ANNUAL REPORT 2012



Australian Safety and Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons



Contents

3 Mission statement

S	urgical Director's report
A	SERNIP-S reviews
Ν	lew assessments completed
Ρ	rocedure nominations
S	pecialist Training Program – Research Project
D	Data collection
Ν	lational Breast Cancer Audit
A	ustralian and New Zealand Gastric and Oesophageal
S	urgical Association Audit
B	i-National Colorectal Cancer Audit
	lew and Emeraina Techniques – Suraical (NET-S)
Н	orizon scanning project
P	roject activities
۲ ۲	
C	Consumer involvement
P	romotional activities
' A	SERNIP-S Advisory Committee
R	epresentation on external committees
Ρ	ersonnel
A	SERNIP-S website
S	tudents
– A	SERNIP-S staff
- A	
А	ppendix A: Hierarchy of evidence

- 27 Appendix B: ASERNIP-S review process
- 28 Appendix C: ASERNIP-S classification system
- 29 Appendix D: Reports and publications 2010–2011

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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

At the end of 2012, it will be almost 15 years since the inception of the ASERNIP-S project. Work has been done over that time for many countries and organisations, and we continue to provide comprehensive reviews for the Australian Government, primarily for the Medical Services Advisory Committee. We also provide regular input into the Committee of New Technologies of the American College of Surgeons. More locally, state governments contract ASERNIP-S to review particular technologies that are giving concern in their healthcare systems.

Horizon scanning has continued to be an important part of the work of the ASERNIP-S group and this has been through the organisation HealthPACT, based in Queensland but supported by all state jurisdictions to provide timely reviews of emerging technologies and procedures. ASERNIP-S has the additional role of hosting the Secretariat of the Health Technology Assessment Group for the South Australian Government. During 2012, this approach has been reviewed by the state government to determine whether it is the optimal way to be advised on new technologies and procedures. At the time of writing this report, the recommendations of the review are yet to be announced.

ASERNIP-S has also been involved in collecting audit data, particularly for the National Breast Cancer Audit and the Australian and New Zealand Gastric and Oesophageal Surgical Association Audit, and was involved in the instigation and now provides advice to the Bi-National Colorectal Audit. As a result of funding obtained from the Australian Government, there has also been work on a research initiative looking into simulation training, particularly using the mobile simulator unit developed by the Royal Australasian College of Surgeons to assist in providing training to Specialist Training Program trainees. This is a research project hoping to develop not only baseline data on appropriate training for such individuals, but also to further develop the concept of team training, particularly



'We remain the only organisation focused exclusively on surgical techniques and procedures, and have become a worldwide reference source for this type of work.'

Guy Maddern Surgical Director, ASERNIP-S

in the operating room. Good progress has been made this year and this activity will be concluded within the next twelve months. It is hoped that a module of team training will become available to all members of the College to develop appropriate processes for building, assessing and feeding back performance within a simulated operating room environment.

All this work has placed ASERNIP-S and the Royal Australasian College of Surgeons clearly on the map of health technology assessment within Australia and, indeed, worldwide. We remain the only organisation focused exclusively on surgical techniques and procedures, and have become a worldwide reference source for this type of work. Although a large number of staff are employed to conduct these activities, this is all done with limited subsidy from the College; the funding for these activities has come from contracts and sponsorship from the various users of the services. This would seem to be the most appropriate and robust model for the ongoing success of the ASERNIP-S initiative. As it is currently designed, the College has all the benefits and resources at little or no direct cost to the membership. We can only look forward to building on the enormous success of the last 15 years into the future, an outcome I have little doubt will be achieved.

Australian Safety & Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons Annual Report 2012

ASERNIP-S reviews

- New assessments completed
- Procedure nominations
- Specialist Training Program Research Project

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

An 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 endusers, including those who have approached ASERNIP-S to investigate the given topic. An 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

ASERNIP-S reports

Systematic reviews

 Surgical simulation for training: skills transfer to the operating room. ASERNIP-S Report no. 80.

Rapid review

- Percutaneous sclerotherapy for vascular malformations: a rapid review.
 ASERNIP-S Report no. 77
- Bariatric surgery for the treatment of obesity: a rapid review.
 ASERNIP-S Report no. 79.

Reports for other organisations

South Australian Health Technology Advisory Group (SA-HTAG)

Commissioned reviews

ASERNIP-S will be conducting a rapid assessment of breast implantation with the use of breast prostheses. The aim of this rapid review is to assess the long-term patient satisfaction, device failure rates (particularly rupture) and safety outcomes of these implants. A draft protocol has been formulated and is receiving further expert clinical input. Given the developments with the Breast Device Registry and following the controversy regarding the Poly Implant Prosthèse (PIP) implants, ASERNIP-S hopes this review will contribute to an area where there is currently a gap in the evidence.

Technologies/policies considered

- rotem coagulation measuring device
- MitraClip device and renal sympathetic denervation (ASERNIP-S provided two brief summaries of selected literature.)
- totally transoral video-assisted thyroidectomy
- draft evidence requirements for assessment of applications for the Prostheses List.

Referral to HealthPACT for evaluation

- robot-assisted lung resection
- external aortic root support for Marfan's syndrome
- PleurX indwelling catheter for the treatment of malignant pleural effusion.

Medical Services Advisory Committee (MSAC)

MSAC assessment reports

 MSAC 1054.1 Review of Interim Funded Service: Hyperbaric Oxygen Therapy (HBOT) for the Treatment of Chronic Non-Diabetic Wounds and Non-Neurological Soft Tissue Radiation Injuries.

MSAC critiques

In 2012 ASERNIP-S provided three critiques of submissionbased assessments for consideration in MSAC deliberations. Two critiques were of co-dependent technologies that were considered in parallel by the MSAC and the Pharmaceutical Benefits Advisory Committee.

Protocol Advisory Sub-committee (PASC)

Nine decision analytic protocols have been written for the PASC in 2012.

Medicare Benefits Schedule (MBS)

Four rapid review protocols have been written as part of the Comprehensive Management Framework for the MBS.

Surgical simulation for training: skills transfer to the operating room

ASERNIP-S Report no 80

Objective

The objective of this systematic review update was to assess the evidence published since 2006 to determine whether skills acquired through simulation-based training transfer to the operative setting.

Methods

This report updates the research on 'Surgical simulation for training: skills transfer to the operating room' published in ASERNIP-S report no. 61 (Sturm et al 2007).

Search strategy – Studies were identified by searching MEDLINE, EMBASE, CINAHL, The Cochrane Library and Current Contents from the period January 2007 to September 2011. The Clinical Trials Database (US), NHS Centre for Research and Dissemination Databases (UK), National Research Register (UK), Meta Register of Controlled Trials, and the Australian Clinical Trials Registry were also searched in September 2011.

Study selection – Only studies that reported the use of simulation for surgical skills training and the transferability of these skills to the patient care setting, were included

for review. To be eligible for inclusion, studies must have contained data on training and/or measures of performance in the simulated setting, and measures of performance in the operative setting. Identified measures of surgical task performance included accuracy of skills, error rates, time to complete the task, and achievement of performance to criterion levels. Outcomes of interest included performance (measured by various validated and non-validated global rating scales and/or task-specific checklists), patient comfort/discomfort scores, and intraand postoperative complications.

Data collection and analysis – Data from the included studies were extracted by one researcher using standardised data extraction tables developed a priori and were checked by a second researcher. Statistical pooling was not appropriate due to the heterogeneity of the included studies.

Results

A total of 20 randomised controlled trials and three nonrandomised comparative studies were included in this review. The review examined surgical simulation and included studies with various training techniques in the surgical setting. The studies reported on different indications, simulation-based training methods, training times, and the amount of guidance and feedback provided to trainees. Simulation-based training was compared to no simulation training in 20 studies. Of the remaining three studies, two compared simulation-based training with patient-based training, and one used interactive seminar-based education as the comparator. Where simulation-based training was compared to no simulation training, it was usually an adjunct to normal surgical training programs. However, one of the 20 studies compared two different simulation-based training methods with two comparators (no simulationbased training [control] and didactic lecture-based training).

For laparoscopic cholecystectomy, bilateral tubal ligation, salpingectomy, Nissen fundoplication, diagnostic arthroscopy of the knee and totally extraperitoneal inguinal hernia repair, camera navigation, participants who received simulation-based training prior to patient-based assessments performed better (higher global assessment score and/or shorter time to complete task) than participants who did not have this training. Simulator-trained groups generally made fewer errors than control groups in subsequent patientbased assessments.

For colonoscopy, cystourethroscopy, endoscopic sinus surgery and transurethral resection of the prostate, participants who received simulation-based training appeared to perform better (higher global assessment score and/or shorter time to complete task) than controls in subsequent patient-based assessments.

There were no differences in time to complete tasks between simulator-trained participants compared with controls when performing oesophagogastroduodenoscopy or nasolaryngoscopy. However, the simulator-trained group required significantly less assistance from the supervisor to complete the task during oesophagogastroduodenoscopy than the control group. There was no significant difference between the simulator-trained participants and the controls for the flexible laryngoscopy procedure time on the standardised patient or the discomfort assigned by the standardised patient, but the authors noted the data was positively skewed by two extremely high values. For other surgical procedures, abdominal fascial closure, cardiopulmonary bypass weaning following cardiac surgery, phacoemulsification on cataract surgery, and knowledge, attitude and skills in the operating room, participants who received simulation-based training prior to patient-based assessments performed better (higher global assessment score and/or shorter time to complete task) than participants who did not have this training.

One study compared patient-based training with simulation-based training for colonoscopy and found that participants who had trained exclusively on a simulator without any mentoring or supervision performed at an equivalent standard on the assessment procedure to those who had received patient-based training. One study compared patient-based training with simulation-based training for in-surgery laparoscopic camera navigation and found that simulator-based camera navigation training for laparoscopic surgery was as effective as, and more time efficient than, traditional teaching of this task.

Conclusions

The studies included in this update on whether surgical skills acquired through simulation-based training transfer to the operating room were of a higher quality (including considerably more randomised controlled trials) than those found in the 2007 systematic review (Sturm et al 2007). These studies have strengthened the evidence base. However, the studies still have variable training and assessment methods, making comparison between studies difficult. Overall the current evidence demonstrates that simulation-based training, as part of a surgical skills training program and incorporating the achievement of reaching predetermined proficiency levels, results in skills transfer to the operating setting.

Classifications

Evidence rating

The evidence-base in this review is rated as average. The studies included were of variable quality, and did not have comparable simulation-based methods for the same indications, resulting in an inability to draw solid conclusions.

Efficacy rating

Efficacy cannot be determined. The studies did not have comparable simulation-based methods for the same indications, resulting in an inability to draw solid conclusions.

2011 clinical and research recommendations

Sturm et al (2007) recommended that further research be conducted into the transfer of skills acquired via simulationbased training to the patient setting, to strengthen the evidence base. This recommendation is still relevant in 2011, although several well-designed studies have strengthened the evidence base since 2006. Areas still requiring further study include:

- 'the nature and duration of training required to deliver the greatest transfer effect
- the stage of training at which trainees receive maximum skill transfer benefits from different forms of simulation
- the effect of different levels of mentoring during the training period on transfer rates
- changes in staff productivity as a result of simulationbased training' (Sturm et al 2007).

Further research could also explore the way that training environments that develop simulation-based technical skills might be used to train and assess non-technical skills, such as decision-making.

Procedure nominations

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

- delivery of conscious sedation
- endoscopic stapling of pharyngeal pouch
- folate fortification of flour in Australia
- gallstones (asymptomatic)
- 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 nominated for review page on the ASERNIP-S website and download a nomination form.

Image provided courtesy of Exstent Ltd., United Kingdom.

Australian Safety & Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons Annual Report 2012

ASERNIP-S reviews



Specialist Training Program-Research Project

The Specialist Training Program-Research (STP-R) Project, funded by the Australian Government through the Department of Health and Ageing, has two research objectives:

- Phase one: To research the delivery, utilisation and appropriateness of a range of basic surgical tasks delivered by the Mobile Simulation Unit (MSU) to Surgical Education and Training (SET) program trainees in both traditional and non-traditional training settings.
- Phase two: To research multidisciplinary teamwork within the operative setting and to use the results to develop a simulation-based curriculum to support SET trainees with rosters in STP environments.

This project commenced in October 2011. Phase one is well underway, with data collection taking place utilising the MSU located at selected metropolitan, outer metropolitan and rural hospitals in South Australia. Phase two is in the planning stage, with assessment tools being identified, scenarios being developed, and simulation and recording equipment being sought.

The program is scheduled for completion in December 2013.

Data collection

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 14 years. It was originally developed as a selfassessment tool for surgeons treating patients with early breast cancer in Australia and New Zealand. The current directors of the audit, the Breast Surgeons of Australia and New Zealand, Inc. (BreastSurgANZ), intend to develop the NBCA into a full clinical audit by completing the audit cycle. This involves an annual assessment of performance against the NBCA key performance indicators (KPIs) for all full members of the society.

Participation

In March 2012, NBCA access was restricted to full members of BreastSurgANZ, for whom participation is mandatory. Surgeons can pay a non-member access fee to utilise the self-audit tools; however, these surgeons will not be included in the full audit cycle, nor will they be listed as 'participating' by BreastSurgANZ.

The NBCA database currently contains over 125,000 cases of early and locally advanced breast cancer, with more than 300 surgeons having active accounts. Only three participants are accessing as non-members.

According to recent figures, the majority of data is submitted to the NBCA through the online portal (81%). A further 13% of data is submitted through the institutional upload program and only 6% of NBCA data is submitted via paper forms delivered to the audit office.

Ten institutions have participated in the institutional upload program in 2012, with the third upload for the year scheduled to occur in October/November.

Participant satisfaction

In December 2011 and January 2012, NBCA participants were given the opportunity to provide feedback on the NBCA through an emailed evaluation form. Responses were overwhelmingly positive, with the online portal described as clear and easy-to-use, particularly the one-page minimum dataset view.

Feedback was forwarded to the NBCA Steering Committee to review in March. Approved amendments will be prioritised and introduced progressively.

Assessment

A review of KPI 4 (percentage of in situ cases undergoing breast-conserving surgery without axillary surgery) has been initiated due to the uptake of sentinel node biopsy over recent years.

The implementation of a sixth KPI (percentage of patients with moderate or high risk of recurrence being referred to a medical oncologist for consideration of chemotherapy) is expected in late 2012 or early 2013.

Starting in late 2012, full members of BreastSurgANZ who fall short of the quality threshold for any KPI will have their data examined by the NBCA Steering Committee, a subcommittee of the BreastSurgANZ Executive Council.

Research

The NBCA has published eight articles in 2012, with a further article currently in press (see the publications section of this report for further details).

Collaborative research with Cancer Australia continued in 2012, with articles produced on:

- factors predictive of immediate breast reconstruction
 following mastectomy
- factors predictive of treatment by mastectomy rather than breast conserving surgery.

A re-linkage with the National Death Index at the Australian Institute of Health and Welfare is set to occur in the last quarter of 2012 as part of this collaboration.

The NBCA also provided aggregated results to:

 an NBCA participant – comparison figures on sentinel nodes positive and personal figures on recurrence rates, to be used for quality assurance

- a Breast Fellow figures on the number of lymph nodes resected and how this varies across regions in Australia, to be used in a research project
- a student figures on the factors associated with patterns of surgical treatment of women according to age, to be used in a Masters project. Factors included geographic remoteness, area disadvantage and insurance status.
- an NBCA participant figures on the number of centres in Australia which use gamma-probe in detection of sentinel nodes, to be used in an application for approval of a multi-centre study
- a student data on breast reconstructions rates in Australia over time, to be used in a research paper.

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 Australian and New Zealand Gastric and Oesophageal Surgical Association (ANZGOSA) Audit has been designed as a self-assessment tool for its members and has been in operation for two years. The audit collects clinical and pathological details of patients undergoing surgery for oesophagogastric cancer or gastrointestinal stromal tumour (GIST) in Australia and New Zealand.

Data collection

It is anticipated that the ANZGOSA Audit will house more than 500 records of oesophagogastric cancer/GIST by the end of 2012. There are currently 60 active surgeon accounts, which translate to 42% of current ANZGOSA full members. This is up from 30% of full members in 2011.

The introduction of the reporting suite has been used as a promotional tool for the audit at the recent ANZGOSA joint meeting with the Sydney Upper Gastrointestinal Surgical Society (SUGSS) and through direct email to members. Almost two-thirds of sign-ups for 2012 requested access to the audit soon after the introduction of this feature in July.

Web portal development

The reporting suite compares patient outcomes for a surgeon's individual practice against the bi-national aggregate. Three reports are available: outcomes, complications and length of stay. Reports can be accessed at any time through the online portal and are generated using real-time data. An exporting function will also be added later in 2012.

The July update also incorporated new validation rules which will assist in preventing accidental data entry errors. A refresh of the portal appearance and various minor dataset amendments were implemented as well.

Institutional upload program

The ANZGOSA Audit has been accepting expressions of interest from institutions wishing to participate in the upload program. The institutional upload program will be an alternative submission pathway for surgeons who already enter data similar to the ANZGOSA Audit dataset into an existing database. Institutions such as hospitals or registries can have data directly uploaded into the audit, which saves surgeons from having to re-enter these data manually. To be eligible for the upload program, an institution must have a large annual case volume and sufficient commonality of fields between their database and the ANZGOSA Audit. Programming for incorporating this function into the ANZGOSA Audit is currently underway. It is estimated that this should be in place by late 2012.

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.

The ANZGOSA Audit fulfilled its first data request in

data on how many (and what percentage) of

to be used for research purposes.

May. A participating surgeon requested aggregated

gastrectomies are being performed laparoscopically,

Data requests



Australian Safety & Efficacy Register of New Interventional Procedures - Surgical Royal Australasian College of Surgeons Annual Report 2012

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 2013 the Colorectal Society will take over full responsibility for this.

New and Emerging Techniques – Surgical (NET-S)

NET-S horizon scanning project



Australian Safety & Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons Annual Report 2012

NET-S horizon scanning project

New and Emerging Techniques-Surgical (NET-S) was developed with the aim of providing an early warning system for identification of new and emerging surgical techniques and technologies prior to their introduction into routine clinical practice. NET-S has developed unique methodologies to improve the horizon scanning process, particularly in the area of surgery.

NET-S is a member of EuroScan through HealthPACT. A synopsis of all technology briefs and new and emerging health technology reports prepared by the NET-S project for HealthPACT is available for download from the EuroScan website (http://euroscan.org.uk/). 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 use of effective, useful and safe health technologies.

Twenty-one technology briefs were prepared for HealthPACT in 2012:

- balloon sinuplasty devices for chronic rhinosinusitis
- Gambro Theralite[™] (high cut-off therapy) for treatment of renal failure in patients with multiple myeloma
- near-infrared spectroscopy for monitoring of paediatric patients at risk of low perfusion following cardiac surgery
- LeGoo®: reverse thermosensitive polymer gel for the temporary occlusion of blood vessels during surgery
- LifeStent® vascular stent for symptomatic lesions of the superficial femoral or proximal popliteal artery
- Sapien TM and Sapien XTTM transcatheter aortic valve implantation devices for the treatment of symptomatic aortic valve stenosis
- hypoglossal nerve stimulation for sleep apnoea

- intravitreal corticosteroid implant for the treatment of diabetic macular oedema
- Exalenz BreathID® breath test device for the diagnosis of liver disease
- Pleurx® catheter system for the treatment of malignant pleural effusion
- microbial sealant to reduce surgical site infections following coronary artery bypass graft
- Health Buddy® for telehealth patients for cardiovascular indications
- Columbia Suicide Severity Rating Scale
- neonatal screening for lysosomal storage disorders
- sutureless aortic valve replacement in patients with severe aortic valve stenosis
- robot-assisted lung resection for pulmonary resection
- bone growth factor procedure to solve chronic ear problems
- autologous blood injection for soft tissue injuries
- pulse oximetry for detecting heart defects in newborns
- Core-Valve® Transcatheter Aortic Valve Implantation device for severe degenerative aortic stenosis
- external aortic root support for Marfan's syndrome.

Eight technology brief updates were prepared for HealthPACT in 2012:

- percutaneous pulmonary valve implantation
- Cerecyte® (bioactive) coils for the treatment of intracranial aneurysms
- natural orifice transluminal surgery transvaginal cholecystectomy
- Carillon mitral contour system® for mitral regurgitation
- Tumour Treating Fields for glioblastoma multiforme
- StomaphyX for revision bariatric surgery
- EndoBarrier® gastrointestinal liner for obesity
- SpyGlass direct visualisation system for cholangiopancreatography.

In addition, in 2012 the NET-S project continued to undertake horizon scanning assessments for the American College of Surgeons, with a focus on general surgery:

- cryotherapy for oesophageal cancer
- single-incision laparoscopic surgery for cholecystectomy
- allogeneic pancreatic islet cell transplantation for the management of type I diabetes mellitus
- microwave ablation for hepatic metastases.

Surgical instruments from *The surgeon's mate*, 1639, by John Woodall, reproduced with permission from the Wellcome Library, London.

Australian Safety & Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons Annual Report 2012

Project activities

- Project Office
- Contracts
- Consumer involvement
- Promotional activities
- ASERNIP-S Advisory Committee
- Representation on external committees
- Personnel
- ASERNIP-S website
- Students

Research, Audit and Academic Surgery Division – Project Office

The Project Office has continued to consolidate its support for the Research, Audit and Academic Surgery (RAAS) Division's research activities. In this capacity, the Project Office manages research projects throughout their lifecycle, from the bid management stage through to close-out and the review of completed assignments. Additionally, the Project Office is a central resource for administrative, legal and editing support and is the principal point of contact with the College's Finance Department in relation to the preparation of quotations and the approval of project budgets. During 2012, services were broadened to include the work carried out through the Morbidity Audit department.

The Project Office is led by the RAAS Deputy Director / Business Manager, Keith Hayes, with support from Felicity England (Contracts Manager), Eleanor Ahern (Editorial Manager) and Joanne Watson (Administrator).

As the conduit for project management activities, Project Office services include:

Project bids

- identification of new opportunities
- research team capacity and capability assessments

- scope definition understanding and responding to client requirements
- preparation and coordination of high quality, competitive research bids including responses to requests for tender issued by various health sector agencies.

Contract management

- oversight and management of contracts, variations and renewals for divisional projects and other business activities
- liaison and negotiation with clients on contractual matters
- invoicing of clients according to agreed milestones and payment schedules.

Project management

 weekly performance reporting to facilitate project management decisions and to help project managers track the progress of deliverables to clients.

Progress and final reports

- ensuring that reports are prepared in accordance with client requirements and edited to a standard consistent with the College's ISO 9001 quality management system
- coordination of financial reports, reconciliations and acquittals.

Scheduling of project activities

- maintenance of a master project schedule to inform resourcing decisions and to ensure that project outcomes can be delivered successfully, in full and on time
- resource planning to accommodate 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 assess performance and to 'tune' future bids.
- The capture and review of 'lessons learned' serves to maximise value and service delivery for our clients and maintains a focus on continuous improvement within the research team.

Contracts

The contract management function has become further consolidated into the Division's Project Office. The recordkeeping function of the Project Office is now well integrated into the Division's activities, providing a single reference point for all critical project information. The Project Office and the Contracts Manager are continuing to review and implement the service delivery model across all of the Division's activities, further streamlining the processes of the Division and its interactions with both internal and external stakeholders. The Contracts Manager has continued to work closely with both the Director and Deputy Director in the areas of strategic advice and has provided ongoing support to the ASERNIP-S Research Manager and the Morbidity Audits Manager in the areas of negotiation strategy, advice and support.

ASERNIP-S

ASERNIP-S completed a significant tender for the Department of Health and Ageing's health technology assessment work in February of this year. While the Department of Health and Ageing is yet to progress the tender to award or conclusion, ASERNIP-S has enjoyed extensions to its Deeds of Standing Offer (panel agreements) to 30 June 2013 for both health technology assessment and research support, and health services evaluation.

All work offered by the Department of Health and Ageing progressed to contracting, with nine contracts for work being processed with MSAC in June 2012. A number of contracts have involved ongoing support and liaison with the department due to topic complexity, highlighting the focus of ASERNIP-S on customer service and ensuring that all contracted work achieves value both for the Department of Health and Ageing and the public at large.

Two contracts were put into effect for the health services evaluation rapid review, and it is likely that they will proceed to full review in the new future.

The South Australian Department of Health (SA Health) has continued its contract with ASERNIP-S for secretariat support to its Health Technology Assessment Group. SA Health has instituted a review of its health technology assessment functions and ASERNIP-S eagerly awaits the outcome of that review.

The skills and reputation of ASERNIP-S in horizon scanning have continued to grow, with the group contributing briefs and brief updates to each HealthPACT meeting. A standing Service Provider Agreement was achieved towards the end of 2011 which supported the HealthPACT work through to 30 June 2012. A further standing agreement was instituted for the balance of the 2012 year and it is hoped that the relationship will continue into 2013.

ASERNIP-S has supported HealthPACT with 21 briefs and eight brief updates throughout the year, including the provision of support for scoping services in order to determine which topics should proceed to report preparation.

A detailed contract was settled at the beginning of the year to support the in-kind contribution of ASERNIP-S to a Macquarie University project funded by the Australian Research Council on the topic 'On the cutting edge: promoting best practice in surgical innovation'. This project is scheduled to continue over three years.

Morbidity Audit

The Morbidity Audit department continues to receive the support of the Australian and New Zealand Gastric and Oesophageal Surgical Association Audit, with the Association renewing a contract for the College to operate the audit to the end of 2013.

This department also continues to support the ongoing National Breast Cancer Audit through its relationship with Breast Surgeons of Australia and New Zealand Incorporated. The College is negotiating a contract with the society to encompass both the current audit work and future activities in order to enhance the growth and value of this longstanding audit.

Consumer involvement 2012

Consumers continue to contribute to the work of ASERNIP-S and the Division of Research, Audit and Academic Surgery as a whole. This involvement includes consumer representation on the ASERNIP-S Advisory Committee and we are grateful to Marg Charlton for her dedicated work in this respect. Consumers and consumer organisations also provide vital input to the steering committees of the mortality and morbidity audits, for example in our collaborative work with Breast Cancer Network Australia. We are active members of the peak consumer group Consumers Health Forum and the HTAi sub-group on patient/ citizen involvement.

This year a new page was created on our website summarising how consumers are involved with the work of the Division (http://www.surgeons.org/for-healthprofessionals/audits-and-surgical-research/asernip-s/ consumer-information/consumer-involvement/).

Consumers are informed of the latest in surgical research through consumer summaries of relevant reports, published on the website. In 2012 we prepared seven new consumer summaries for National Breast Cancer Audit publications.

We thank all the consumers and consumer organisations involved in the work of the Division over the past twelve months. The input of these individuals and organisations is highly valued.



The operating theatre, 1896, Metropolitan Hospital, London, reproduced with permission from the Wellcome Library, London.

Promotional activities

Peer-reviewed publications 2012

Cronin P, Hoggan B, Goodall S, Cameron A. CE3 Hyperbaric oxygen therapy for the treatment non-neurological soft tissue radiation injuries – a cost effectiveness analysis. *Value in Health* 2012; 15(7): A602.

Gurgacz S, Smith J, Truskett P, Babidge W, Maddern, G. Credentialing of surgeons: a systematic review across a number of jurisdictions. ANZ Journal of Surgery 2012; 82(7-8): 492–498.

Hailey D, Werkö S, Bakri R, Cameron A, Göhlen B, Myles S, Pwu J, Yothasamut J. Involvement of consumers in HTA activities by INAHTA agencies (For the INAHTA Working Group on Impact of HTA). International Journal of Assessment in Healthcare Technology (accepted for publication).

Kanhere M, Kanhere H, Cameron A, Maddern G. Does patient volume affect clinical outcomes in adult intensive care units? *Intensive Care Medicine*. 2012; 38(5): 741-751. Epub 5 April 2012.

Morris T, Wetzig N, Sinclair S, Kollias J, Zorbas H. Evaluation of implementation of sentinel node biopsy in Australia. *ANZ Journal of Surgery* 2012; 82(7-8): 541–547.

Ogilvy M, Kollias J. Operating principles for running a Clinical Quality Registry: are they feasible? ANZ Journal of Surgery Epub (ahead of print) 3 September 2012.

Ooi C, Campbell I, Kollias J, de Silva P. National Breast Cancer Audit: overview of invasive breast cancer in New Zealand. New Zealand Medical Journal 2012; 125: 1359.

Roder D, De Silva P, Zorbas H, Kollias J, Malycha P, Pyke C, Campbell I. Survival from breast cancer: an analysis of Australian data by surgeon case load, treatment centre location, and health insurance status. *Australian Health Review* 2012; 36(3): 342–348.

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* 2012; 82(7-8): 524–528.

Roder D, De Silva P, Zorbas H, Kollias J, Malycha P, Pyke C, Campbell I, Webster F. Survival from synchronous bilateral breast cancer: the experience of surgeons participating in the Breast Audit of the Society of Breast Surgeons of Australia and New Zealand. *Asia Pacific Journal of Cancer Prevention* 2012; 13(4): 1413–1418.

Roder D, De Silva P, Zorbas H, Webster F, Kollias J, Pyke C, Campbell I. Adherence to recommended treatments for early invasive breast cancer: decisions of women attending surgeons in the Breast Cancer Audit of Australia and New Zealand. *Asia Pacific Journal of Cancer Prevention* 2012; 13(4): 1675–1682. Tan S, Marlow N, Field J, Altree M, Babidge W, Hewett P, Maddern G. A randomized crossover trial examining lowversus high-fidelity simulation in basic laparoscopic skills training. *Surgical Endoscopy* 2012; 26(11): 3207–3214.

Whitfield R, Kollias J, De Silva P, Turner J, Maddern G. Management of ductal carcinoma in situ according to Van Nuys Prognostic Index in Australia and New Zealand. *ANZ Journal of Surgery* 2012; 82(7-8): 518–523.

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* 2012; 82(4): 234–239.

Zamora L, Humphreys K, Watt A, Forel D, Cameron A. A systematic review of computer-navigated total knee arthroplasty. *ANZ Journal of Surgery* 2012; Epub (ahead of print) 18 September 2012.

Other publications 2012

The year in review. Royal Australasian College of Surgeons Surgical News, March 2012; 13(2): 34.

Presentations 2012

Maddern G. A clinician's view of disinvestment. HTAi Policy Forum, San Francisco, 23 January 2012.

Maddern G. Hypothetical: Conduct under the microscope. Medical Insurance Group Australia, 11 February 2102, Brisbane, 18 February 2012, Adelaide 3 March 2012, Sydney.

Maddern G. Evaluating new technologies in surgery: Are they worthwhile? Australian Healthcare Week, Future of Surgery 2012, Melbourne, 22 February 2012.

Maddern G. Do audits of surgical mortality alter surgical outcomes? Recognising the Deteriorating Patient, South Australian Audit of Perioperative Mortality/SA Health, Adelaide, 28 February 2012.

Maddern G. When to treat, when to refer on. Specialist Surgery for the General Surgeon, 19th Seminars in Operative Surgery, Adelaide, 9 March 2012.

Maddern G. Significance of comparative effectiveness through health technology assessment e-Health – Delivering improved, high quality care. 2012 Australian e-Health Research Colloquium, Brisbane, 13 March 2012.

Kollias J. Adherence to recommended treatments for early invasive breast cancer – results from the BreastSurgANZ National Breast Cancer Audit. Royal Australasian College of Surgeons Annual Scientific Congress, Kuala Lumpur, May 2012. Kollias J. 20011: has it changed Australian practice? Royal Australasian College of Surgeons Annual Scientific Congress, Kuala Lumpur, May 2012.

Gurgacz S, Credentialing of surgeons: a systematic review across a number of jurisdictions. The South Australian Health Technology Advisory Group, Adelaide, 5 June 2012.

Maddern G. Surgical research at TQEH. What it means for you! The Hospital Research Foundation Corporate Research Breakfast, Adelaide, 19 June 2012.

Maddern G. How to best use limited capacity for pragmatic evidence generation internationally. Panel session, 9th HTAi Annual Meeting, Bilbao, Spain, 25 June 2012.

Maddern G, Methods in HTA. Session Chair, 9th HTAi Annual Meeting, Bilbao, Spain, 26 June 2012.

Maddern G. Common bile duct injury. Session Chair, 9th HTAi Annual Meeting, Bilbao, Spain, 26 June 2012.

Maddern G. Traps in new technologies. Johnson & Johnson Market Access Pathways Program, Sydney, 26 July 2012.

Babidge W. Moving forward with new visions. Chair 20th Annual Meeting, International Network of Agencies for Health Technology Assessment, Bilbao, Spain, 27-28 June 2012.

Maddern G, Gurgacz S, Smith J, Truskett P, Babidge W. Credentialing of surgeons: a systematic review across a number of jurisdictions. Joanna Brigg Institute National Australian Conference on evidence-based clinical leadership, Adelaide, 13 August 2012.

Maddern G, Hypothetical: Dr Jekyll or Mr Hyde – Will you let the Court decide? Medical Insurance Group Australia, Melbourne, 4 August 2012; Sydney, 18 August 2012; Adelaide, 8 September 2012; Barossa Valley, 22 September 2012; Adelaide, 24 November 2012.

Maddern G. What simulation works and with whom. Royal Australasian College of Surgeons (New Zealand) Annual Scientific Meeting, Queenstown, New Zealand, 27 August 2012.

Maddern G, How to get the best out of audit. Royal Australasian College of Surgeons (New Zealand) Annual Scientific Meeting, Queenstown, New Zealand, 28 August 2012.

Maddern GJ. Comparative effectiveness: Just another way to restrict surgical innovation? 10th Annual AAQHC Conference, Cairns, 5 September 2012.

Walters D. Recent outcomes from the National Breast Cancer Audit. Breast Surgeons of Australia and New Zealand, Inc. Workshop, Hobart, September 2012. Altree M, Tan S, Marlow N, Babidge W, Field J, Hewett P, Maddern G. Surgeon versus non-surgeon simulation training. SimHealth 2012: Making teams work, Sydney, 12 September 2012.

Babidge W. Surgical Skills Training. Chair. SimHealth 2012: Making teams work, Sydney, 12 September 2012.

Babidge W, Daruwalla J, Field J, Altree M, Marlow N, Hewett P, Maddern G. The effects of mild fatigue on laparoscopic skills. Poster presentation, SimHealth Sydney, September 2012.

Babidge W. Making Audit Easy. Invited presentation, Queensland Regional Committee, RACS Annual State Meeting, North Stradbroke Island, September 2012.

Azzopardi J, Walsh D, Taylor C. Surgical treatment for women with breast cancer in relation to remoteness, socioeconomic disadvantage and insurance. Poster presentation, General Surgeons Australia Annual Scientific Meeting, Hobart, September 2012.

Maddern G, Simulation: Return on Investment – Real issues in sustainable simulation.

2012 International Conference on Surgical Education and Training, Ottawa, Canada, 17 October 2012.

Maddern G. Training the well rounded surgeon – meeting society's needs. 2012 International Conference on Surgical Education and Training, Ottawa, Canada, 17 October 2012.

Maddern G. How do we ensure quality and safety from new technology? International Society for Quality in Health Care 2012, Geneva, Switzerland, 22 October 2012.

Maddern G. Simulation in surgery, ANZHPBA Annual Meeting, Coolum, Queensland, 5 November 2012.

Maddern G. History of academic surgery in ANZ including the Surgical Research Society of Australasia. RACS Section of Academic Surgery Annual Meeting, Basil Hetzel Institute, Adelaide, 8 November 2012.

Maddern G. RACS Section of Academic Surgery Annual Meeting. Basil Hetzel Institute, Adelaide, 8 November 2012.

Maddern G. Quality assurance initiatives and mortality audits. RACS ACT Annual Scientific Meeting, Canberra, ACT, 10 November 2012.

Maddern G. Unwanted variations and disinvestment. Private Healthcare Australian Conference 2012, Park Hyatt, Melbourne, 14 November 2012.

Maddern G. The Australian and New Zealand Audit of Surgical Mortality (ANZASM): Has it had an impact? 3rd Annual Clinical Audit Improvement Conference, Sydney, 28 November 2012.

Project activities

ASERNIP-S Advisory Committee

The members of the ASERNIP-S Advisory Committee are:

A/Professor Ian Bennett	Chair
Hon Dr Michael Armitage	Chief Executive, Australian Health Insurance Association
Mr Andrew Brooks	Royal Australasian College of Surgeons Councillor
Ms Margaret Charlton	Consumer representative, Health Consumers Alliance SA
Professor Kingsley Faulkner	College Fellow
Dr David Hailey	Health Technology Assessment Expert
Mr Brian Johnston	Chief Executive, Australian Council on Health Care Standards
Professor Brendon Kearney	South Australian Health Technology Advisory Group Representative
Professor Guy Maddern	ASERNIP-S Surgical Director
Professor Donald MacLellan	New South Wales Health
Professor Adrian Nowitzke	Royal Australasian College of Surgeons Councillor
Mr Terry Symonds	Victorian Department of Health

In May 2012 Mr Ian Civil resigned from the committee due to the completion of his term as College President. We thank him for his valuable contribution while Chair of the committee.

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
- Advisory Committee on the Safety of Medical Devices (ACSMD), a statutory committee which provides independent advice to the Therapeutic Goods Administration (TGA)

 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 that provides independent advice to the 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), External Partnerships subcommittee member

 Associate Professor Wendy Babidge
- HTA Glossary Steering Committee (HTAi/INAHTA)
 Associate Professor Wendy Babidge.

Personnel

During 2012 we welcomed:

- Dr Alun Cameron, Senior Research Officer
- Jennifer Chadbourne, Research Officer
- Corey Taylor, Senior Research Officer
- Dr Guilherme Pena, Project Officer
- Robyn Lambert, Research Officer
- Dr Mark Geier, Research Manager
- Arlene Vogan, Research Officer
- Dr Merrîcc Edgar-Hughes, Research Manager

In 2012 we benefited from the following consultancy support:

• 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, guideline development and health policy evaluation. 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. Ann established a freelance HTA consultancy in January 2006 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 computerbased 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 in medical informatics and public health. From 1996 to 2000 she worked as a medical consultant at the British Columbia 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 Defense. For the past two years she has contributed to a World-Bank-funded project introducing HTA in the Republic of Kazakhstan.

• 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.

• Dr Kathy Stiller

Kathy has a background in physiotherapy and worked in the intensive care unit at the Royal Adelaide Hospital for over 20 years. Kathy gained her PhD in 1995 through the University of South Australia. Kathy is currently employed part time as the Research Coordinator, Physiotherapy Department, Royal Adelaide Hospital. Kathy has an international profile as a physiotherapy researcher, with over 70 publications, and has presented a similar number of papers at national and international conferences, many of these as an invited keynote speaker. The research in which Kathy has been involved covers a wide range of clinical areas (e.g. intensive care, cardiac surgery, burn injury, orthopaedic in-patients, cystic fibrosis and clinical education). Kathy has also successfully supervised numerous post-graduate students, ranging from honours to PhD students, and is frequently asked to review grant applications and journal manuscripts. Since 2007, Kathy has also worked part time as a freelance professional medical writer and research consultant. Given her extensive experience in clinical research and a broad general knowledge of medicine, Kathy is able to adapt her skills to a diverse range of areas. Kathy's clients have included Hampstead Rehabilitation Centre, Burns SA, orthopaedic surgeons, a cardiologist and, in 2012, ASERNIP-S.

CHERE

Since April 2007 ASERNIP-S has collaborated 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). Professor Marion Haas, Dr Stephen Goodall, Mr Richard Norman, Mr Changhao Hou, Ms Jody Church, Ms Bonny Parkinson, Ms Paula Cronin and Ms Sheena Arora have been assisting with numerous MSAC and Pharmaceutical Benefit Advisory Committee health technology assessment reports and co-dependent critiques of submission-based assessments in order to provide economic evaluation of procedures under consideration for Medicare and Pharmaceutical Benefits Scheme funding. CHERE also provides teaching and research in health economics and is one of five centres in Australia that undertakes the evaluation of PBAC submissions.

ASERNIP-S website

The College website started the year with a new look, features and functionality. ASERNIP-S reports are now available from the website at http://www.surgeons.org/forhealth-professionals/audits-and-surgical-research/. Many of our reports are written as easy-to-read summaries prepared for consumers, patients and healthcare professionals.

The ASERNIP-S homepage also provides access to the Australian and New Zealand Horizon Scanning Network (ANZHSN) website and the EuroScan database. These are regularly updated with new technology briefs and health technology reports.

We continue to benefit from the accreditation of HealthInsite, Australia's online gateway for easy access to quality health information, and 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.

Medical students

Todd Matthews

Todd Matthews has spent the last three years completing his PhD in Medicine with the Discipline of Surgery, University of Adelaide, and with the collaboration of the Therapeutics Research Centre and Cancer Research groups from the University of South Australia. The title of his thesis is 'Clinical Analysis of Liver Function: Development of a novel method for detection of portosystemic shunts'. The aim of the thesis is to investigate why some colorectal cancer patients present with secondary cancer that has metastasised beyond the liver, before it metastasises in the liver itself. It was hypothesised that portosystemic shunts may be a reason for this. However, as there are no standardised clinical tests for portosystemic shunts, Todd aims to develop a cost effective, non-invasive technique that can determine and measure portosystemic shunts in functionally healthy livers. Todd worked with ASERNIP-S during the protocol design phase of his project and his thesis is currently in progress.

Surgical students

Simon Tan

Simon is a Masters Degree student in Surgical Science, University of Adelaide. He is undertaking a systematic review of the literature looking at the importance of team simulation in the operative setting and how it impacts surgical training. The provisory title of his work is: 'Impact of intraoperative team simulation in surgical training: A systematic review'. Research, Audit and Academic Surgery Division – Royal Australasian College of Surgeons ASERNIP-S organisational chart



Staff

Professor Guy Maddern A/Prof Wendy Babidge Keith Hayes Eleanor Ahern Meryl Altree Dr Yasoba Atukorale Dr Alun Cameron Jennifer Chadbourne Susan Dawe Katherine Economides Dr Merrîcc Edgar-Hughes Felicity England Deanne Forel Jane Franklin Dr Mark Geier Pat Green Stefanie Gurgacz Kylie Harper Ben Hoggan Karen Humphreys Louise Kennedy Robyn Lambert Wendy Morros Michelle Ogilvy Dr Guilherme Pena

Corey Taylor Dr Prema Thavaneswaran Dr Meegan Vandepeer Arlene Vogan Joanne Watson Heath White Vicki Xafis Megan Zille

Staff



Professor Guy Maddern



Keith Hayes



Katherine Economides



Felicity England



Eleanor Ahern



Associate Professor Wendy Babidge



Meryl Altree



Dr Merrîcc Edgar-Hughes



Stephanie Gurgacz

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 Head of the UGI/HPB Unit, The Queen Elizabeth Hospital; Head of the Discipline of Surgery and Head of the School of Medicine, University of Adelaide; 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 has a base in Adelaide, as well as staff across all regions in Australia. As well as directing the ASERNIP-S program, Wendy oversees the College morbidity and mortality audits, the provision of scholarships for surgical research and the Section of Academic Surgery. Another major focus in the Division is the Morbidity Audit and Logbooks Tool (MALT) which has been updated to provide not only a platform for Trainees to keep their Logbook but also an auditing tool for Fellows. 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 and a Fellow of the Australian Institute of Management. She is the current 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. In addition to supporting the RAAS Director, Keith oversees the administration of the Scholarships program, the Board of Surgical Research, the Section of Academic Surgery and the Surgical Research Society. He also leads the divisional Project Office, which provides centralised management support for contracted research, according to a robust business management framework. 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 the grape and wine sector.

Australian Safety & Efficacy Register of New Interventional Procedures — Surgical Royal Australasian College of Surgeons Annual Report 2012

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 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. 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 National Breast Cancer Audit and the Australian and New Zealand Gastric and Oesophageal Surgical Association Audit. She also oversees administrative support given to the Bi-National Colorectal Cancer Audit, 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.

Research Manager, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical Dr Merrîcc Edgar-Hughes

Dr Merrîcc Edgar-Hughes joined ASERNIP-S in November 2012 from the Medicines and Technology Policy and Programs area within SA Health. She was previously the Executive Officer of the South Australian Therapeutics Advisory Group - SATAG (now renamed the South Australian Medicines Advisory Committee, SAMAC) and most recently was responsible for Commonwealth funded special access programs for medicines and for distribution logistics associated with the antiviral drugs during influenza pandemic and interpandemic phases for South Australia. For four years Merrîcc was the South Australian member of the Australian Health Ministers Advisory Council's (AHMAC) Highly Specialised Drugs Working Party and the state coordinator for the Highly Specialised Drugs Program (HSDP). She also has 10 years experience in the Product Safety, Medical Information, Regulatory Affairs and Quality Systems fields (including four years as Head of Department) within the medical technologies and pharmaceutical

industries. Merrîcc has an Honours degree in Science and a PhD in Chemistry. She is a member of the Royal Australian Chemical Institute.

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 also provides strategic and risk management advice to the Division in relation to issues that arise throughout its varied activities. Felicity is an experienced solicitor having extensive experience in contract negotiation and drafting, dispute resolution, and commercial and insurance litigation. Felicity holds a Bachelor of Arts, a Bachelor of Laws and a Graduate Diploma in Legal Practice.

ASERNIP-S Acting Horizon Scanning Manager, and Senior Research Officer Stefanie Gurgacz

Stefanie Gurgacz joined ASERNIP-S in 2009, where she conducts systematic literature reviews and surgical research for a number of stakeholders. She holds a Bachelor of Science majoring in Pharmacology from the University of South Australia and her research interests include evidence-based medicine, clinical pharmacology and public health. She has written reviews and reports for a number of stakeholders, including the Medical Services Advisory Committee, the Therapeutic Goods Administration, HealthPACT, the American College of Surgeons (horizon scanning), the Australian Government Department of Health and Ageing, and the Victorian Department of Health. As Project Manager for the Horizon Scanning project and Senior Research Officer, Stefanie undertakes all elements of health technology assessment and provides mentoring and training for junior staff.

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

Appendix B : The ASERNIP-S review process

Appendix C : The ASERNIP-S classification system

Appendix D : Reports and publications 2010-2011

Appendix A

Hierarchy of evidence Designation of levels of evidence

Level of evidence	Study design
la	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 (pretest/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 2010-2011

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.

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