ANNUAL REPORT 2011

Australian Safety and Efficacy Register of
New Interventional Procedures — Surgical

Royal Australasian College of Surgeons

ASERNIP-S

Contents

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

The year 2011 has been one of consolidation for the ASERNIP-S project. During this time we have settled into our new offices adjacent to the local headquarters of the Royal Australasian College of Surgeons. The new facilities have proven to be an outstanding work environment with significant enhancement from our previous offices. The team has been able to work with less disturbance, improved meeting and work facilities, and hence a more professional and appropriate environment.

The contracts for the Medical Services Advisory Committee and HealthPACT have continued, as has additional work performed for the New Zealand Government, state departments of health and, indeed, the College of Surgeons, particularly in the area of credentialing of surgeons. This has been combined with the conclusion of the Simulated Surgical Skills Program, from which eight to ten manuscripts are currently being generated.

As one would expect in such a diverse and dynamic project, arrivals and departures are inevitable. It is with great regret that we lose Nicholas Marlow from the Simulated Surgical Skills Program after six years of service to ASERNIP-S and the simulation agenda. In addition we saw the departure of Alun Cameron, who had been with us also for six years performing research and later management roles within the ASERNIP-S team.

Over the last twelve months Wendy Babidge has been able to maintain her management role across the Research, Audit and Academic Surgery Division of the College while also holding the position of Chair of INAHTA (International Network of Agencies for Health Technology Assessment). Her endless energy and wise guidance has been a stabilising force not only for the College projects but also in her role as chair of an international organisation.

"There can be little doubt that the role of ASERNIP-S is becoming increasingly relevant."

Guy Maddern
Surgical Director

In 2012 I have been asked to help lead the Scientific Committee for the Health Technology Assessment International meeting in Bilbao. This again reflects well on the leadership shown by the ASERNIP-S group over the last decade and our place as the premier evaluator of new surgical technologies worldwide.

During the year there has also been the opportunity to present the work of ASERNIP-S in a number of venues both within Australia and overseas. The International Society for Quality in Health Care meeting held in Hong Kong enabled me to participate in a plenary session discussing issues of comparative effectiveness research, particularly as it has now been taken up by the Obama Administration.

There can be little doubt that the role of ASERNIP-S is becoming increasingly relevant. The quality of the work continues to be of the highest standard and the research conducted remains an essential activity for the College.

ASERNIP-S reviews

- New assessments completed
- Procedure nominations
- Simulated Surgical Skills Program

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

- Credentialing in surgery: a systematic literature review
  ASERNIP-S Report no. 78

Reviews for other organisations

- Radiofrequency ablation for Barrett's oesophagus with dysplasia
  (MSAC Application 1143)
- Matrix-induced autologous chondrocyte implantation and autologous chondrocyte implantation
  (MSAC Application 1140)
- Computer-navigated total knee arthroplasty
  (MSAC Application 1123)
- Artificial intervertebral disc replacement – lumbar
  (MSAC Application 1090.1)
- Percutaneous sclerotherapy for vascular malformations
  (Department of Health, Victoria)
- Two evaluations for the Therapeutic Goods Administration
  (Federal Department of Health and Ageing)
- MBS Quality Framework
  (Federal Department of Health and Ageing)

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 Procedures page of the website and download a nomination form.

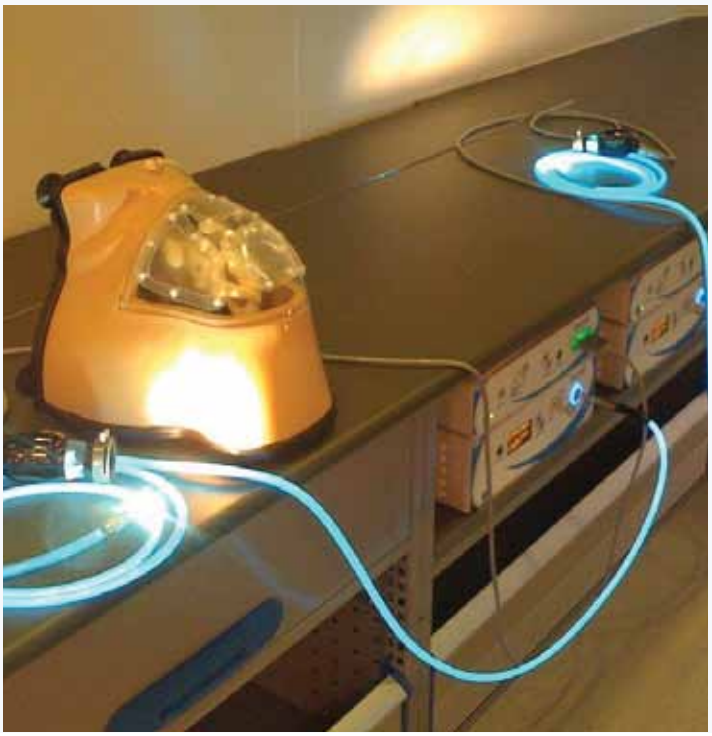
Other commissioned projects

Simulated Surgical Skills Program

The Simulated Surgical Skills Program (SSSP), funded by the Australian Government Department of Health and Ageing, was charged with the development, implementation and assessment of a new laparoscopic surgical skills training curriculum. This curriculum incorporates the use of laparoscopic simulators alongside traditional training techniques, to provide a new mode of surgical skills training in Australia. Furthermore, the SSSP also developed a 'train the trainer' program to assess the best way to teach the new laparoscopic curriculum.

This project concluded on 30 September 2011 following the submission of the SSSP final report. This document provides in comprehensive detail the operations of the project over its four-year duration. The success of the SSSP is a testament to the coordination of efforts of SSSP staff, the governing committees of the project and the dedication of participant trainees.

It is hoped that the substantial findings detailed in this report will be used to provide an informed direction to this form of surgical training throughout Australia.



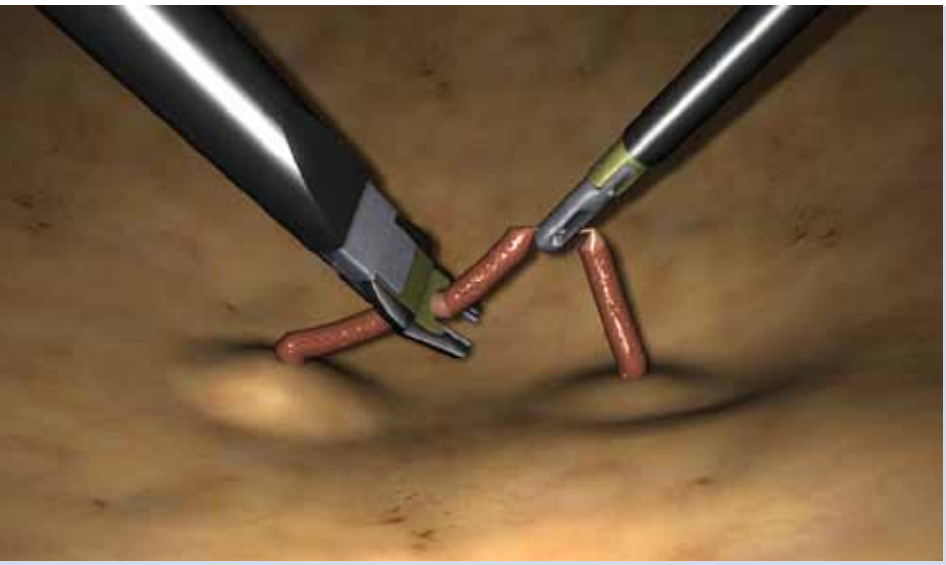
The Simulated Surgical Skills Program

The Simulated Surgical Skills Program (SSSP) was established to assess the feasibility of a curriculum for simulation training in Australia for laparoscopic surgery. Various aspects were studied in detail regarding type of simulator, length and frequency of training, maintenance of skills, training site, mode of training, effect of fatigue and the potential to use non-surgeon trainers. All reporting requirements were met and the overall goals of the project were achieved.

Implementation

The SSSP received operation guidance from both its Steering and Scientific Advisory committees. Bi-annual meetings were held for both committees where progress regarding the implementation at each site, data analysis and reporting were discussed. The significant involvement of each committee member was important in assuring the success of the SSSP. Their feedback provided valuable guidance to SSSP staff.

At the height of its implementation, the SSSP operated with five full-time staff members. These staff members managed or assisted in the operation of each SSSP training site. Sites operated in each mainland Australian state between April 2009 and December 2010; the duration of these sites differed due to the research study being investigated. The quality of the research data that was produced at each site was exceptional. Study methodologies were adhered to, no participant incidents occurred and losses to follow-up were minimal.



An extension to the timeframe for this project enabled the SSSP to trial the use of a Mobile Simulation Unit (MSU) as a teaching modality. It is important to highlight the considerable interest from hospitals and industry regarding the MSU. Indeed, this vehicle has become synonymous with the SSSP and was requested at conferences and other meetings in Perth, Adelaide and Launceston.

The research program conducted by the SSSP incorporated information from a number of different sources. A systematic review was conducted that examined peer-reviewed literature on the transferability of laparoscopic skills from the training room to the operating room; stakeholder consultations were performed to ascertain current opportunities for laparoscopic training; feedback was provided from international leaders in laparoscopic training and education; and finally, extensive primary research studies were conducted on laparoscopic simulation training. Central to the research studies were the low fidelity Fundamentals of Laparoscopic Surgery (FLS) and the high fidelity Surgical Science LapSim simulators.

Systematic review

The systematic review, which examined articles on the transferability of laparoscopic skills from the training room to the operating room, indicated significant benefits of simulation training.

Stakeholder consultations

The SSSP contacted universities, state health departments, state branches of the Royal Australasian College of Surgeons and industry groups to establish the range of laparoscopic training opportunities available. This research identified a range of courses that were centralised around major skills centres; however, it was clear that there were no universally accessible basic laparoscopic skills courses available.

Feedback

International feedback was provided at the first SSSP Steering and Scientific Advisory Committee meeting. Several renowned international experts provided an overview of the current trends in surgical simulation training for their country. These accounts demonstrated that the current status of laparoscopic skills training in Australia was similar to that experienced overseas.

Primary research

The SSSP conducted primary research across each of the following research areas:

Mobile Simulation Unit

The focus of the MSU research was to determine whether or not location influenced participant training outcomes, specifically, whether there were any issues for training in the MSU compared with fixed sites. Research data were collected from a total of 228 participants enrolled from Western Australia (WA), South Australia (SA) and New South Wales (NSW). The mean crossover scores of the two cohorts (fixed site-trained and MSU-trained) were compared. The MSU FLS-trained LapSim crossover scores were significantly better than the fixed site FLS-trained LapSim crossover scores ($p<0.001$). There was no statistically significant difference between MSU or fixed site LapSim-trained FLS crossover scores.

This result demonstrated that the MSU performed as well as, if not better than, fixed sites.

Skills acquisition

The skills acquisition research examined whether laparoscopic simulator fidelity type influenced the rate at which participants learnt. The number of attempts taken to reach a predetermined level of proficiency was recorded for 398 participants. This dataset comprised results from participants at each SSSP site. The mean number of training attempts for FLS and LapSim participants was compared.

Participants trained on the FLS simulator reached task proficiency and overall proficiency in fewer attempts than participants trained on the LapSim simulator ($p<0.001$, for both comparisons).

This significant result controlled for the different number of tasks per FLS and LapSim simulator, and demonstrated that training times can be reduced if the FLS simulator is used to teach basic laparoscopic skills.

Skills maintenance

The examination of skills maintenance compared the attrition rates of participants who had achieved a predetermined level of proficiency. Assessments were held at one, three and six months: of an initial cohort of 57 participants from SA, 26 completed all follow-up assessments. Participant follow-up assessment scores were compared to their proficiency scores and changes in their skill level examined. Participant skills were maintained at different rates depending on which simulator the participant trained. FLS participant scores did not differ at any point from the proficiency scores. LapSim-trained participant scores dropped significantly at their first and second follow-up assessments ($p<0.001$); however, this decrease was recovered by the final follow-up, when participant scores were not significantly different from their proficiency score.

Although FLS-trained participants maintained a higher skill level overall, by the end of the follow-up period participant skill levels were not significantly different from proficiency for both simulators.

Low versus high fidelity simulation

This research study compared simulation training outcomes for each simulator. Participants from NSW, WA and SA trained to proficiency on one simulator, before completing a crossover assessment on the other. Proficient FLS participants were assessed on the LapSim and vice-versa. These results identified a skills increase in FLS-trained participants of 11.9% and in LapSim-trained participants of 11.0%; however, the difference was not significant. FLS participants were significantly more likely than LapSim participants, on average, to pass a task at crossover ($p=0.016$).

The finding that FLS participants were more likely to pass tasks at crossover demonstrated that training on this simulator resulted in better training outcomes for participants.

Simulation versus traditional training

The research comparing simulation and traditional laparoscopic skills training methods enrolled participants from NSW, WA and SA. A crossover score was produced to assess the impact of simulation training, and an assessment score was similarly produced to assess the impact of traditional training.

Scores were collected and compared separately for the FLS and LapSim simulators. These comparisons showed no statistically significant differences in basic laparoscopic skill levels between simulation-trained and traditionally-trained participants (FLS $p=0.11$; LapSim $p=0.27$).

The equality in simulation-trained and traditionally-trained participant basic laparoscopic skill levels demonstrated that both simulators can be used as an adjunct to the current operatively-based mentored approach.

Fatigue

Fatigue level 1

The impact of fatigue was examined in this research study, specifically, the effect that a 10-hour day has on a participant's basic laparoscopic skills. The 73 participants enrolled, trained and assessed in this study came from Victoria. These participants were trained to proficiency and then performed an assessment after working a 10-hour shift. Fatigue was found to have a detrimental effect over and above the normal attrition rate. Fatigued FLS-trained participants suffered a decrease in score of 0.73, which is significantly above the normal attrition rate of 0.13 ($p=0.02$). Similarly, fatigued LapSim-trained participants suffered a decrease of 1.14, which is also significantly greater than the attrition rate for that simulator of 0.32 ($p=0.02$).

This research has demonstrated that fatigue leads to significantly decreased basic laparoscopic skills.

Fatigue level 2

This research study was unable to enrol, train and assess enough participants at the higher level of fatigue (24 hours on call) to perform any meaningful statistical analyses.

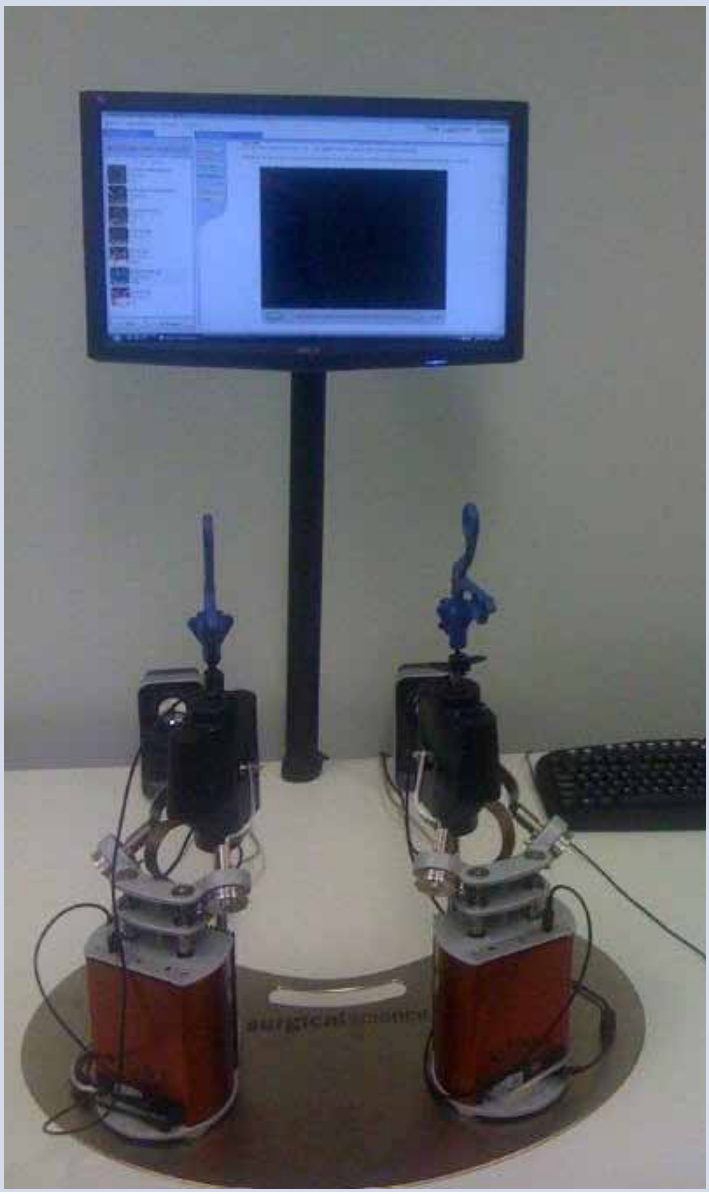
Surgeon versus non-surgeon training

In this research surgeon and non-surgeon trainers were used to determine whether or not their experience backgrounds had any implications on the learning outcomes of participants. Attempt data were used from 398 participants from QLD, NSW, Vic., SA and WA. The number of attempts taken to reach proficiency for both surgeon and non-surgeon trained cohorts were compared. The results identified that non-surgeon trained FLS participants reached overall proficiency in significantly fewer attempts than those who were trained by surgeons ($p<0.001$). Non-surgeon trainers also trained participants to proficiency faster than surgeon trainers for the following tasks: peg transfer ($p=0.003$), extracorporeal knot-tying ($p=0.03$) and ligating loop ($p<0.001$). Only one significant difference was identified when the training outcomes of surgeon and non-surgeon trained LapSim participants were examined: non-surgeon trainers trained participants to proficiency with significantly fewer attempts than surgeon trainers for the coordination task ($p=0.01$).

These results demonstrated that trained non-surgeon trainers can teach basic laparoscopic skills as well as experienced surgeon trainers.

Conclusion

The research conducted by the SSSP examined the current status of laparoscopic skills training. The review of the literature demonstrated that there was some evidence to suggest that the skills taught in the training room can have positive implications in the operating room. Feedback from international leaders has shown that current international approaches to laparoscopic skills training are faced with the same issues as those found in Australia. This primary research study has produced a number of statistically significant and important results which can guide the use of laparoscopic simulation training as part of the surgical curriculum in Australia.



Data collection

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

National Breast Cancer Audit

The National Breast Cancer Audit (NBCA) has been in operation for 13 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 2011, the NBCA has continued to strive for this quality through improving coverage of cases collected and providing valuable output for research.

Data collection

As of 7 September, the NBCA had 113,310 episodes of early breast cancer recorded and 332 active accounts for the online data portal. The audit collects data through its online data portal, but also through uploading data from existing registries and hospital databases. There are two uploads performed each year, combining data from different sources – in 2011 almost 4000 episodes will have been contributed to the audit in this way by the end of the year. As an aggregate of the total database, institutional upload normally contributes about 17% of all the data collected.

Feedback and assessment

The online data portal provides participating surgeons with real-time assessment against national benchmarks for the treatment of early breast cancer. These Key Performance Indicators (KPIs) are developed by the Steering Committee and based on the National Breast and Ovarian Cancer Centre recommendations, specifically the *Clinical Practice Guidelines for the management of early breast cancer* (2001) and the *Clinical management of ductal carcinoma in situ, lobular carcinoma in situ and atypical hyperplasia of the breast* (2003).

Data collection

A fifth KPI regarding high risk cases was implemented in early 2011. The KPIs available now are:

	Description	Threshold
1	Percentage of invasive cases undergoing breast conserving surgery referred for radiotherapy	≥85%
2	Percentage of oestrogen-positive invasive cases referred for hormonal therapy treatment	≥85%
3	Percentage of invasive cases undergoing axillary surgery	≥90%
4	Percentage of in situ cases undergoing breast conserving surgery without axillary surgery	≥90%
5	Percentage of high risk invasive cases undergoing mastectomy referred for radiotherapy	≥85%

Output and partnerships

- The NBCA continues to provide data and analyses for peer-reviewed publications, with one article on the use of Trastuzumab in Australia and New Zealand being accepted for publication and more in development.
- The NBCA has been pleased to continue its collaboration, begun in 2010, with the National Breast and Ovarian Cancer Centre (now Cancer Australia), researching factors that influence survival from breast cancer in Australia. In 2011 for the first time this study included New Zealand data, with the support of the Cancer Society of New Zealand. The study examined two factors: bilateral synchronous cancer and declining treatment. Papers on the results are currently in production. This research has been possible due to funding from the National Breast Cancer Foundation and the Cancer Society of New Zealand.
- The NBCA has also been pleased to continue its collaboration with the Ministry of Health in New Zealand, and will later this year produce the third of three annual reports comparing patients diagnosed through BreastScreen Aotearoa with patients diagnosed via other means. This was made possible due to funding from BreastScreen Aotearoa. The NBCA is currently in negotiations to continue this collaboration for a further three annual reports.

Governance

In 2010, the Breast Surgeons of Australia and New Zealand (BreastSurgANZ) took over responsibility for the audit from the College. The Research, Audit & Academic Surgery (RAAS) Division of the College continues to manage the day-to-day running of the audit; however, a new governance structure has been formed under the auspices of the BreastSurgANZ.

The Clinical Director of the NBCA is Dr David Walters. The Chair of the Steering Committee is Mr James Kollias.

For further information or feedback regarding the National Breast Cancer Audit please see our website at www.surgeons.org/nbca or contact the Helpdesk at breast.audit@surgeons.org or +61 8 8219 0918.

ANZGOSA Audit

The ANZGOSA Audit has been designed for the Australian and New Zealand Gastric and Oesophageal Surgical Association (ANZGOSA) as a self-assessment tool for their members and has been in operation for one year. The audit collects clinical and pathological details of patients undergoing surgery for oesophago-gastric cancer or gastrointestinal stromal tumour in Australia and New Zealand. Collated bi-national data will form an accurate picture of upper gastrointestinal cancer treatment for research and assessment purposes.

Data collection

Surgeons submit data through an online portal via secure log-in. This portal can be accessed through the ANZGOSA website (www.anzgosa.org) or the College website (www.surgeons.org/anzgosa).

As at 28 September 2011 (just over one year after commencing), the audit had 44 active surgeon accounts (about 30% of ANZGOSA Fellows) and had collected 284 cases.

An institutional upload program is currently in development. An upload program allows institutions with a large case volume and sufficient commonality of fields to have their data directly uploaded into the system each year, rather than having to re-enter data manually.

Data dictionary

The data dictionary was published online in 2011, and is available from the College website and the Help & Support section of the data portal.

Data portal development

In 2011, a new feature was added to the data portal. Data manager access allows an approved third party to log-in and enter data for multiple surgeons, while restricting access to only those cases where permission has been granted.

Data export and reporting functions are also in development. These new features will allow for further analysis of personal data, as well as comparisons of surgical performance against a bi-national aggregate on pre-determined areas of interest.

Data analysis

A preliminary report was produced in March 2011; however, as limited data were available, no conclusions were drawn. The analysis did bring to light some issues with the dataset and database structure. Necessary changes have since been implemented.

Legal indemnity

In 2011, the ANZGOSA Audit was declared a Quality Assurance Activity under the *Commonwealth Health Insurance (Quality Assurance Confidentiality) Amendment Act 1992* in Australia and a protected quality assurance activity under the *Health Practitioners Competence Assurance Act 2003* in New Zealand. The purpose of this legislation is to ensure that information that becomes available as a result of the activity cannot be disclosed, other than for general reporting purposes.

For further information on the ANZGOSA Audit, visit the website (www.surgeons.org/anzgosa) or contact the audit helpdesk at anzgosa.audit@surgeons.org or +61 8 8219 0918.

Bi-National Colorectal Cancer Audit

As of late 2010, the Bi-National Colorectal Cancer Audit has been managed and operated solely by the Colorectal Surgical Society of Australia and New Zealand. The College continues to house the database and provide data entry support; however, in 2012 the Colorectal Society will take over full responsibility for this.

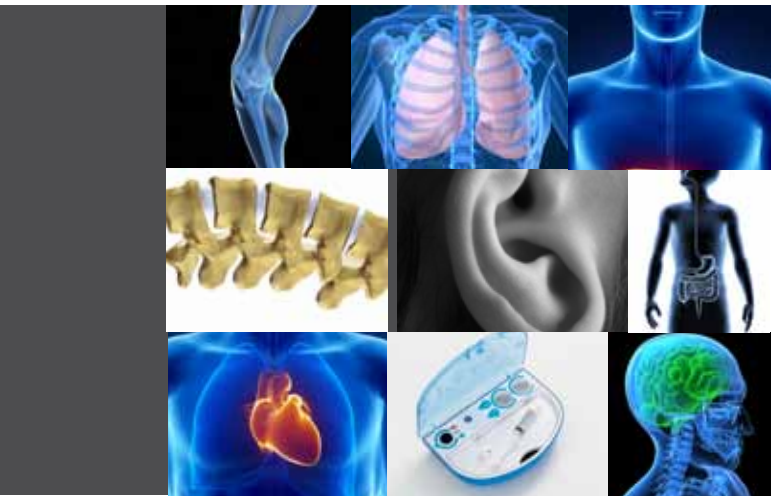
New and Emerging Techniques – Surgical (NET-S)

- NET-S horizon scanning project
- NET-S on the web

NET-S 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 NET-S project continues to work with the Health Policy Advisory Committee on Technology (HealthPACT) of the Australia and New Zealand Horizon Scanning Network (ANZHSN), the management of which transferred from the Department of Health and Ageing to Queensland Health in 2011. The NET-S assessments that are prepared for HealthPACT are presented in the form of technology briefs (formerly known as prioritising summaries) or new and emerging health technology reports (formerly known as horizon scanning reports). Technology briefs are short documents designed to provide readers with background on a particular technology and present the available evidence pertaining to the safety and efficacy of that technology. When a procedure or technology is considered to be of substantial impact and has a considerable evidence base, a more detailed assessment, in the form of a new and emerging health technology report, will be undertaken.



NET-S on the web

All briefs and reports prepared by the NET-S project for HealthPACT are available for download from the:

- NET-S website (http://www.surgeons.org/racs/research-and-audit/asernip-s/new-and-emerging-techniques-surgical)
- ANZHSN website (http://www.horizonscanning.gov.au/).

Technology briefs prepared for HealthPACT in 2011:

- 90Y Zevalin for the treatment of non-Hodgkin's lymphoma
- regional hyperthermia for soft-tissue sarcoma
- selective internal radiation therapy for the treatment of liver cancer
- high sensitivity troponin assays for the diagnosis of myocardial infarction.

New and emerging health technology report prepared for HealthPACT in 2011:

- peptide receptor radionuclide therapy using somatostatin analogues to treat neuroendocrine tumours.

The EuroScan International Network is a leading global collaborative network of member agencies that collects and shares information on innovative technologies in healthcare, in order to support decision-making and the adoption and use of effective, useful and safe health technologies. As a member of EuroScan through HealthPACT, all NET-S technology briefs are also uploaded to the EuroScan database (http://euroscan.org.uk/), where they are available for viewing.

In addition, the NET-S project has continued to undertake horizon scanning assessments for the American College of Surgeons, with a focus on general surgery.

Horizon scanning assessments prepared for the American College of Surgeons in 2011:

- anal fistula plugs
- radiofrequency-assisted liver resection.

Project activities

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

Project Office – function and activities

During 2011, the RAAS Division began to develop a centralised 'Project Office', as part of the implementation of an improved service delivery model to the Division and ASERNIP-S, a key area of the Division. The brief of the Project Office is to manage all aspects of research projects undertaken by the Division throughout their lifecycle, from the bid management stage through to close-out and post-implementation reviews of completed assignments. Additionally, the Project Office is a central resource for the provision of administrative, editing and legal support to the Division, as well as acting as a principal point of contact with the College's Finance Department.

The Project Office is the responsibility of RAAS Deputy Director, Keith Hayes, with support from Felicity England (Projects Contracts Manager), Eleanor Ahern (Editorial Manager) and Administration staff (Jane Franklin and Pat Green).

A number of functions are coming onstream as the model develops. As the conduit for project management issues, Project Office activities include:

Research project bids

- scope definition – understanding and responding to customer requirements
- preparation of consistent, competitive, high-quality bids.

Contract management

- oversight and management of contracts, variations, extensions and renewals for all Divisional projects and other business activities
- liaison and negotiation with clients on contractual matters.

Progress and final reports

- ensuring that reports are prepared in accordance with client requirements and to a high standard that is consistent with the College's ISO 9001 Quality Management System
- coordination of financial reconciliations and acquittals.

Scheduling of project activities

- maintenance of a Master Project Schedule to ensure that projects have adequate staff, materials and equipment resources available to deliver outcomes successfully, within agreed timeframes
- forward planning for future opportunities.

Project implementation/performance reviews

- On completion of projects, the Project Office reviews the work delivered against the original scope agreed with clients. This information is used to provide feedback on performance and can also be fed forward to inform and 'tune' future bids to maximise value and service delivery.
- The Project Office reviews 'lessons learned' from projects, to inform future proposal development and retain a focus on continuous improvement.
- The Project Office carries out periodic 'client satisfaction surveys' to build relationships and maintain a productive dialogue with key clients. This is intended to provide a mechanism for continuous improvement of the RAAS service delivery model.

Contracts

The Division's contract management function has moved into the new management structure created by the Project Office, overseen by the Division's Deputy Director. As part of this move, additional resources became available to help the contract office modernise and streamline the record keeping for contractual documents. In turn, the Projects Contracts Manager has contributed to new and developing procedures for the service delivery model for the Division's contracts. It is anticipated that these new procedures will add further value to the important work of the Division's project managers in continuing to deliver high quality project work for all clients of the Division.

The Projects Contracts Manager has continued to work closely with both the Director and Deputy Director in the areas of strategic advice, particularly as regards the Division's various information technology systems.

ASERNIP-S

Earlier this year, a renewed Master Agreement was entered with the South Australian Department of Health (SA Health). This contract has supported the renewal of the ASERNIP-S contract with the SA Health's Health Technology Assessment Group.

This year has seen the end of the longstanding horizon scanning contract with the Australian Government. The secretariat for the Australian horizon scanning work has now moved to Queensland Health. A contract was entered for four technology briefs and one technology report. It is hoped that in the near future an opportunity to enter a standing agreement will arise with HealthPACT.

ASERNIP-S was successful in tendering and settling a Head Agreement with the New Zealand Accident Compensation Corporation.

Variations to the health services evaluation work contracts were processed and the work successfully completed. Both the Head Agreement for Health Services Evaluation work and the Medical Services Advisory Council (MSAC) consultancy contract were extended to 30 June 2012. Ten contracts were entered to support MSAC consultancy services for seven different applications.

SSSP

With the finalisation of the SSSP, the RAAS Division has successfully negotiated a new research project which represents an enhancement to the existing Surgical Training Program undertaken within the Education and Training Administration Division.

Consumer involvement

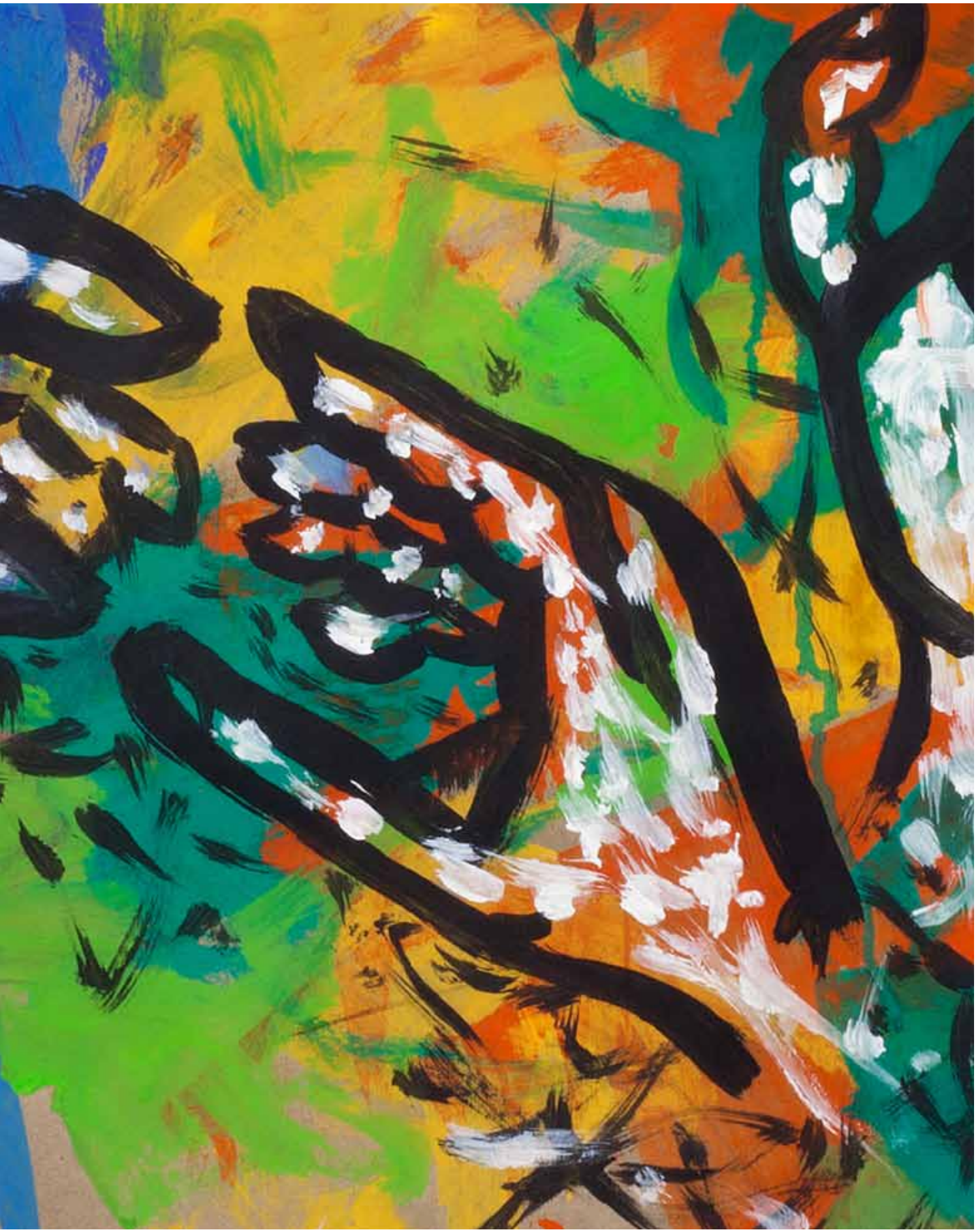
Consumer involvement continues to play a major role in the work of ASERNIP-S. We benefit from consumer representation on the ASERNIP-S Advisory Committee. We work with organisations such as Breast Cancer Network Australia, in collaboration with the National Breast Cancer Audit, and Consumers Health Forum (of which we are a member).

The consumer representatives on the Advisory Committee, Marg Charlton from the Health Consumers Alliance and Jane Doyle, professional communicator, provided expert advice on consumer issues and helped us to disseminate our research to a wide audience. This year we increased our efforts to inform consumers of the information available on our website. After uploading our latest consumer summary on autologous fat transfer for breast augmentation to the website, we prepared articles for publications targeted at surgeons (Royal Australasian College of Surgeons *Surgical News*) and consumers (newsletters of Australian Health Insurance Association, Consumers Health Forum and Health Consumers Alliance). We are grateful to Marg and Jane for their wonderful contribution to the work of ASERNIP-S, and thank Jane, who resigned from the committee earlier this year due to work commitments, for her hard work and enthusiasm since 2002.

An article outlining the many roles of consumers in the RAAS Division entitled 'Consumer perspectives in surgical research and audit' was published in the consumer issue of the *International Journal of Technology Assessment in Health Care*.

This year we continued to keep in touch with the international community's work on consumer involvement. We provided input to the subgroup of Health Technology Assessment International (HTAi) on patient/public participation and reviewed consumer abstracts for the HTAi 2011 Conference.

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



Promotional activities

Peer-reviewed publications 2011

Ahern E, Thavaneswaran P, Babidge W, Maddern G. Consumer perspectives in surgical research and audit. *International Journal of Technology Assessment in Healthcare* 2011; 27(4): 337-342

Roder D, De Silva P, Zorbas H, Kollias J, Malycha P, Pyke C, Campbell I. Age effects on survival from early breast cancer in clinical settings in Australia. *ANZ Journal of Surgery* (in press)

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* 2011; 81(1-2): 9-17

Sturm L, Dawson D, Vaughan R, Hewett P, Hill A, Graham J, Maddern G. Effects of fatigue on surgeon performance and surgical outcomes: a systematic review. *ANZ Journal of Surgery* 2011; 81(7-8): 502-509

Whitfield R, Kollias J, De Silva P, Turner J, Maddern G. Management of DCIS according to Van Nuys Prognostic Index in Australia & New Zealand. *ANZ Journal of Surgery* (in press)

Whitfield R, Kollias J, De Silva P, Zorbas H, Maddern G. The use of Trastuzumab in Australia and New Zealand - results from the National Breast Cancer Audit. *ANZ Journal of Surgery* (in press)

Other publications 2011

Cosmetic and reconstructive breast augmentation procedures: patient information *HealthInsite News*, 8 March 2011

Consumer information: ASERNIP-S, *YouShouldKnow - latest updates,* Australian Health Insurance Association, viewed on 9 March 2011, <http://youshouldknow.com.au/latestupdates.html>.

College hub in South Australia. Royal Australasian College of Surgeons *Surgical News*, March 2011; 12(2): pg 23

Consumers Health Forum of Australia. New research on cosmetic and reconstructive breast augmentation procedure, April 2011; 5(2): pg 19-20

The National Breast Cancer Audit. Royal Australasian College of Surgeons *Surgical News*, May 2011; 12(4): pg 22

Autologous fat transfer for breast augmentation. Royal Australasian College of Surgeons *Surgical News*, May 2011; 12(4): pg 25-25

Middle ear implant for hearing loss. Royal Australasian College of Surgeons *Surgical News,* July 2011; 12(6): pg 24

Presentations 2011

Maddern GJ. *Supervision and mortality*. ANZASM Workshop, Royal Australasian College of Surgeons Annual Scientific Congress, Adelaide, 3 May 2011.

Maddern GJ. *Simulated surgical skills program*. Skills Training Session, Royal Australasian College of Surgeons Annual Scientific Congress, Adelaide, 6 May 2011.

Cameron AL. *ERAS what is the evidence – an ASERNIP-S review.* Rural Surgery Workshop, Royal Australasian College of Surgeons Annual Scientific Congress, Adelaide, 6 May 2011.

Maddern GJ. *Turning the light on reform – perspectives on consumer outcomes*. Q&A panel, Australian College of Health Service Management Annual Conference, Adelaide, 10 June 2011.

Maddern GJ. *Percutaneous sclerotherapy for vascular malformations – a systematic review*. Eighth Annual Health Technology Assessment International (HTAi) conference 2011, Rio de Janeiro, 27 June 2011.

Perera CL, Thavaneswaran P, Lee IH, Maddern GJ, Babidge WJ. *Middle ear implant for sensorineural, conductive and mixed hearing loss*. Poster presentation, Eighth Annual Health Technology Assessment International (HTAi) conference 2011, Rio de Janeiro, 27–29 June 2011.

Maddern GJ. *Surgeons' views of health technology assessment (HTA) process in Australia*. Eighth Annual Health Technology Assessment International (HTAi) conference 2011, Rio De Janeiro, 29 June 2011.

Babidge W. *Bridging the gap for the reimbursement of medical technology.* Opening plenary, 2011 ARC Reimbursement and Access Conference, Canberra, 2 August 2011.

Babidge W. *Implementing recommendations of the HTA review: challenges and perspectives, panel discussion*. Pre-conference consumer workshop, Medicines, Health Technologies and Reform, Joint Medicines Policy Conference 2011, Hotel Realm, Canberra, 29 August 2011.

Maddern GJ. *Knowledge transfer: challenges in putting HTA into practice*. Health Technology Assessment International/ International Society for Quality in Health Care Workshop, Hong Kong, 14 September 2011.

Maddern GJ. *Comparative effectiveness: just another way to restrict surgical innovation*? Opening plenary, International Society for Quality in Health Care, Hong Kong, 15 September 2011.

Maddern GJ. *Intra-corporeal micro instruments and nanotechology*. Plenary, Asian Pacific HPBA Congress 2011, Melbourne, 29 September 2011.

Maddern GJ. *Irreversible electroporation (IRE)*. Plenary, Asian Pacific HPBA Congress 2011, Melbourne, 29 September 2011.

Babidge W. *INAHTA, Twinning and support for health technology assessment agencies*. World Health Organization meeting with the Regional Advisors in Health Technologies, Geneva, Switzerland, 13–14 October 2011.

Maddern GJ. *Innovations in surgery*. Plenary, Australian Private Hospital 31st Annual National Congress, Sydney, 17 October 2011.

Maddern GJ. *Credentialing in surgery – a systematic review*. Surgical Leaders' Forum, Royal Australasian College of Surgeons, Melbourne, 27 October 2011.

Maddern GJ. *Current training pathway for academic surgery in Australia and New Zealand: research supervisor perspective,* Royal Australasian College of Surgeons, Section of Academic Surgery, Adelaide, 10 November 2011.

Maddern GJ. *Surgical audit, inevitable or essential?* 62nd Uruguayan Congress of Surgery, Montevideo, 24 November 2011.

Maddern GJ. *How should we assess new surgical technologies*? 62nd Uruguayan Congress of Surgery, Montevideo, 25 November 2011.

Maddern GJ. *How should we assess new surgical technologies?* Carman Oration, Christian Medical College, Vellore, India, 1 December 2011.

South Australian Health Technology Advisory Group

In 2011 the South Australian Health Technology Advisory Group (SA-HTAG) achieved the following:

- assessed an application for the rotem coagulation measuring device (via SA Pathology)
- received presentations from Tracy Merlin and Graeme Suthers regarding genetic testing and personalised medicine
- reviewed the Southern Adelaide Local Health Network's *Introduction of new interventions* procedure
- provided feedback on the CADTH report *Guidance on 1.5 tesla magnetic resonance imaging scanners compared with 3.0 tesla magnetic resonance imaging scanners*
- provided advice to the South Australian Medicines Advisory Committee on three draft SA Health policy directives:
    - *interaction between SA Health and the therapeutic goods industry*
    - *medicines access programs in South Australian public hospitals and health services*
    - *the use of samples (product starter packs) in South Australian public hospitals and health services*
- provided advice to the Chief Pharmacist, SA Health, on the use of receptor targeted radionuclide therapy with 177 lutetium octreotate (Lutate) for inoperable neuroendocrine tumours
- reviewed SA-HTAG membership in line with the formation of the five local health networks
- welcomed expert cardiology knowledge (Professor Derek Chew, Flinders Medical Centre)
- welcomed Ms Tracy Merlin (Adelaide Health Technology Assessment)
- referred the following topics to HealthPACT for evaluation at a national level:
    - pleurx device
    - femtosecond lasers in ophthalmology
    - balloon sinuplasty devices
    - electroporation-based techniques in cancer treatments
    - near infrared spectroscopy.

ASERNIP-S Advisory Committee

The members of the ASERNIP-S Advisory Committee are:

Mr Ian Civil	*Chair, and College President*
The Hon Dr Michael Armitage	*Chief Executive, Australian Health Insurance Association*
Ms Margaret Charlton	*Consumer Representative, Health Consumers Alliance*
Ms Jane Doyle	*Consumer Representative* (resigned 2011)
Professor Kingsley Faulkner	*College Fellow*
Dr David Hailey	*Health Technology Assessment Expert*
Mr Brian Johnston	*Chief Executive, Australian Council on Healthcare Standards*
Professor Brendon Kearney	*South Australian Health Technology Advisory Group Representative*
Professor Guy Maddern	*ASERNIP-S Surgical Director*
Mr Keith Mutimer	*College Fellow*
Professor Julian Smith	*Chair, Research Audit and Academic Surgery Board*

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
- National Health and Medical Research Council Health Care Committee (NHMRC HCC)
  – Professor Guy Maddern
- Orthopaedic Expert Working Group (OEWG), a statutory committee which provides independent advice to Therapeutic Goods Administration (TGA)
  – Professor Guy Maddern
- Health Technology Assessment (HTA) Prostheses Consultative Committee
  – Professor Guy Maddern
- International Network of Agencies for Health Technology Assessment (INAHTA) Board
  – Associate Professor Wendy Babidge, Chair
- International Network of Agencies for Health Technology Assessment (INAHTA), Impact of Health Technology Assessment sub-committee
  – Associate Professor Wendy Babidge, Co-Chair.

Personnel

During 2011 we welcomed:

- Kylie Harper, Project Officer
- Vicki Xafis, Senior Research Officer
- Joanne Watson, Project Office Administrator

In 2011 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, the Guidelines International Network and Health Technology Assessment international, Ann continues to develop her skills in systematic review and guideline adaptation methods, and is a long-standing 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 HTA which has included direction of HTA programs in Canada and Australia. He is currently Professorial 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, multi-slice CT and telerehabilitation. Current research interests include effects of introducing computer-based documentation and telehealth to residential aged care.

- **Dr Vicki Foerster**

Dr Vicki 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.

- **Dr John Field**

John Field has had over 40 years of experience as a statistical consultant in tropical agriculture, the environment, medicine and health, electricity generation and distribution, defence, winemaking and other industries. John is an Accredited Statistician and holds an Honours Science degree and a PhD in statistics from the University of Adelaide. John has spent most of his working life at CSIRO, including ten years as Officer-in-Charge of the Adelaide office of Mathematical and Information Sciences. In 2001 he set up his own consultancy business, with clients largely from the wine, electricity, insurance/legal, steelmaking and research sectors; his research involvement has been with viticulture, other agriculture and medicine. For over seven years he has been a part-time consultant to research staff and students at The Queen Elizabeth Hospital. John has published over 60 papers in refereed journals.

- **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 recognised research strength of the University of Technology, Sydney and is led by Professor Jane Hall (Director). Dr Stephen Goodall, Ms Jody Church, Ms Bonny Parkinson and Ms Paula Cronin have been assisting with numerous MSAC reports in order to provide economic evaluation of procedures under consideration for Medicare funding. CHERE also provides teaching and research in health economics and is one of five centres in Australia that undertakes the evaluation of Pharmaceutical Benefit Advisory Committee submissions.

ASERNIP-S website

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

The web-interface database for the NET-S horizon scanning project is linked via the ASERNIP-S homepage. The database is regularly updated with new technology briefs and health technology reports.

The College website was redeveloped in 2011, with new features and functionality. 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.

Students

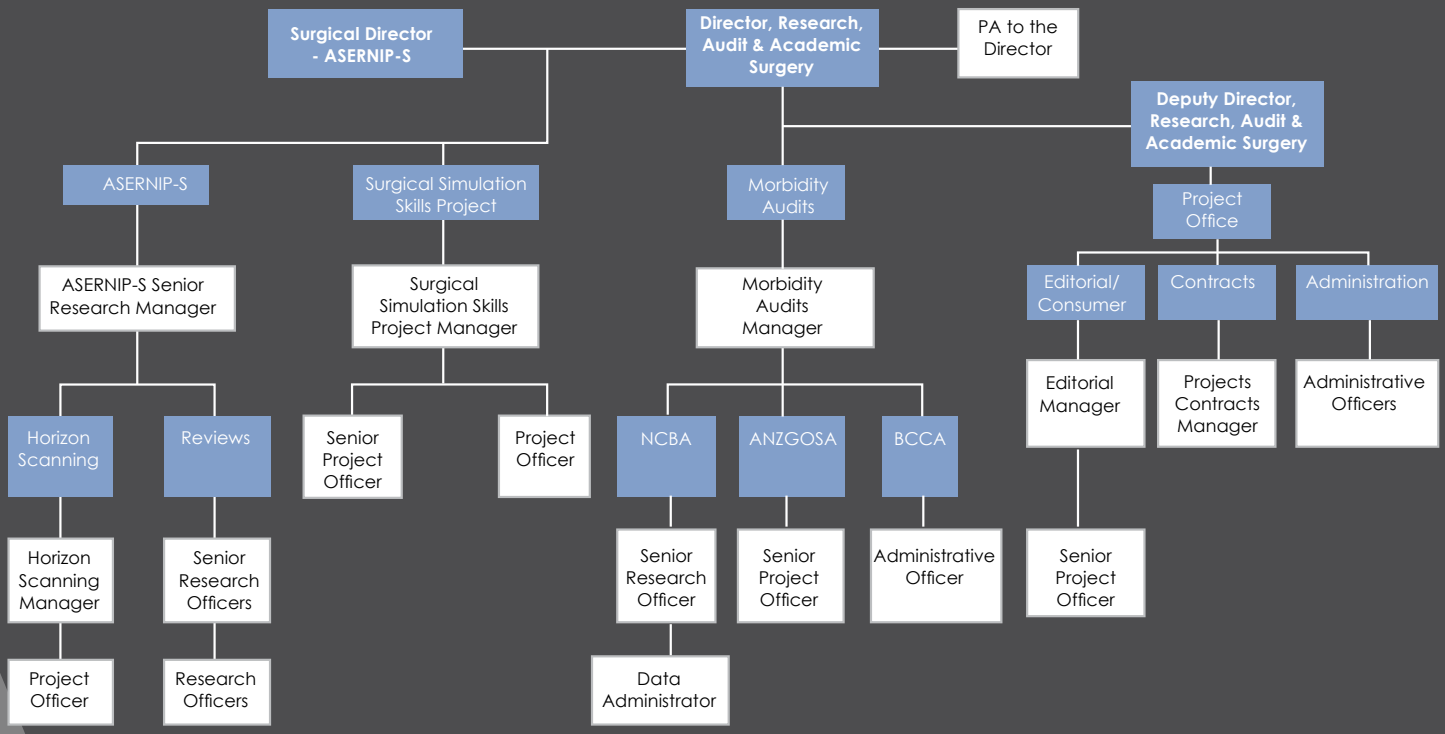
The NBCA worked with a team of fourth-year medical students who, as part of their assessment, developed a research proposal that could be addressed by analysing the audit dataset. The proposal examined the factors affecting local recurrence rates for early invasive breast cancer treated with mastectomy without radiotherapy, with the view to ascertaining whether radiotherapy provides additional benefit in reducing local recurrence rates.

Staff

Professor Guy Maddern
Associate Professor Wendy Babidge
Keith Hayes
Eleanor Ahern
Meryl Altree
Dr Yasoba Atukorale
Caryn Butler
Dr Alun Cameron
Susan Dawe
Dr Primali De Silva
Katherine Economides
Felicity England
Deanne Forel
Jane Franklin
Pat Green
Stefanie Gurgacz
Ben Hoggan
Karen Humphreys
Louise Kennedy
Nicholas Marlow
Wendy Morros
Michelle Ogilvy
Dr Prema Thavaneswaran
Dr Meegan Vandepeer
Joanne Watson
Heath White
Vicki Xafis

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

ASERNIP-S organisational chart



Professor Guy Maddern

Associate Professor Wendy Babidge

Keith Hayes

Dr Alun Cameron

Meryl Altree

Katherine Economides

Felicity England

Deanne Forel

Dr Prema Thavaneswaran

Eleanor Ahern

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 College. 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

Associate Professor Wendy Babidge

Associate Professor Wendy Babidge is Director of the RAAS Division of the College. 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.

Deputy Director, Research, Audit and Academic Surgery Division

Keith Hayes

Keith Hayes joined the College in November 2010 in the role of Deputy Director, RAAS Division. 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 Project 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.

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 was mainly involved with managing MSAC projects and wrote or assisted with numerous reports. He then assumed a more senior role in managing the ASERNIP-S research program. Alun left ASERNIP-S in 2011.

ASERNIP-S Senior Project Manager - Simulated Surgical Skills Program

Meryl Altree

Meryl Altree joined ASERNIP-S in September 2008. Meryl holds a Diploma of Applied Science and a Bachelor of Nursing. She has recently completed coordinating the activities of the SSSP: a national multi-site project investigation of the applicability of laparoscopic surgical simulators to the education and maintenance of the surgical workforce in Australia. Meryl is currently managing a Commonwealth Government grant investigating the training needs of participants in the Specialist Training Program.

ASERNIP-S Manager, Morbidity Audit Projects

Katherine Economides

Katherine Economides joined the College in February 2010. She is the Manager, Morbidity Audit Projects, which includes the NBCA and the ANZGOSA. She also oversees administrative support given to the BCCA, which is managed by the Colorectal Surgical Society of Australia and New Zealand. 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 Projects Contracts 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. At ASERNIP-S Deanne was involved in conducting various systematic reviews. Deanne became increasingly involved in the horizon scanning program, for which she took on the Project Manager role in August 2010. Deanne is currently on maternity leave.

ASERNIP-S Acting Horizon Scanning Manager

Dr Prema Thavaneswaran

Dr Thavaneswaran joined ASERNIP-S in January 2005. She has a Bachelor of Science degree, majoring in Microbiology, Immunology and Physiology, and an Honours degree in Physiology, both from the University of Adelaide. She completed a PhD in perinatal Physiology at the University of Adelaide, investigating the early life programming of the Insulin Resistance Syndrome. Prema has extensive tertiary-level teaching experience in basic science and is currently a tutor in the Discipline of Public Health at the University of Adelaide. At ASERNIP-S, Prema has been a primary researcher on several evidence-based evaluations. She became a Senior Research Officer in 2007 and worked on policy-focused projects and research on consumer involvement in evidence-based surgery. In August 2011, she began acting in the role of Project Manager for the horizon scanning project.

ASERNIP-S Editorial Manager

Eleanor Ahern

Eleanor joined ASERNIP-S in October 2000. She has a Master of Arts Degree in International Relations, an Advanced Diploma of Arts in Professional Writing and a background in medical studies. She is an IPEd Accredited Editor. At ASERNIP-S Eleanor manages the editorial section and promotes consumer involvement in the research process.

Appendices

Appendix A

Hierarchy of evidence
Designation of levels of evidence

Level of evidence	Study design
I[a]	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • non-randomised, experimental trial[b] • cohort study • case-control study • interrupted time series with a control group
III-3	A comparative study without concurrent controls: • historical control study • two or more single arm study[c] • interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

a A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

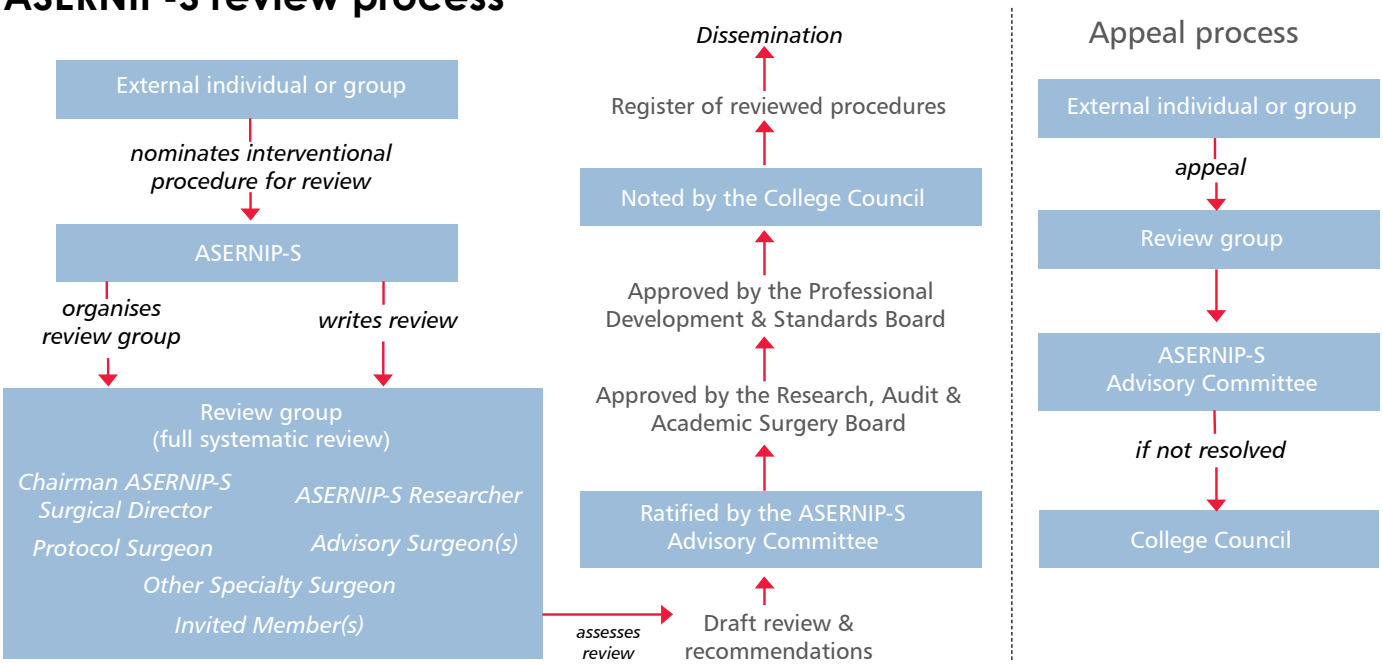
b This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (i.e. utilise A versus B and B versus C, to determine A versus C with statistical adjustment for B).

c Comparing single arm studies i.e. case series from two studies. This would also include unadjusted indirect comparisons (i.e. utilise A versus B and B versus C, to determine A versus C but where there is no statistical adjustment for B).

Source: NHMRC 2009, National Health and Medical Research Council (NHMRC), *NHMRC levels of evidence and grades for recommendations for developers of guidelines*, Canberra, Australia.

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 2009-2010

2010

ASERNIP-S Report no. 70
Autologous fat transfer for cosmetic and reconstructive breast augmentation, September 2010

ASERNIP-S Report no. 73
Radiofrequency ablation for the treatment of renal tumours (evidence essential), March 2010

ASERNIP-S Report no. 76
Veress needle laparoscopic entry technique (evidence essential), September 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* 2010; 40(5): 572-579

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, Boult M, Rice J, Maddern G. Disparities in access to breast care nurses for breast surgeons: a national breast cancer audit survey. *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

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

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

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

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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

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 Australasian 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 2010; 11(10): 26-27

Appendices

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

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