ASERNIP-S website at <http://www.surgeons.org/asernip-s/>. We include regular updates of new projects and a comprehensive archive of previous work. Many of our reports are written in easy-to-read summaries prepared for consumers, patients and healthcare professionals.

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 College website is under redevelopment, and new features and functionality will be in place by next year. We continue to work as an information partner with HealthInsite, Australia's online gateway for easy access to quality health information. Internationally, we are recognised by HONcode, the international standard for quality health information. These partnerships ensure that the quality of the information presented on our website remains of the highest standard.

## South Australian Health Technology Advisory Group

In 2010 the South Australian Health Technology Advisory Group (SA-HTAG) achieved the following:

- nominated as an appropriate group to assess new applications for molecular pathology testing (via SA Pathology)
- met with SA Health and Adelaide Health Service representatives to discuss clinical governance and the role of SA-HTAG
- considered an application for the PowerPort and PowerPICC technology
- advised SA Health on potential safety issues associated with SILS cholecystectomy
- contacted the public hospital Human Research Ethics Committees to organise information sharing of new device trials taking place
- advised SA Health to collect prospective safety and effectiveness data on the use of the extra-corporeal membrane oxygenation (ECMO) technology and percutaneous heart valve implantation
- received a presentation from RDNS regarding their innovative Strategy 15 Telehealth initiative
- welcomed Dr Peter Marshall (Southern Health representative – FMC).



## ASERNIP-S Advisory Committee

The members of the ASERNIP-S Advisory Committee are:

Mr Ian Civil	<i>Chairman, and College President</i>
The Hon Dr Michael Armitage	<i>Chief Executive, Australian Health Insurance Association</i>
Ms Margaret Charlton	<i>Consumer Representative Health Consumers Alliance</i>
Ms Jane Doyle	<i>Consumer Representative</i>
Professor Kingsley Faulkner	<i>College Fellow</i>
Dr David Hailey	<i>Health Technology Assessment Expert</i>
Mr Brian Johnston	<i>Chief Executive, Australian Council on Healthcare Standards</i>
Professor Guy Maddern	<i>ASERNIP-S Surgical Director</i>
Mr Keith Mutimer	<i>College Fellow</i>
Professor Julian Smith	<i>Chair, Research Audit and Academic Surgery Board</i>

## Representation on external committees

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

- Advisory Committee on Medical Devices (ACMD), 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 Advisory Committee on Medical Devices (ACMD) – 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, Chair
- International Network of Agencies for Health Technology Assessment (INAHTA), Impact of Health Technology Assessment subcommittee – Dr Wendy Babidge, Co-Chair.

# Personnel

During 2010 we welcomed:

- Katherine Economides, A/Manager, Morbidity Audit Projects
- Felicity England, Project Contracts Manager
- Pat Green, Administration Officer
- Ben Hoggan, Research Officer (returned from overseas)
- Heath White, Project Officer
- Dr Yasoba Atukorale, Research Officer
- Keith Hayes, Deputy Director, Research Audit and Academic Surgery Division.

In 2010 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 Provincial HTA Program of Alberta. 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.

- **Dr David Hailey**

Dr David Hailey has extensive experience in health technology assessment (HTA) which has included direction of HTA programs in Canada and Australia. He is currently Senior Fellow, School of Information Systems and Technology, University of Wollongong, a Visiting Scholar at the Centre for Online Health, University of Queensland and Senior Advisor to the Institute of Health Economics, Edmonton, Alberta. Previous appointments included Professor, Department of Public Health Sciences, University of Alberta; Director, Health Technology Assessment, Alberta Heritage Foundation for Medical Research; and Head, Health Technology Division, Australian Institute of Health and Welfare. Recent HTA projects have included reports on pulmonary rehabilitation for COPD, CT and MRI services in Alberta, re-processing of single use devices, and availability and benefits of telemental health services. Current research

interests include effects of introducing computer-based documentation to residential aged care, and care coordination in the delivery of health services to veterans.

- **Vicki Foerster**

Dr. Foerster has a background in medical practice, HTA, government services and medical writing. She was a family physician for 12 years in urban and rural settings in Canada, followed by graduate work at the University of Utah and University of British Columbia (BC). From 1996 to 2000 she worked as a medical consultant at the BC Ministry of Health and in 2000 became the Vice President of Research at the Canadian Agency for Drugs and Technologies in Health (CADTH) in Ottawa. Since 2003 she has been an independent medical consultant undertaking projects for clients such as national and provincial HTA agencies and ministries of health, Accreditation Canada, the Health Council of Canada, the Office of the Chief Scientist, First Nations and Inuit Health, and the Department of National Defence.

- **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, Ms Jody Church, Ms Bonny Parkinson and Ms Pamela Cronin 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.

# Students

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

The Simulated Surgical Skills Program supported Abbey LeBlanc in her fourth-year research proposal. Abbey's proposal utilises laparoscopic surgical simulation to investigate the effects of caffeine on a fatigued surgeon's performance.

Lodewyk du Plessis has spent the past year undertaking a project with the Australian and New Zealand Audit of Surgical Mortality. The focus of Lodewyk's proposal was whether or not thoracic epidural neuro-axial anaesthesia reduces interstitial fluid accumulation in the perioperative setting for elective major colorectal surgery. He was faced with the challenge of investigating whether optimal perioperative fluid management could in fact reduce morbidity and mortality associated with surgery, especially seeing that the South Australian Audit of Perioperative Mortality (SAAPM) implicated fluid management as a confounding factor in 7% of surgical deaths in 2008.

Ataliah Ainol Shahrir worked with the National Breast Cancer Audit as part of her medical course in 2010. She developed a research proposal to evaluate the axillary recurrence in breast cancer patients after sentinel node biopsy surgery, according to other axillary surgery treatment, adjuvant therapy and tumour characteristics.

Patrick Wolff worked with the Bi-National Colorectal Cancer Audit (BCCA) in 2010 as part of his Health Data Administrator Studies. Patrick worked across a number of specialised multi-site audit activities; this included spending time in the ASERNIP-S office in South Australia, and also travelling to Melbourne to the College head office. Whilst in Melbourne Patrick worked with the Victorian Audit of Surgical Mortality (VASM) assisting in the management and review of health documentation from a range of health services.

# Staff

Professor Guy Maddern

Dr Wendy Babidge

Keith Hayes

Nicola Robinson

Dr Alun Cameron

Dr Prema Thavaneswaran

Eleanor Ahern

Meryl Altree

Dr Yasoba Atukorale

Susan Dawe

Dr Primali De Silva

Katherine Economides

Felicity England

Deanne Forel

Jane Franklin

Jessica Gadsby

Pat Green

Stephanie Gurgacz

Ben Hoggan

Karen Humphreys

Louise Kennedy

Irving Lee

Tania Margitich

Nicholas Marlow

Claire Marsh

Wendy Morros

Michelle Ogilvy

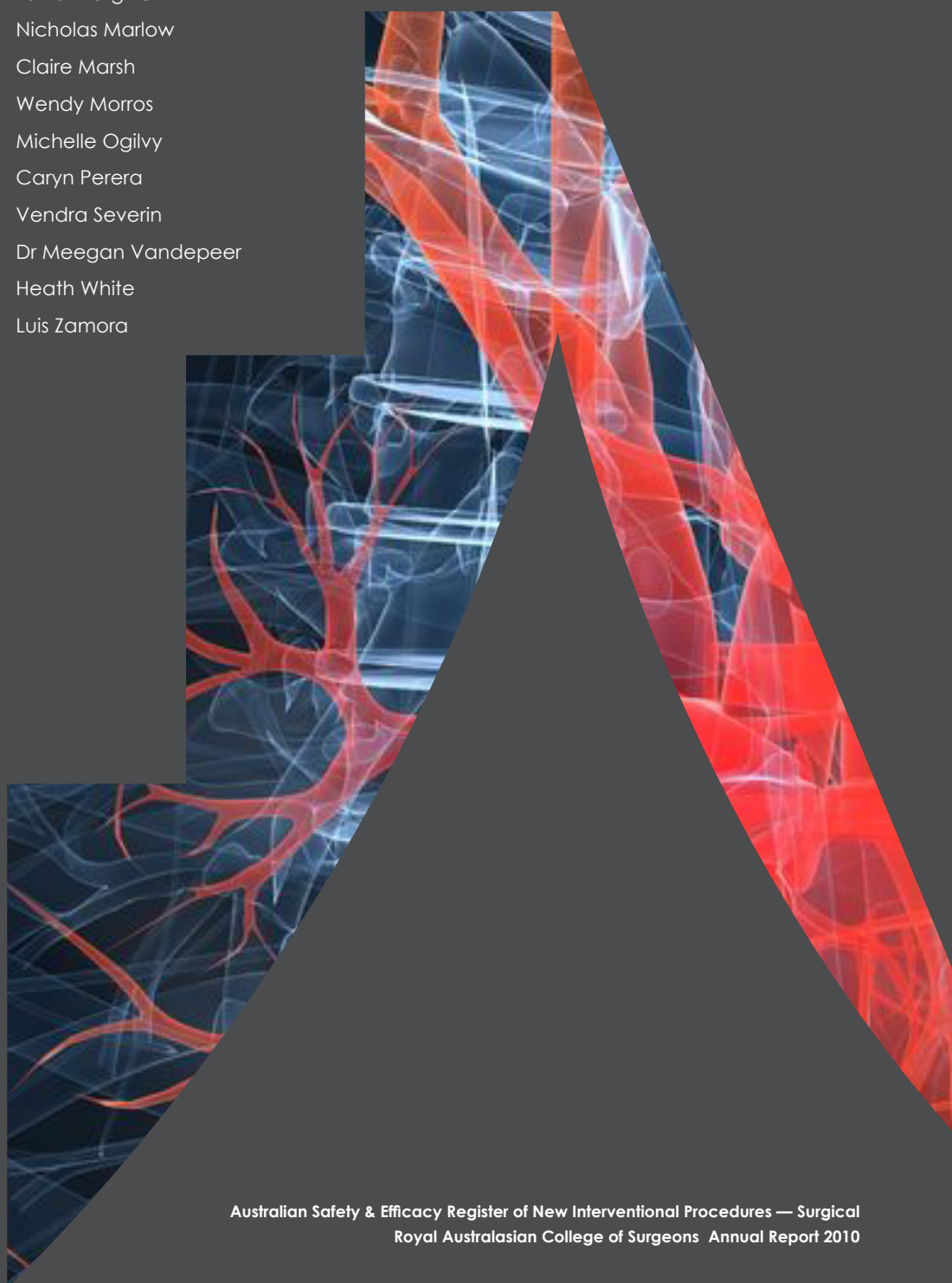
Caryn Perera

Vendra Severin

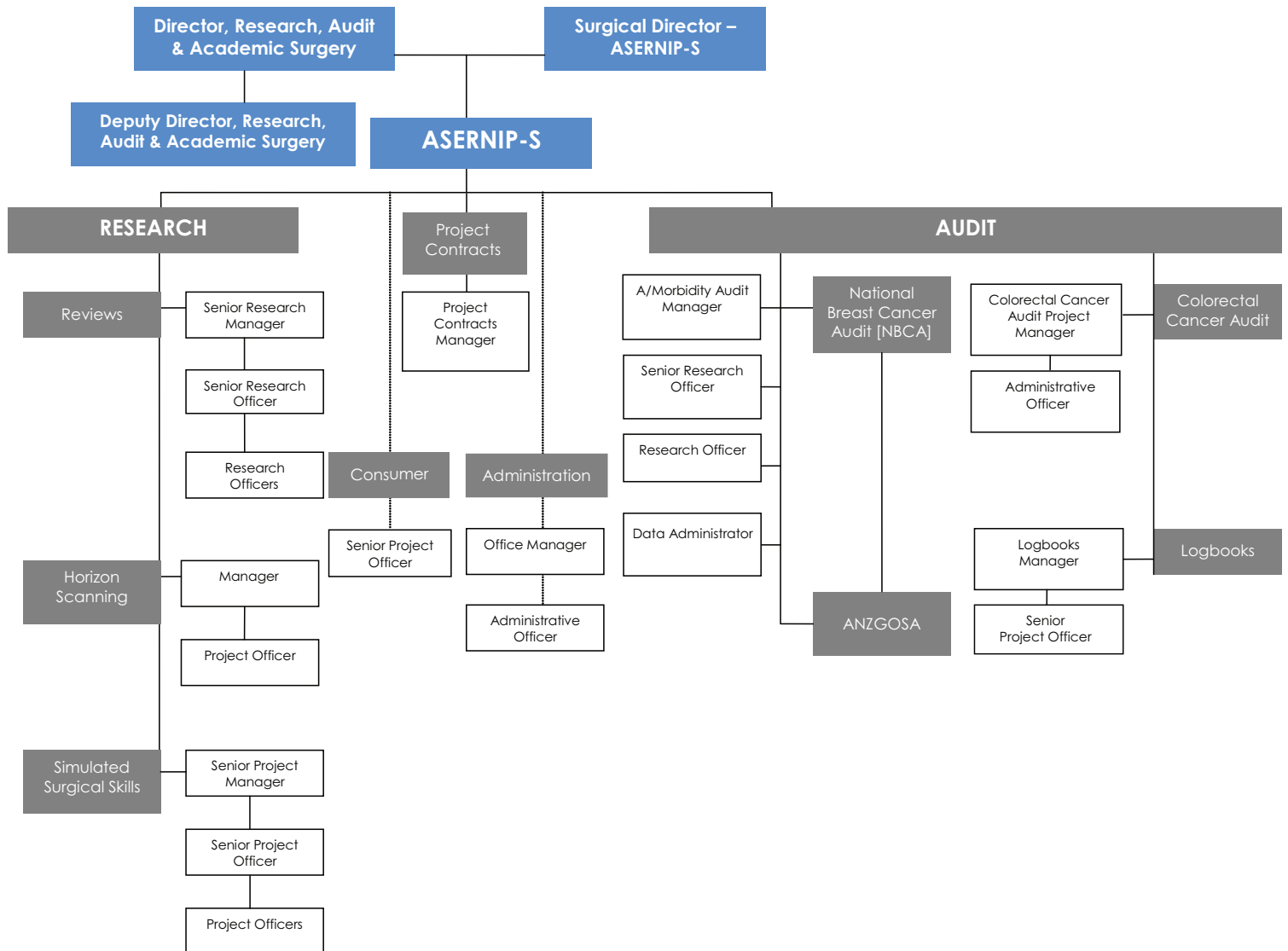
Dr Meegan Vandepeer

Heath White

Luis Zamora



## Research, Audit and Academic Surgery Division – Royal Australasian College of Surgeons ASERNIP-S organisational chart





## Staff



**Professor Guy Maddern**



**Dr Wendy Babidge**

### **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 has over 50 staff members across Australia, with approximately 30 in Adelaide. 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. She is a Graduate of the Australian Institute of Company Directors. In 2010 she was appointed as Chair of the International Network of Agencies for Health Technology Assessment Board.



**Keith Hayes**



**Nicola Robinson**

### **Deputy Director, Research, Audit and Academic Surgery Division**

#### **Keith Hayes**

Keith Hayes joined the Royal Australasian College of Surgeons in November 2010, replacing Nicola Robinson in the role of Deputy Director, Research, Audit and Academic Surgery. Keith oversees the administration of the Scholarships program, the Board of Surgical Research, the Section of Academic Surgery and the Surgical Research Society. He is also leading the establishment of a dedicated divisional Research Office, to provide a robust framework for the development of high quality research funding proposals. Keith holds an Honours degree in Chemistry from Flinders University and brings to the College a broad range of senior management experience, gained from numerous roles within the water industry and, most recently, the grape and wine sector.

#### **Nicola Robinson**

Nicola Robinson was the Deputy Director of the Division of Research, Audit and Academic Surgery of the Royal Australasian College of Surgeons. Nicola had oversight of the College mortality audits, the provision of scholarships for surgical research and associated fundraising activities. She was 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. Nicola left the Division in 2010.



**Dr Alun Cameron**



**Meryl Altree**



**Katherine Economides**



**Felicity England**



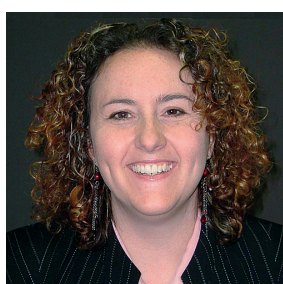
**Deanne Forel**



**Claire Marsh**



**Wendy Morros**



**Vendra Severin**

### **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 is responsible for coordinating the activities of the Simulated Surgical Skills Program: a national multi-site project investigation of the applicability of laparoscopic surgical simulators to the education and maintenance of the surgical workforce in Australia.

### **ASERNIP-S Acting Manager, Morbidity Audit Projects**

#### **Katherine Economides**

Katherine Economides joined the College in February 2010. She is the A/Manager, Morbidity Audit Projects. Previously she has worked in a diverse range of environments primarily in large acute care public hospitals, including human resource management, frontline management and project management. She has a Diploma in Frontline Management.

### **ASERNIP-S Project Contract Manager, Research, Audit and Academic Surgery Division**

#### **Felicity England**

Felicity England commenced as the Projects Contracts Manager in February 2010. Felicity is responsible for the review and negotiation of the various contracts which both inform the Division's project activities for external stakeholders and support its activities in the form of externally provided services. Felicity has 10 years experience as a solicitor in South Australia working in the interpretation of contracts, negotiation and with extensive experience in commercial and insurance litigation. Felicity has a Bachelor of Arts, a Bachelor of Laws and a Graduate Diploma in Legal Practice.

### **ASERNIP-S Horizon Scanning Manager**

#### **Deanne Forel**

Deanne Forel joined ASERNIP-S in October 2007 as a Research Officer to carry out systematic literature reviews. She has a Bachelor of Science, specialising in Microbiology. During her time at ASERNIP-S she has been involved in conducting various systematic reviews. Deanne has also been increasingly involved in the Horizon Scanning program, for which she took on the Project Manager role in August 2010.

### **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. Claire left ASERNIP-S in 2010.

### **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 of Research Audit and Academic Surgery, 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 was the Bi-National Colorectal Cancer (BCCA) Project Manager and the Logbooks Manager. As BCCA Project Manager she was responsible for the establishment of a bi-national surgical audit for the Colorectal Surgical Society of Australia and New Zealand (CSSANZ). As Logbooks Manager she was responsible for the development of a web-based Logbook application for Trainees and Fellows of the College. Previously she has worked in a diverse range of registry/audit environments, specialising in cancer data, more specifically urology and colorectal. She has a Graduate Certificate in Health (Health Service Management), Flinders University South Australia. Vendrea left the Division in 2010.

# 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 2008-2009



# Appendix A

## Hierarchy of evidence

### Designation of levels of evidence<sup>1</sup>

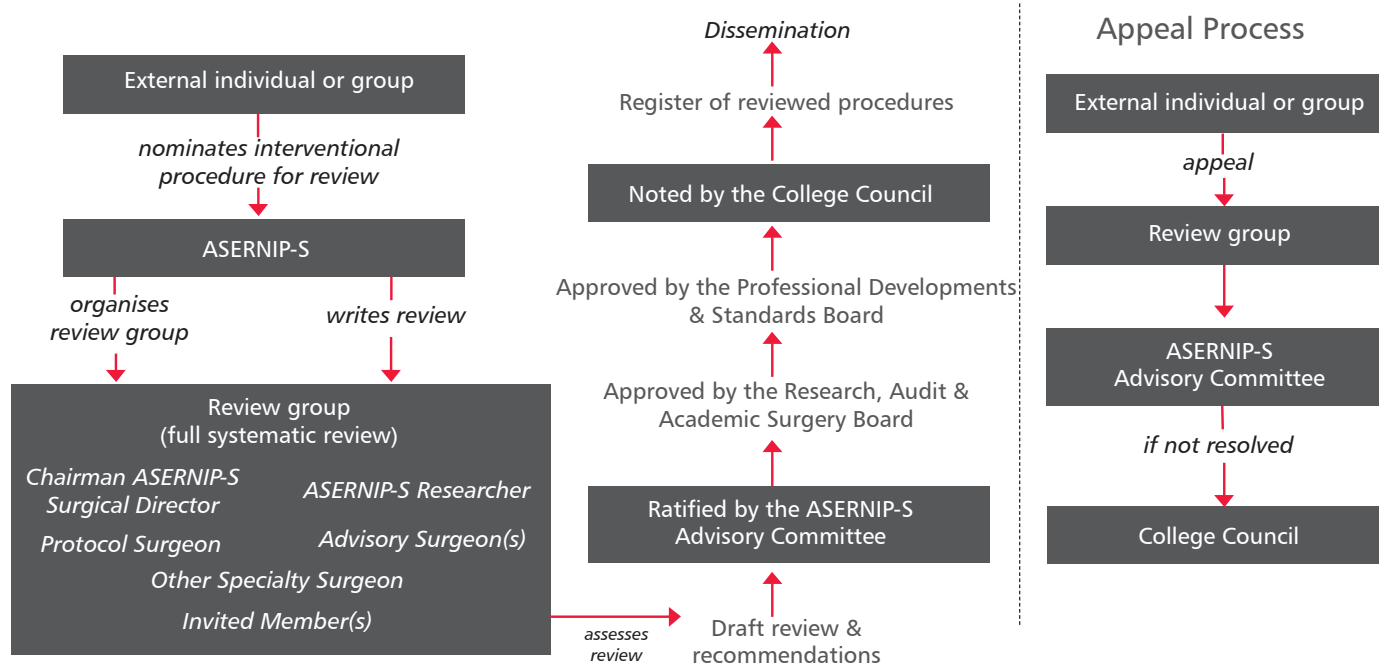
Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation 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 2008-2009

### 2009

ASERNIP-S Report no 55

Permanent and semi-permanent dermal fillers, February 2009

ASERNIP-S Report no. 68

The effect of fatigue on surgeon performance and surgical outcomes, August 2009

ASERNIP-S Report no. 71

Endoscopic thoracic sympathectomy (evidence essential), August 2009

ASERNIP-S Report no. 72

Neoadjuvant radiochemotherapy for rectal cancer (evidence essential), August 2009

ASERNIP-S Report no.73

Radiofrequency ablation for the treatment of renal tumours (evidence essential), March 2010

Ananda SS, McLaughlin SJ, Chen F, Hayes IP, Hunter AA, Skinner IJ, Steel MCA, Jones IT, Hastie IA, Rieger NA, Shedda S, Compston DJ, Gibbs P. Initial impact of Australia's National Bowel Cancer Screening Program. *MJA* 2009; 191(7): 378-381

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

Leopardi D, Hoggan BL, Fitridge RA, Woodruff PW, Maddern GJ. Systematischer Review zur Therapie von Varizen. *Vasomed* 2009; 6: 234-235

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

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* 2010 Nov; 80(11): 776-780

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, 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* 2009; 18: 378-381

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

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

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

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

Simulated Surgical Skills Program. *Royal Australasian College of Surgeons Surgical News*, August 2009; 10(7): 16

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

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

### 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
- 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
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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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