

Annual Report 2007

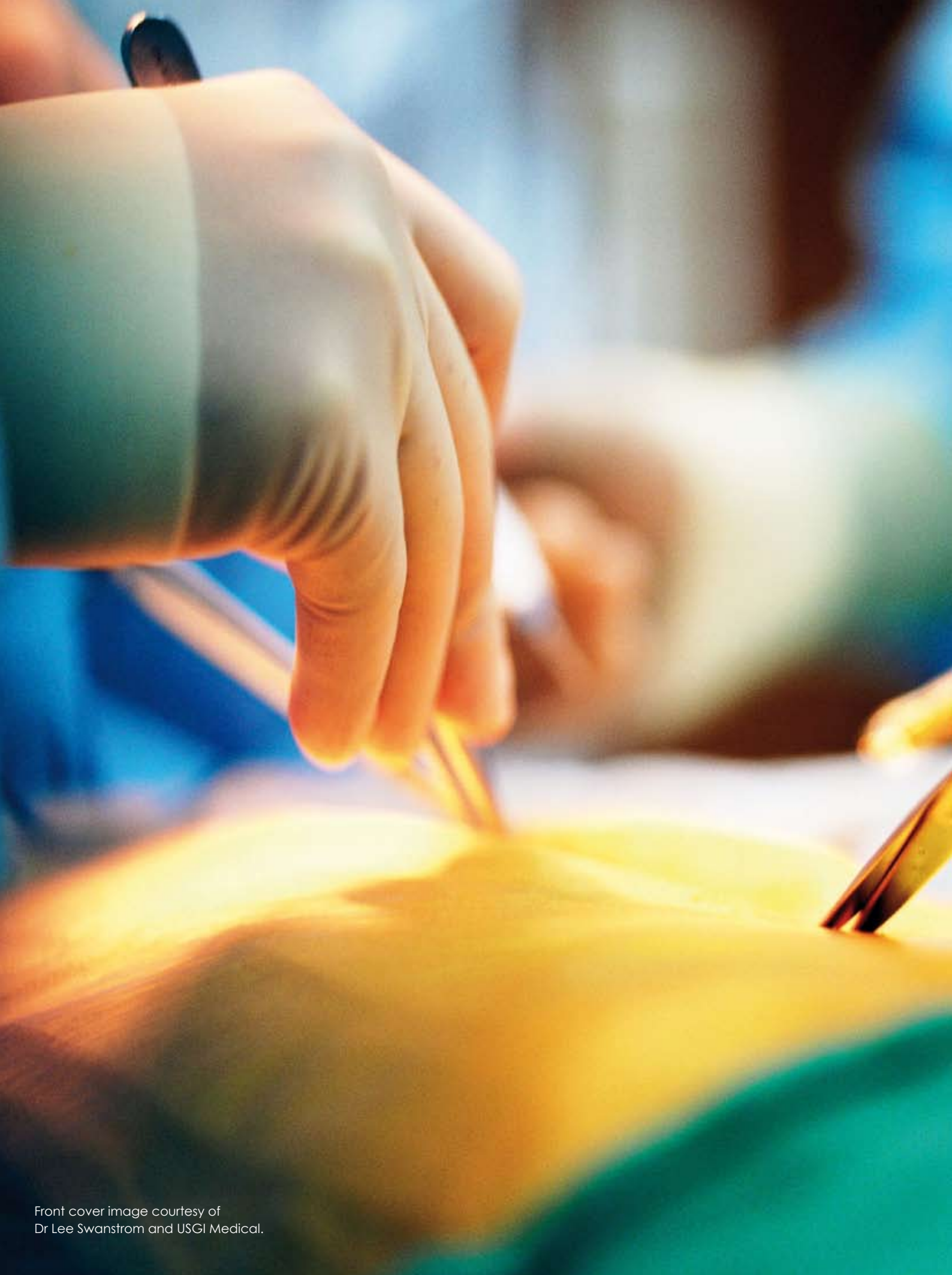


Australian Safety and Efficacy Register of New Interventional Procedures — Surgical
Royal Australasian College of Surgeons



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Front cover image courtesy of
Dr Lee Swanstrom and USGI Medical.



Mission statement

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

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



Surgical Director's report

Guy Maddern
Surgical Director

Over the past twelve months, ASERNIP-S has undergone a significant series of developments which should position the organisation well for the future growth and development of its activities. For example, our work in horizon scanning for HealthPACT and as a contractor to MSAC has become an important part of our efforts to provide high-quality assessments of surgical procedures appearing on the horizon and arriving into practice. These activities reinforce the role of ASERNIP-S as the premier surgical assessment body both within Australia and internationally.

"This important initiative will enable the College over the next three years to define the curriculum and infrastructure support required to provide simulation environments to trainees and Fellows at a variety of sites around the nation."

I have been fortunate for the last eighteen months to be Chairman of the International Network of Agencies for Health Technology Assessment (INAHTA) and this, coupled with my position as Secretary of Health Technology Assessment International (HTAi), has helped to promote the work of ASERNIP-S within the international health technology assessment community.

In October 2007 ASERNIP-S was invited to present to the American College of Surgeons meeting in New Orleans on its current activities. The work was well received and discussions regarding closer collaboration have commenced.

The Federal Government has again provided us with funding for twelve months, to look at how technologies reaching the end of their life can be assessed in order to free up resources for new and emerging technologies. This project should be completed by the middle of next year.

The resources available to ASERNIP-S in study design and evaluation have enabled us to secure a \$5 million grant from the Commonwealth Government for the Royal Australasian College of Surgeons to assess simulated surgical technologies in high and low fidelity environments across Australia. This important initiative will enable the College over the next three years to define the curriculum and infrastructure support required to provide simulation environments to trainees and Fellows at a variety of sites around the nation.

The existence of our outstanding core of researchers, administrative officers and bureaucratic expertise has enabled the number of staff, publications and funding to increase dramatically over the past twelve months.

The reputation of audits overseen and managed by ASERNIP-S continues to grow, with the Breast Audit now recognised as one of the most outstanding practice audits available nationwide. Attempts to establish a Colorectal audit and also maintain the existing Audit of Endovascular Aneurysm Repair demonstrate clearly that ASERNIP-S is positioned to work closely with many of the Government's new initiatives in providing relevant assessments of procedures and outcomes across the country.

There can be no doubt that ASERNIP-S continues to provide an invaluable service to the College as the pre-eminent authority on the introduction, assessment and monitoring of new surgical technologies, not only in Australia but worldwide.

reviews



New assessments completed

Systematic literature reviews

- Centralisation of selected surgical procedures: implications for Australia
ASERNIP-S Report no. 57
- Scalpel safety in the operative setting
ASERNIP-S Report no. 59
- Surgical simulation for training: skills transfer to the operating room
ASERNIP-S Report no. 61
- Natural orifice transluminal endoscopic surgery (NOTES)™ for intra-abdominal surgery
ASERNIP-S Report no. 62

Other reviews

- A review of policies and processes for the introduction of new interventional procedures
ASERNIP-S Report no. 58
- Rapid versus full systematic reviews: an inventory of current methods and practice in Health Technology Assessment
ASERNIP-S Report no. 60

Systematic reviews for other organisations

- Endovascular neurointerventional procedures (MSAC reference 1093)
- Injectable silicone biomaterial for severe passive faecal incontinence (MSAC reference 1100)
- Repetitive transcranial magnetic stimulation as a treatment for depression (MSAC reference 1101)

Assessments in progress

Procedure nominations

Systematic reviews

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

Accelerated systematic reviews

Accelerated systematic reviews (ASRs) are produced in response to a pressing need for a systematic summary and appraisal of the available literature for a new or emerging surgical procedure. ASRs use the same methodology as full systematic reviews, but may restrict the types of studies considered (for example, by only including comparative studies and not case series) in order to produce the review in a shorter time period than 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.

New assessments completed

Systematic literature reviews

Centralisation of selected surgical procedures: implications for Australia

ASERNIP-S Report no. 57

Objective

The objective of this systematic review was to assess the efficacy of centralisation for the following surgical procedures in the Australian setting: abdominal aortic aneurysms, knee arthroplasty, liver resection, oesophagectomy and prostatectomy.

Methods

Search strategy: Two search strategies were used in this review. Firstly a broad search was performed to identify the range of centralisation studies on surgical procedures. For this search MEDLINE, EMBASE, CINAHL, the NHS CRD databases and Current Contents Connect were examined. Once the procedures of interest had been determined by the review group, a secondary targeted search was performed. This search used a separate procedure-specific search algorithm in each of the following electronic databases: CINAHL, Clinical Trials Databases, Current Contents Connect, Current Controlled Trials, EMBASE, MEDLINE, National Research Register, NHS CRD Database, PubMed, and The Cochrane Library.

Study selection: Studies were included if they met the inclusion criteria and reported at least one of the following outcome measures: patient mortality, morbidity and length of stay. Additionally, financial data comparing the differences between patient volumes were included.

Data collection and analysis: Data from all included studies were extracted by one researcher and checked by a second researcher using standardised data extraction tables that were developed a priori. When overlapping patient groups were reported in studies, only the paper quoting the most complete data set was used.

Results

The following results overview has been presented separately for each procedure of interest.

Abdominal aortic aneurysm:

- **Unruptured**

The relationship between hospital volume and both patient morbidity and length of stay was inconclusive. There were data to suggest an inverse relationship between hospital volume and patient mortality rates. None of the included studies examined the relationship between surgeon volume and patient morbidity. Limited data supported an inverse relationship between surgeon

volume and patient mortality. A statistically significant inverse relationship between surgeon volume and patient length of stay was reported by the one study that investigated this relationship.

- **Ruptured**

None of the included studies examined the relationship between hospital volume and patient morbidity. Limited data supported a relationship between surgeon volume and patient mortality. Very limited data indicated that hospital volume did not affect patient length of stay. None of the included studies examined the relationship between surgeon volume and patient morbidity. A statistically significant relationship between surgeon volume and both patient mortality and length of stay was reported by one study.

Knee arthroplasty:

- **Primary**

Reported data indicated an inverse relationship between hospital volume and patient morbidity, mortality and length of stay; however, due to the methodology used in this study patient mortality was not clearly separated from patient morbidity, potentially confounding both outcomes. Limited data provided opposing results regarding the impact of surgeon volume and patient morbidity. No study reported a relationship between surgeon volume and patient mortality. No definitive conclusion was reported by the one study examining the relationship between surgeon volume and patient length of stay.

- **Revision**

No data were available on the relationship between hospital volume and patient morbidity. Limited data produced inconsistent results supporting an inverse relationship between hospital volume and patient mortality. Very limited data reported an inverse relationship between hospital volume and patient length of stay. None of the included studies examined the relationship between surgeon volume and patient morbidity, mortality or length of stay.

Liver resection:

- **Minor**

No data were available on the relationship between hospital volume and patient morbidity. Limited data indicated an inverse relationship between hospital volume and both patient mortality and length of stay. None of the included studies examined the relationship between surgeon volume and patient morbidity, mortality or length of stay.

- **Major**

None of the included studies examined the relationship between hospital volume and patient morbidity. Limited data supported an inverse relationship between hospital volume and patient mortality. No data were available on the relationship between hospital volume and patient length of stay. None of the included studies examined the relationship between surgeon volume and patient morbidity, mortality or length of stay.

Oesophagectomy:

There were no data to suggest a relationship between hospital volume and patient morbidity rates. There were data identifying an inverse relationship between hospital volume and patient mortality. The relationship between hospital volume and patient length of stay was inconclusive. Very limited data were available which examined the relationship between surgeon volume and either patient morbidity or length of stay; in each instance no statistically significant relationship was reported. The majority of study data identified a statistically significant relationship between surgeon volume and patient mortality.

Prostatectomy:

There were data to suggest a relationship between hospital volume and patient morbidity, mortality and length of stay. There were data to suggest a relationship between surgeon volume and patient morbidity rates. None of the included studies reported a statistically significant relationship between surgeon volume and mortality; however, very limited data reported an inverse relationship between surgeon volume and patient length of stay.



Conclusions

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations regarding the centralisation of abdominal aortic aneurysm surgery, knee arthroplasty, liver resection, oesophagectomy and prostatectomy.

Classifications

Evidence rating:

The evidence base for this review is rated as 'average'. The evidence comprised comparative studies, the majority of which were also retrospective. Definitions of patient mortality, morbidity and length of stay differed not only between procedures of interest, but also between the primary studies examined for each procedure. Additionally, no common numerical definitions of either hospital or surgeon volume were used for each procedure of interest, limiting the accuracy of any comparisons.

Clinical and research recommendations

Although trends in the relationship between volume and outcome have been identified for some procedures of interest, these are indicative of North American healthcare systems. Each of the procedures of interest should continue to be monitored in Australia.

This review identified only a limited number of studies examining the financial implications of centralisation for any of the procedures, none of which included Australian data. It is recommended that financial analyses are commissioned to provide a representative assessment of the Australian healthcare system.

Any future research commissioned in Australia (and the rest of the world) should use common clinical terminology; that is, mortality and morbidity must be uniformly defined to enable more efficacious comparisons.

A number of Australian-based research studies across a range of surgical procedures, using common clinical terminology, must be conducted before any definitive assessment of the impact of centralisation in Australia can be made. Attention to the quality factors which affect skills development and maintenance of surgeons in low and high volume hospitals should also be included. These studies require nationally representative data from low and high volume Australian hospitals to assess standards of care, to ensure centralisation is not instituted solely for political or financial reasons.

Review Group membership

Protocol Surgeon: Professor Bruce Barraclough; Advisory Surgeons: Mr Neil Collier, Mr Ian Dickinson, Mr Jonathon Fawcett, Mr John Graham; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Mr Nicholas Marlow



Scalpel safety in the operative setting

ASERNIP-S Report no. 59

Objective

To identify and assess the efficacy and effectiveness of devices and procedures designed to lower the incidence of scalpel injuries in the operative setting, through a systematic review of the literature.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, CINAHL, The Cochrane Library, Current Contents, PubMed and AMI from inception to December 2006. The Clinical Trials Database (US), NHS CRD Database (UK), The National Research Register (UK) and the Meta Register of Controlled Trials were also searched in January 2007.

Study selection: Included for review were randomised controlled trials (clinic and laboratory based), randomised comparative studies, non-randomised comparative studies, observational studies, surveys and modelled data. Outcomes examined included rates of glove perforation, injuries and user satisfaction.

Data collection and analysis: Data from the included studies were extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher. Studies that were sufficiently homogeneous were examined by meta-analysis. Heterogeneous studies that did not meet the criteria for meta-analysis were reported qualitatively.

Results

A total of 19 studies were included in this review: 13 examining cut-resistant gloves and glove liners; three assessing the hands-free passing technique; one reporting on protective footwear; one investigating the feasibility of sharpless surgery and one evaluating a single-handed scalpel blade remover. Seven of these studies were randomised trials (NHMRC Level II), three were non-randomised comparative studies (Level III-2), two were comparative studies with historical controls (Level III-3), one was a Level IV study and seven were experimental studies to which the NHMRC Hierarchy of Evidence could not be applied.

In both clinical and experimental (laboratory) conditions, the use of a cut-resistant glove or glove liner reduced the number of inner latex glove perforations in comparison to double latex. While statistical pooling of the data pertaining to cloth gloves confirmed a significant protective effect resulting from the use of cloth gloves, there were not enough studies reporting outcomes on each glove material to be able to

determine which material was the most effective in lowering the rate of inner latex glove perforation overall. Furthermore, given the aggregate outcomes reported, it was not possible to determine precisely how many injuries were directly attributable to scalpels, and how many were as a result of other sharp instruments.

Cut-resistant gloves and glove liners were found to lessen the wearer's dexterity and tactile sensation and resulted in minor impairment when tested against a number of comparators.

Based on the evidence reported in three studies, benefit derived from the use of the hands-free passing technique appeared equivocal, but its implementation may provide greater potential benefits in operations involving more than 100mL of blood loss. While the procedure did not appear to impact adversely on injury rates, it must also be acknowledged that there will remain the need for occasional hand-to-hand passing between members of the operative team, particularly in complex or emergent situations.

One study indicated that sharpless surgery provided a feasible alternative to the use of traditional sharps in surgery.

Theoretical modelling data presented in one study indicated that the use of a passive single-handed scalpel blade remover in conjunction with a passing tray had the potential to prevent approximately as many injuries as an active safety scalpel with a 100% activation rate, and up to five times as many injuries as a safety scalpel with a lower activation rate.

Evidence from one study indicated that materials such as non-pliable leather, rubber with leather lining and new rubber provided superior foot protection from dropped scalpel blades under experimental conditions.

Classification and recommendations

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning scalpel safety in the operative setting:

Classifications

Evidence rating

The evidence base in this review is rated as poor, limited by the quantity and quality of the available evidence. Specific limitations of the evidence included the diversity of interventions and outcomes considered, the lack of a standard comparator and the differences in clinical settings

and experimental environments in which the interventions were employed.

Effectiveness

Effectiveness outcomes were considered for those interventions that were undertaken in clinical settings:

Cut-resistant gloves & glove liners

Based on the published literature, the effectiveness of cut-resistant gloves and glove liners in the clinical setting cannot be determined.

Hands-free passing technique

Based on the published literature, the effectiveness of the hands-free passing technique in the clinical setting cannot be determined.

Sharpless surgery

Based on the published literature, the effectiveness of sharpless surgery in the clinical setting cannot be determined.

Pass tray & single-handed scalpel blade remover

Based on the published literature, the effectiveness of a pass tray used in conjunction with a single-handed scalpel blade remover in the clinical setting cannot be determined.

Efficacy

Efficacy outcomes were considered for those interventions that were undertaken in laboratory experimental settings:

Cut-resistant gloves & glove liners

Based on the published literature, the efficacy of cut-resistant gloves and glove liners in experimental settings cannot be determined.

Protective footwear

Based on the published literature, the efficacy of protective footwear in experimental settings cannot be determined.

Clinical and research recommendations

There are few studies published that systematically assess the effectiveness of safety devices in reducing percutaneous injuries, despite the proliferation of such devices. As noted in this review, available reports show substantial variation in study methodology and measurement of outcomes. Standardisation of these features needs to be considered by trial designers in order to compile a clinically relevant and statistically valid body of evidence by which to assess new safety procedures and devices; however, the undertaking of randomised controlled trials (particularly of cut-resistant gloves and glove liners) is both feasible and desirable.

Additionally, the undertaking of a suitably detailed audit of scalpel injuries would assist in contextualising the incidence, prevalence and epidemiology of these injuries within the Australian healthcare setting, allowing targeted interventions



to specific areas of the operative process where large numbers of injuries are occurring.

However, it should be emphasised that a large part of preventing sharps injuries involves creating a culture of safety within an institution and its operative personnel. The concept of 'scalpel safety' must be reinforced through practice and education in order to achieve lowered rates of scalpel injury in the operative setting in the long-term.

Review Group membership

Protocol Surgeon: Mr Michael Parkin; Advisory Surgeons: Dr Michael Sinnott, Mr Robert Black; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Amber Watt

For the full review and executive summary, please visit the publications page of our website at <http://www.surgeons.org/asernip-s/publications.htm>.

Surgical simulation for training: skills transfer to the operating room

ASERNIP-S Report no. 61

Objective

To assess whether skills acquired via simulation-based training transfer to the operative setting.

Methods

Search strategy: Studies were identified by searching MEDLINE, EMBASE, CINAHL, The Cochrane Library and Current Contents from inception to December 2006. 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 December 2006.

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. The articles must have contained training and/or measures of performance in the simulated setting and measures of performance in the operative setting. Measures of surgical task performance included accuracy of skills, time taken to complete technique, efficiency of movement, error rates and achievement of performance to criterion levels.

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

Results

A total of 12 randomised controlled trials and two non-randomised comparative studies were included in this review. The review looked at simulation as a concept and included studies with various training techniques in the surgical setting. There were differences in indications, simulation-based training methods, training times, and the amount of guidance and feedback provided to trainees. In most cases, simulation-based training was an add-on to normal surgical training programs. Only one study compared simulation-based training with current training methods (patient-based training).

For laparoscopic cholecystectomy, participants who received simulation-based training prior to conducting patient-based assessment generally performed better than their counterparts who did not have this training. This improvement was not universal for all of the parameters measured, but the untrained group never outperformed the trained group. Trained groups generally made fewer errors, and had less instances of supervising surgeon takeover than participants who did not have the training.



For colonoscopy/sigmoidoscopy, simulation-based training prior to patient-based assessment generally appeared to provide participants with some advantage over their untrained controls, particularly during the initial stages of learning.

For catheter-based intervention for occlusive vascular disease and total extraperitoneal hernia repair, simulation-based training appeared to show benefits for participants when later conducting patient-based assessment.

There were no differences in performance between endoscopic sinus surgery simulator-trained residents compared with controls when performing endoscopic sinus surgery.

The study that compared patient-based training with simulation-based training for colonoscopy/sigmoidoscopy found that participants who received training in the



assessment procedure exhibited better performance than those who had trained exclusively on a simulator without any mentoring or supervision.

Classification and recommendations

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the transferability of skills acquired via simulation-based training to the surgical 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.

Clinical and research recommendations

It is recommended that further research be done into the transfer of skills acquired via simulation-based training to the patient setting to strengthen the current evidence base.

Future studies could explore:

- 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, and
- changes in staff productivity as a result of simulation-based training.

Review Group membership

Protocol Surgeon: Professor John Windsor; Advisory Surgeons: Mr Patrick Cregan, Mr Peter Hewett; Mr Peter Cosman; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Lana Sturm

For the full review and executive summary, please visit the publications page of our website at <http://www.surgeons.org/asernip-s/publications.htm>.

Natural Orifice Transluminal Endoscopic Surgery(NOTES)TM for intra-abdominal surgery

ASERNIP-S Report no. 62

Objective

To assess the safety and efficacy of various intra-abdominal Natural Orifice Transluminal* Endoscopic Surgery (NOTES)TM procedures which do not cut the dermis, in comparison with traditional intra-abdominal surgery which cuts the dermis, through a systematic review of the literature.

Methods

Search strategy: Studies were identified by performing electronic searches of MEDLINE, EMBASE, CINAHL, Current Contents, The Cochrane Library and PubMed from 2000 to March 2007. The Clinical Trials database (US), NHS CRD databases and National Research Register (UK) were also searched in March 2007, and the SAGES 2006 and 2007 annual meeting abstracts were sourced for information.

Study selection: Studies conducted in live humans or animals involving surgical procedures in the intra-abdominal region using natural orifice access were included for review; however, studies in cadavers were excluded. Studies where the new intervention involved an incision to the dermis were excluded, and studies reporting established endoscopic procedures that were not transluminal such as abscess or cyst drainage or debridement were not included as they are standard practice. Efficacy outcomes included procedure success rate, viscerotomy creation and closure, and operation time. Safety outcomes included mortality, infection, toxic or adverse effects, pain, intraoperative/procedural complications and recovery times.

Data collection and analysis: Data from the included studies were extracted by the ASERNIP-S researcher using standard data extraction tables developed a priori and checked by a second researcher.

Results

The evidence base for this review was very limited, as there were no comparative studies and all the 22 included studies were conducted in animals, in order to test the feasibility of NOTES. There were no comparative studies, study numbers were low, and safety and efficacy outcomes were limited; thus it was difficult to compare the safety and efficacy of using NOTES to perform intra-abdominal surgery with existing techniques. However, it can be determined that at the present stage of development, NOTES does not appear to be as safe or effective as current surgical techniques. This indicates that the use of NOTES for intra-abdominal surgery requires further development before it can be considered in a clinical setting. Although intra-abdominal access via oral, anal or urethral orifices could be achieved reliably in all cases, the evidence does not indicate the optimal access route and method. Viscerotomy closure could not be achieved reliably in all cases and risk of peritoneal infection has not been adequately minimised.

Although the majority of interventions were able to be performed in animals using NOTES, a number of technical



problems were encountered that will need to be resolved. The large number of abstracts relating to NOTES at the recent SAGES 2007 meeting suggests that this area of surgery is developing rapidly and, accordingly, the evidence base will increase substantially. The review does indicate that it is feasible to use NOTES for some intra-abdominal surgical procedures; however, it is too early to determine if these will be comparable to current procedures and if the advantages of using NOTES outweigh the disadvantages.

Classifications

Evidence rating

The available evidence was assessed as being poor.

Safety

At this point in time, NOTES for intra-abdominal surgery is less safe than laparoscopic and laparotomic alternatives.

Efficacy

NOTES for intra-abdominal surgery is currently less efficacious than laparoscopic and laparotomic alternatives.

Clinical and research recommendations

NOTES is still in early stages of development and more robust technologies will be needed to achieve reliable closure and overcome technical challenges. Well-managed human studies need to be conducted to determine the safety and efficacy of NOTES in a clinical setting. This may be approached by performing hybrid NOTES/laparoscopic procedures, which may help to evaluate the safety of NOTES in a human model, before moving into larger trials. NOTES procedures and studies should be performed under strict guidelines, such as the membership criteria developed by NOSCAR.

Review Group membership

Protocol Surgeon: Dr Ian Martin; Advisory Surgeons: Mr Thomas Wilson, Mr Nicholas O'Rourke; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Eliana Della-Flora

For the full review and executive summary, please visit the publications page of our website at <http://www.surgeons.org/asernip-s/publications.htm>.

*Transluminal is used in the trademarked name "Natural Orifice Transluminal Endoscopic Surgery"; however, transluminal is the accepted Australian spelling of the word.



Other reviews

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

ASERNIP-S Report no. 58

Objective

To identify and review both Australian and international policies and processes for the introduction of new interventional procedures into clinical practice, with the aim of determining:

- how decisions about the adoption of new interventional procedures are made
- the extent to which evidence-based information, particularly health technology assessments (HTAs), is used in the decision-making process.

Methods

Search strategy: Literature pertaining to policies and processes for the introduction of new interventional procedures was identified by searching MEDLINE, EMBASE, CINAHL, Current Contents and PubMed from inception to February 2007. Relevant journals including the *British Medical Journal*, *Lancet*, *Health Technology Assessment*, *International Journal of Technology Assessment in Healthcare* and *Health Policy* were hand-searched from 2000 to February 2007. In addition, relevant online sources were also searched.

Study selection: Documents outlining specific policies and processes were selected for inclusion in the review if they evaluated the clinical need, safety, efficacy, clinical effectiveness and/or financial implications of a new interventional procedure. Where outcomes were reported for specific policies, these policies were given preference for inclusion in the review. In addition, studies that examined the use of HTAs in decision making about the adoption of new interventional procedures were also included.

Data collection and analysis: Data from all included documents were extracted by one researcher and checked by a second using standardised data extraction tables that were developed a priori. Data for the main outcomes were reported narratively.

Results

Searches of the published literature revealed only one paper outlining relevant policy information. Targeted website searches were more fruitful, and uncovered a large number of relevant policy documents, the vast majority of which were from NHS Trusts in the UK. A total of six policies, two Australian, two Canadian, and one each from Denmark and the UK, were selected for inclusion in this review. Each of the included policies contained a clearly defined purpose and an explicit description of the approval process, including the role of relevant clinical governance structures.

Five of the six included policies employ an application form as part of the approval process, while the McGill University Health Centre in Canada bases its policy decisions largely

on the recommendations of Technology Assessments produced by its own Technology Assessment Unit. These technology assessments evaluate the safety, efficacy and cost-effectiveness of the new technology, as well as any ethical and legal implications its introduction may have for the organisation. Information on clinical outcomes, including the clinical need and burden of disease, and the safety, efficacy and effectiveness of the procedure, was required by all five policies that incorporated application forms as part of their approval process, as was information on organisational outcomes, including the cost considerations and training requirements of the procedure. Both Australian policies required patient information sheets and informed consent forms as part of their approval process. Similarly, the policy of the Luton and Dunstable NHS Trust in the UK also required that the issues of patient information and informed consent be addressed; however, these issues were not addressed by the Canadian or Danish policies.

Three studies that have evaluated the outcomes of specific policies in Australia, Canada and the UK were uncovered through searches of the published literature, while targeted website searches revealed one document describing the outcomes of a second Australian policy. These studies have focused largely on the number and type of procedures that have been approved since the implementation of specific policies; however, two studies have provided additional information on their organisational impact.

Searches of the published literature uncovered three studies, two in Israel and one in Denmark, that have examined decision making at the hospital level, while targeted website searches revealed one document describing District Health Board decision-making processes in New Zealand. The results from these studies have shown that while the safety, efficacy and clinical and cost-effectiveness of new health technologies are important considerations in the decision-making process, a number of other factors also play an important role, and decisions are never based solely on the findings of HTAs. A lack of access to relevant and timely HTAs has been identified as an important barrier to an optimal decision-making process.

Conclusions

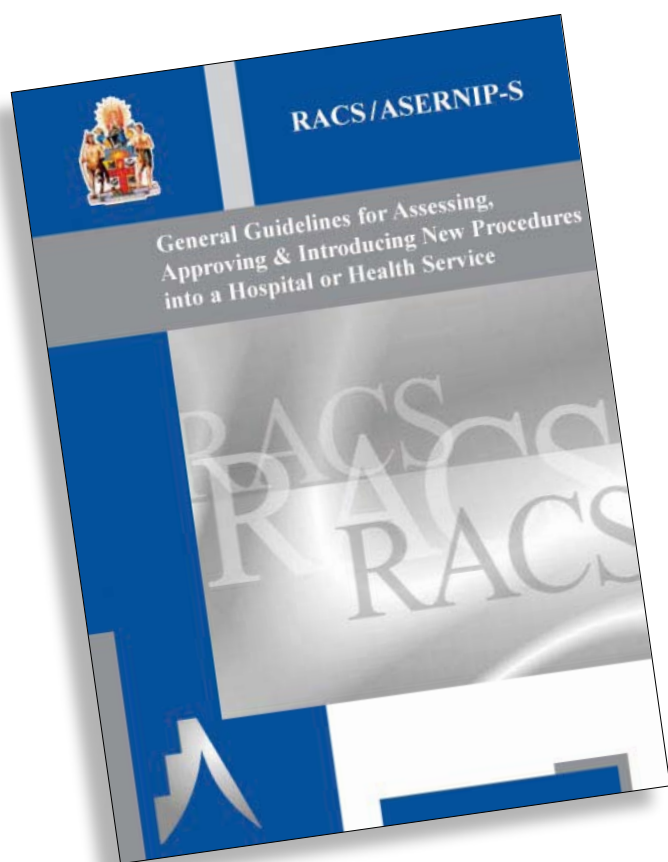
Increasing numbers of healthcare organisations, both in Australia and internationally, are establishing formal policies and processes for the safe introduction of new interventional procedures into clinical practice. Decision making about the adoption of such procedures appears to be focused largely on clinical outcomes such as the clinical need and

burden of disease and the safety, efficacy and effectiveness of the procedure, as well as organisational outcomes such as the cost considerations and training requirements of the procedure. However, few organisations have reported their experience with such policies and processes, and there is a paucity of information on the outcomes and organisational impact of these initiatives. While it is clear that evidence-based information, such as HTAs, is frequently used in decision making about the adoption of new interventional procedures, a lack of access to relevant and timely HTAs has been identified as an important barrier to optimal decision making. Therefore, greater effort needs to be put into establishing information infrastructure in order to make evidence more readily available to decision makers.

Review Group membership

Dr Helen O'Connell, Professor Chris Baggoley,
Professor Allan Spigelman; ASERNIP-S Surgical Director;
Professor Guy Maddern; ASERNIP-S Researcher;
Ms Prema Thavaneswaran

For the full review and executive summary, please
visit the publications page of our website at
<http://www.surgeons.org/asernip-s/publications.htm>.



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

ASERNIP-S Report no. 60

Objective

The objectives of this report were:

- to assess current practice in the preparation of rapid reviews by health technology assessment (HTA) organisations nationally and internationally
- to examine the current evidence base pertaining to the methodology of rapid reviews
- to determine if there are differences in the essential conclusions of rapid and full reviews on the same topic.

Methods

Three concurrent methodologies were employed to inform this report. A survey tool was developed and distributed electronically to 50 national and international HTA agencies, identified through INAHTA membership records and Review Group advice. Data on a broad range of themes related to the conduct of rapid reviews and their comparison to full reviews were collated via spreadsheet tabulation, discussed narratively and subjected to simple statistical analysis where appropriate. Systematic literature searches of the Cochrane Database of Methodology Reviews, the Cochrane Methodology Register, EMBASE, MEDLINE and the Australasian Medical Index were undertaken in March 2007 to identify any literature pertaining to methodology developed for undertaking rapid reviews. Comparative studies, guidelines, program evaluations, methods studies, commentaries and surveys were considered for inclusion.

The internet sites of 75 international HTA organisations were searched for rapid reviews meeting pre-defined inclusion criteria. For each rapid review identified, a literature search was undertaken utilising the University of York CRD database to identify full reviews (systematic reviews or HTA reports) published on the same topic within approximately one year of the identified rapid review. Clinical outcomes, the scope of the report, the methodology employed in its production and the essential conclusions of each review were used to compare rapid reviews with full systematic reviews.

Results

Survey of HTA organisations: 23 surveys were returned, with 18 agencies reporting the production of 36 rapid review products. Seventeen of these products were completed between one to three months, and a further 16 between three to six months. Three products did not fit into these categories and were considered separately. Collectively, the most common reason for conducting a rapid review was in response to political urgency and/or to support decisions (44%), and 69% of respondents indicated that macro-level decision makers



commissioned rapid reports. Search strategies varied widely; however, there was an overall focus on identifying higher levels of evidence wherever possible. The components of reviews also varied between product types, with full reviews more likely to report clinical outcomes (100% vs. 94%), examine economic factors (92% vs. 72%) and consider social issues (85% vs. 53%).

Literature on rapid review methodology: A total of 11 relevant studies were identified: one guideline abstract, three program evaluations, one comparative study, two methods studies, three commentaries and one survey. None of the included studies detailed guidelines for the methodology underpinning rapid reviews; rather, many offered examples and discussion surrounding the complexity of the area. Authors suggested restricted research questions and truncated search strategies as potential methods by which to limit the time taken to complete a review.

Identification and comparison of rapid reviews and full systematic reviews: A manual search of HTA agency websites identified eight agencies that produced rapid products. Where there was uncertainty surrounding a product, the agency was contacted to provide clarification. Comparisons were carried out between full and rapid reviews on the topics of drug eluting stents, lung volume reduction surgery, living donor liver transplantation and hip resurfacing. Axiomatic differences between the products were identified; however, there were no instances in which the essential conclusions of the different reviews were opposed. The full reviews consistently provided a greater depth of information and more detailed recommendations pertaining to the implementation of each particular health technology.

Conclusions

This report identified that the current rapid review products being produced by HTA agencies are not well defined and are highly variable in their methodology. However, it is a reality of the HTA environment that there will continue to be pressure to produce reviews that are both timely and accurate, in order to support the ever-increasing speed of the policy making process in this area.

It is therefore recommended that, rather than developing a formalised methodology by which to conduct rapid reviews, which may be inappropriate and oversimplified, agencies work to increase the transparency of the methods utilised for each review. It would thus be useful if HTA agencies could clearly identify their HTA products, with respect to the commissioning group and purpose of the review along with some general details outlining the methodologies used in their preparation. Despite this, it should be appreciated that certain parts of a comprehensive systematic review (such as an independent and complete economic evaluation) may not realistically be completed in a rapid timeframe. Furthermore, methods for incorporating the advice of expert panels in a timely manner need to be developed to ensure that rapid reviews reach appropriate conclusions at both clinical and policy levels. A rapid review should be written in answer to a specific question, rather than as a quick alternative to a comprehensive systematic review. In this manner, rapid reviews could be used to inform specific policy decisions in a timely manner without losing any of the important information that may be expected from a comprehensive review. It is perhaps the focus on appropriate use, along with suitable methodologies, of a rapid review that requires future consideration.

Systematic reviews for other organisations

- Endovascular neurointerventional procedures (MSAC reference 1093)
- Injectable silicone biomaterial for severe passive faecal incontinence (MSAC reference 1100)
- Repetitive transcranial magnetic stimulation as a treatment for depression (MSAC reference 1101)



Assessments in progress

Systematic literature reviews

- Permanent and semi-permanent dermal fillers
ASERNIP-S Report no. 55

Other commissioned projects

- Maximising health outcomes from government investment in surgical interventions

The aim of the project is to strengthen the evidence base regarding certain clinical practices, with a view to improving clinical outcomes in relation to government funding of surgical interventions.

The project will provide a framework for identifying and reviewing surgical items that may be of questionable clinical benefit. Following an evidence-based assessment of identified surgical items, a range of implementation strategies will be developed to improve health outcomes in relation to the reviewed surgical items.

ASERNIP-S will engage key stakeholders through the establishment of a specific advisory group comprising representatives of the following organisations:

- Royal Australasian College of Surgeons
- Australian Commission on Safety and Quality in Health Care
- Australian Health Insurance Association
- Consumers' Health Forum of Australia
- National Health and Medical Research Council
- National Institute of Clinical Studies

- Medical Services Advisory Committee
- Medicare Australia
- Department of Health and Ageing
- Australian Medical Association
- Australian Association of Surgeons.

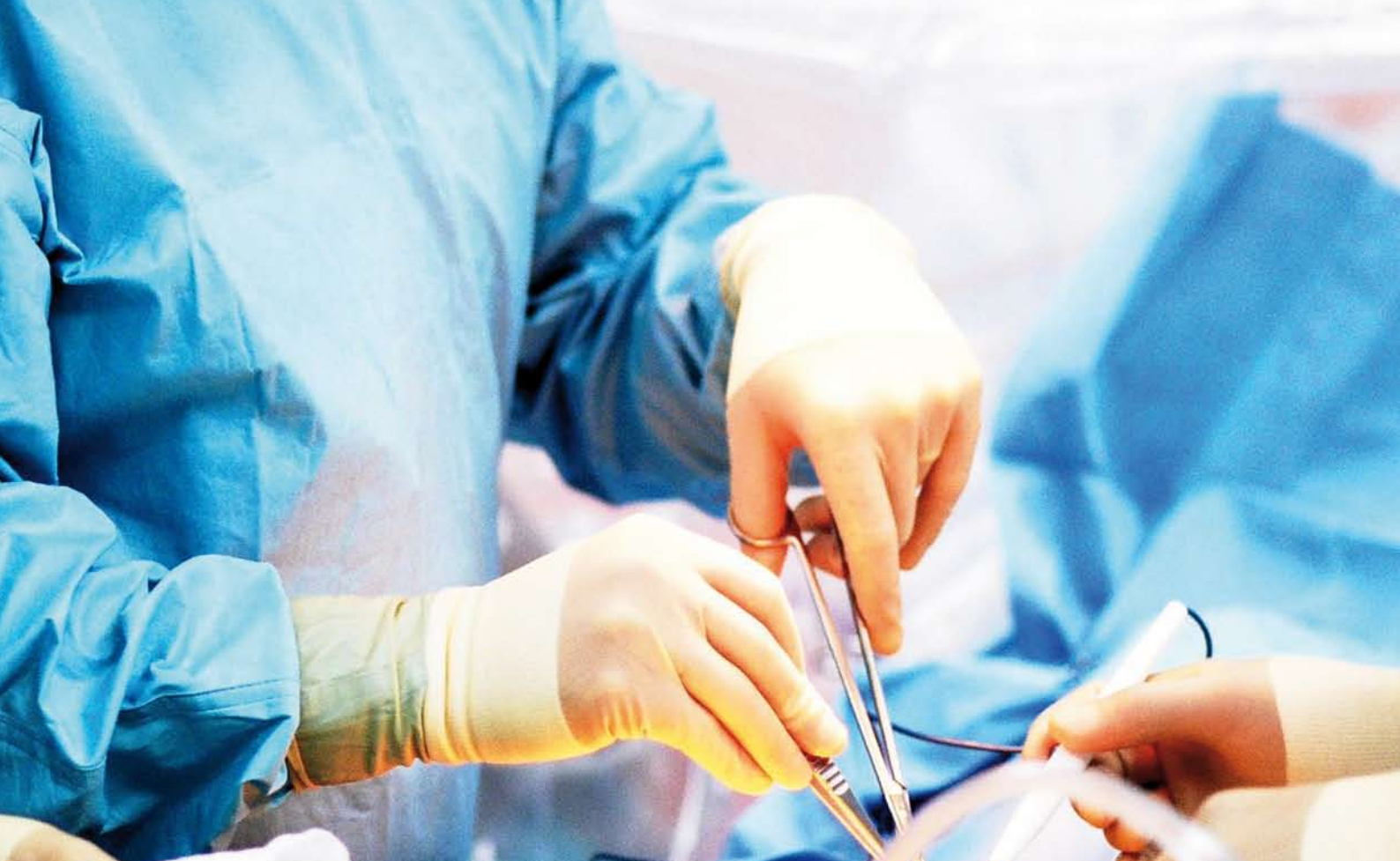
This group will focus on the development of criteria for the identification and prioritisation of items for further action and review. In addition to this group, specific surgical expertise will be sought throughout the project.

- Simulated Surgical Skills Program

ASERNIP-S has recently been commissioned by the Commonwealth Government Department of Health and Ageing to manage the Simulated Surgical Skills Program. This program will develop, implement and assess a curriculum focused on the use of laparoscopic surgical simulators in clinical education. This curriculum will be based on the highest international standards, culminating in a course specifically designed for both new and experienced Australian surgeons.

A second curriculum will be developed in order to 'train the trainer' as a means of assessing the best way to teach the use of surgical simulators. This work will be performed in most Australian states, including New South Wales, Victoria, Queensland, South Australia and Western Australia. Additionally there is the provision for the development of a 'mobile training unit' for use in rural and remote areas.

This program, which commenced in mid-December 2007 and will finish in September 2010, further demonstrates the diversification of work performed at ASERNIP-S.



Procedure nominations

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

- Asymptomatic gallstones
- Computer-assisted cardiac surgery
- Delivery of conscious sedation
- Downstaging of rectal cancer using neoadjuvant radiochemotherapy
- Endoscopic stapling of pharyngeal pouch
- Injectable silicone for incontinence, reflux and other indications
- Laparoscopic adhesion division
- Laparoscopic hemi-hepatectomy
- Palatal procedures for snoring
- Provision of emergency surgical services in Australia
- Radiofrequency ablation of tumours (not liver)
- Refractive keratoplasty
- Small vessel angioplasty
- Spinal endoscopy
- Spinal fusion apparatus
- The evidence for safe surgical working hours
- Thermal capsular shrinkage (for shoulder ligament laxity)
- Trans-oral laser resection for laryngeal cancer
- Transpupillary thermotherapy
- Trauma systems
- Use of biological osteoinductive agents for treatment of fractures (non-union)

To nominate a new procedure for review by ASERNIP-S, visit the website and use an online form or download a PDF version at <http://www.surgeons.org/asernip-s/publications.htm>.



Data collection

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

Audit of endovascular aneurysm repair

The procedure involves the elective repair of abdominal aortic aneurysms (AAA) using an endovascular graft. The graft is inserted through an incision in the femoral artery and positioned within the aorta at the site of wall weakening (the aneurysm) in order to prevent rupture.

The audit was established in 1999 to assess the mid- to long-term safety and effectiveness of the endovascular graft in the Australian setting following recommendations made by the Medical Services Advisory Committee (MSAC), and is now in its sixth year of follow-up for the original cohort. On 4 June 2007 the Minister for Health and Ageing the Hon Tony Abbott endorsed MSAC's recommendation to support permanent funding for the audit of endovascular aneurysm repair (EVAR) following consideration of the audit report on procedures with 5-year follow up.

Of the 961 patients enrolled in the audit, around 60% survived to five years, and to date 55% of patients are alive. Ninety three per cent of procedures were classified as 'technical successes'. Mid-term 'clinical success' was 85%; however, 6% of patients experienced a period of clinical failure before success. Some patients in the clinical success group required further interventions for their aneurysm; 4% had additional endovascular procedures (assisted success) and 1.2% had additional surgical procedures (secondary success) performed to ensure continued exclusion of the aneurysm or graft patency.

Of the 593 patients entering the long-term follow-up period, 6-year follow-up information was received for 52% (312). Data collection for the audit is ongoing; however, collection of long-term data is challenging as the sample size of remaining living patients decreases and patients become harder to track as time goes on. For many patients it has now been seven years or more since their original EVAR procedure; some are no longer being reviewed regularly by their surgeons or have been signed off by the surgeon as 'cured' making it more difficult to obtain long-term data for these patients. The audit's ongoing collaboration with the National Death Index data through AIHW has proven very useful in maintaining patient status and establishing date and cause of death.

The audit's funding agreement with the Australian Government reached the end of its contract in October 2006. Generous sponsorship from Cook Australia has now allowed the audit to continue data collection for a further two years. Results of this audit and overseas studies examining the long-term outcomes of EVAR continue to emphasise the importance of vigilant ongoing surveillance. As evidence of

long-term outcomes is limited and despite improvements in graft devices, late onset complications such as endoleaks and aneurysm enlargement may occur in the long term. As such, there is interest in extending the audit to 10 years follow-up. Longer term data would be very beneficial as there are so few studies of this kind.

The success of this audit is also due to the ongoing support of our contributing surgeons. We would like to acknowledge the efforts of those surgeons who originally contributed operative data and those who continue to contribute follow-up data; a participation list has been added to the ASERNIP-S page on the Royal Australasian College of Surgeons website.

The results of the audit have been published in international peer-reviewed journals and publicly presented. Future research to come from the audit may include exploring issues associated with ongoing monitoring of EVAR patients, such as exposure to radiation from yearly CT scans.

The final report to the Australian Government has been made available on the Medicare Services Advisory Committee website: <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Asernips+-+Australian+audit+of+Endovascular+An+eurysm+Repair>

The final report, previous progress reports and statistical analyses of the audit data are available on the College website; in addition, the audit and CSIRO have produced a Predictive Model based on the audit's findings, which is also available to surgeons. The model is an Excel workbook which allows surgeons to use pre-operative patient and aneurysm variables to gauge the likelihood of success of treating a patient with EVAR. All these resources can be accessed at <http://www.surgeons.org/asernip-s/audit.htm>.

Bi-National Colorectal Cancer Audit

Through a collaboration between the Colorectal Surgical Society of Australia and New Zealand (CSSANZ), the Research, Audit & Academic Surgery Division (RAAS) of the College and the Molecular Medicine Informatics Model (Bio21:MMIM) project, the Bi-National Colorectal Cancer Audit has been established. This has faced many challenges in its first 12 months of development; however, significant progress is now being made.

Patients undergoing resection or treatment for colorectal cancer will be recorded into the auditing system. It will incorporate and link into the successfully implemented multi-disciplinary, multi-institutional medical platform (Molecular Medicine Informatics Model, Bio21:MMIM project) that has been established by a large group of Melbourne researchers. The number of participants involved is unlimited.

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

The full ACCORD colorectal database is extensive. A minimum dataset (MDS) has been developed using this database as well as the well-established Association of Coloproctology of Great Britain & Ireland (ACPGBI) dataset. The aim is to potentially use the MDS initially and at a later date those surgeons wishing to contribute further data could do so using the full ACCORD dataset.

The aim of the collaboration is to create a large dataset containing Australian and New Zealand data for research and quality improvement purposes. This data will be used to advance knowledge and understanding of the optimum treatment for colorectal cancer and help ensure best practice.

An important part of establishing this collaborative audit has been the creation of a formal Memorandum Of Understanding between all three stakeholders, and this agreement is currently being signed for a further three years. In particular, this has addressed funding issues, with significant financial contributions from all three parties.

The initial phase of the audit has included gauging the interest of surgeons across Australia and New Zealand and obtaining approval for the activity, in the first instance in South Australia. To determine the interest of surgeons, both within the private and public sectors, and assess the number of individual colorectal databases in existence across the states, a registration

of interest and other documentation were sent to all colorectal surgeons. Supporting documentation included: the MDS, data dictionary, patient information sheet, ethics applications, letters to CEO and other relevant documents. More than 85% of surgeons signalled their intention to participate in the CSSANZ Colorectal Cancer Audit. Those who did not wish to participate indicated that they had existing databases or were involved with other research groups collecting colorectal cancer data.

“The aim of the collaboration is to create a large dataset containing Australian and New Zealand data for research and quality improvement purposes. This data will be used to advance knowledge and understanding of the optimum treatment for colorectal cancer and help ensure best practice.”

The Colorectal Cancer Audit wishes to enable data linkage/sharing opportunities with existing databases and other sources of data. Those surgeons with existing databases have been approached to participate in the audit where possible. Preliminary investigations have revealed there may be opportunities for data linkage at various levels, particularly within South Australia. The linkage of data provides an opportunity to improve quality, accuracy and validity of data collection. Discrepancies can be assessed and processes put into place to reduce flawed data as well as data duplication.

Reducing duplication of data entry is a consideration of the audit. Some surgeons with existing databases have agreed to use the MDS to continue their existing data collections as well as the CSSANZ Colorectal Cancer Audit. These surgeons, using the colorectal audit ethics documentation, received approval from their local ethics committees to participate and commence data collection using the MDS.

Approval was sought from the ethics committees so that the activity could be undertaken at the major metropolitan hospitals within South Australia, which included: the Royal Adelaide Hospital, The Queen Elizabeth Hospital, Lyell McEwin Health Services and Flinders Medical Centre. Other ethics committees were also approached namely the Repatriation

National Breast Cancer Audit

This year has been an interesting and challenging one for all involved with the National Breast Cancer Audit (NBCA).

The main purpose of the audit is to improve the surgical care for all patients with early breast cancer in Australia and New Zealand through the careful collection and analysis of audit data and the application of a full cycle of clinical audit. Other related objectives include ensuring the accuracy and validity of the data collection and disseminating information to practitioners and the broader community.

A number of areas of concern for the audit were identified by surgeons at the annual meeting of the Section of Breast Surgery held during the College Annual Scientific Congress in Christchurch, New Zealand, May 2007. These concerns included the complexity and time required to enter data into the online system, the inability of surgeons to retrieve their data in a specific format and the unsuccessful attempts of audit staff to combine established institutional datasets with the NBCA dataset.

Significant time, effort and resources have been put into addressing these issues and it is expected that this work will continue into 2008. The development of a minimum dataset will be based on advice received from surgeons and consultation with national breast cancer organisations. Once approved by the Breast Cancer Audit Steering Committee the minimum dataset will be made available to surgeons who are not able to contribute to the full dataset.

In order to improve the reporting features of the audit and to incorporate data from institutional datasets it was necessary to enlist the assistance of the Alcidion group of IT consultants, who worked closely with audit personnel to develop the necessary processes. Considerable effort has been put into incorporating data from Strathfield Private Hospital and Royal Melbourne Hospital. Discussions have been ongoing with representatives from other institutions.

The way in which surgeons retrieve their data from the online database into an Excel spreadsheet also came under review during 2007. The format of this spreadsheet has been improved and is now more 'user friendly'. Surgeons can use their data for research or self-auditing purposes.

To understand surgeons' requirements for improved reporting, a survey was distributed requesting this information. Results will help inform any changes made to online reporting services. The online system was upgraded in 2007 and this included the purchase of a new server and improvements to the security and backup of the system.

The web-based data entry system enables surgeons to review their results and compare them with values

General Hospital (approved) and the Royal Australasian College of Surgeons (the College). The College ethics committee approved the audit in October of this year. The College also approved the audit activity under the Continuing Professional Development Program (Category One: Surgical Audit and Peer Review). It is expected that the ethics committees of other institutions will be approached as necessary to facilitate the audit activities. Formal notification was received in October 2007 that the audit has been declared under the Australian Government, Commonwealth Qualified Privilege Scheme.

Through regular feedback regarding audit activities to CSSANZ members and other stakeholders, concerns have been adequately addressed prior to the commencement of the audit and this has reduced further delays and interruption. Regular communication will be an ongoing focus for the audit.

With many of the establishment issues resolved, the rollout of the MDS to all major metropolitan hospitals in South Australia occurred in July 2007. Data collection has been assisted with the installation of the ACCORD database at the College. The number of records being entered each week is on the rise.

Having successfully established data collection in Adelaide, other states have now been approached to also enter their data. In addition, web-based data entry is being finalised as a preferred option for data collection.

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

Ultimately, the aim of this audit activity is to maintain and improve the surgical practices for the purpose of quality assurance. There will be regular reporting and feedback to surgeons and hospitals, and it is envisaged that this will contribute to the identification of benchmarks, peer review, and development of multicentre research projects. Through the continued collaborative efforts of CSSANZ, the College and MMIM, the Colorectal Cancer Audit will continue to work towards achieving this ultimate aim.

established as indicators of good practice (quality thresholds). Slight changes were made to the way these were calculated in 2007 to improve their accuracy. There are currently four thresholds, as shown below:

Quality threshold	Suggested level
Percentage of invasive cancer cases treated with breast conserving surgery referred for radiotherapy	85% or more
Percentage of cases prescribed or referred for SERM or aromatase inhibitor treatment for oestrogen positive tumours	85% or more
Percentage of cases undergoing axillary surgery for invasive cancer	90% or more
Percentage of in situ cases who underwent breast conserving surgery undergoing no axillary surgery	90% or more
* SERM = Selective Estrogen Receptor Modulator	

In 2007, a subcommittee of the Breast Cancer Audit Steering Committee identified two further key issues, namely, referral for radiotherapy after mastectomy for 'high-risk' breast cancer and referral for chemotherapy for 'moderate and high-risk' breast cancer. These have been endorsed by radiotherapy experts and the Medical Oncology Group of Australia. The subcommittee is currently working to determine whether quality thresholds for these key issues can be established.

Before beginning a process to assess surgeons' standards of care, it was necessary to review the completeness and validity of the audit data. This work was able to proceed with funding provided by Breast Cancer Network Australia. On the whole, completeness of the required data items was very high; however, surgeons with more than 5% of data missing from one or more fields were contacted with the request that they provide this information or rectify anomalous data. The results of this work will inform further progress through the standards assessment process.

Towards the end of 2006 a survey was circulated to surgeons regarding aspects of multidisciplinary care and use of breast care nurses. Both issues had been identified as important aspects of quality management by the steering committee. The response rate to this survey was phenomenal, reaching 93% before the cut-off date. This information will be summarised for reporting purposes.

The NBCA continues to undertake research based on data submitted by breast surgeons with the aim of improving understanding of patterns of care. A number of manuscripts have been prepared and submitted to peer-reviewed journals. In addition, a public health report will be produced following a collaborative approach by audit personnel and Professor David Roder from the National Breast Cancer Centre.

The audit is in a strong position at the present time with stable funding provided from the National Breast Cancer Foundation and administered through the National Breast Cancer Centre. This arrangement was initiated in 2006 and is expected to continue until 2009.





NET-S horizon scanning project

NET-S

New and Emerging Techniques — Surgical

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

The identification of new and emerging medical technologies continues to play a significant role in health technology assessment. Established in 1999, the New and Emerging Techniques – Surgical (NET-S) project aims to identify and assess advances in surgery and medical devices that are likely to significantly impact on the Australian and New Zealand health systems in the near future. NET-S is currently contracted by the Department of Health and Ageing and is a collaborator of the Australia and New Zealand Horizon Scanning Network (ANZHSN), along with Adelaide Health Technology Assessment (AHTA) from the University of Adelaide.

The assessments of these emerging procedures and medical technologies are presented in the form of prioritising summaries and horizon scanning reports. Prioritising summaries are concise documents that provide the reader with the background and basis of the procedure or medical device as well as evidence on its safety and efficacy. Meanwhile, horizon scanning reports are more detailed assessments that discuss the potential of the procedure or technology utilising the best available evidence and are typically reserved for procedures or technologies that are deemed high impact with a considerable evidence base. Both prioritising summaries and horizon scanning reports are available on the NET-S website and the ANZHSN website. In addition, prioritising summaries are uploaded to the EuroScan website (<http://www.euroscan.bham.ac.uk/index.htm>) as a means of sharing information with other horizon scanning agencies worldwide. The ANZHSN is one of the most active contributors to this effort, and NET-S continues to play a significant part in this initiative.

The NET-S project continues to evolve and strives to provide timely and valuable assessments on emerging surgical procedures and technologies.

NET-S on the web

Prioritising summaries and horizon scanning reports are available for download on the NET-S website (<http://www.surgeons.org/asernip-s/nets.htm>) and the ANZHSN website (<http://www.horizonsscanning.gov.au>). Please do not hesitate to contact us if you wish to nominate a potential procedure for assessment or provide comments on completed summaries or reports.

The following is a list of prioritising summaries prepared in 2007:

- Biodegradable stents for coronary artery disease
- Bronchial thermoplasty (Alair® bronchial thermoplasty system) for asthma
- Excimer laser assisted nonocclusive anastomosis for intracranial bypass surgery
- Pillcam ESO capsule endoscopy
- Postoperative hernia prophylaxis in open bariatric surgery
- Intrabronchial valve for chronic obstructive pulmonary disease
- Intraoperative ultrasonography for breast cancer surgery
- Laparoscopic sleeve gastrectomy
- Low-frequency ultrasound debridement for chronic leg ulcers
- Ovarian cryopreservation and transplantation for fertility preservation
- Percutaneous aortic valve replacement (Cribier-Edwards Aortic Percutaneous Heart Valve)
- Percutaneous radiofrequency ablation for osteoid osteoma
- Perioperative epirubicin, cisplatin and 5-fluorouracil chemotherapy for resectable gastric cancer
- Photoselective vaporisation for benign prostate hyperplasia
- Polyflex® oesophageal stent for patients with oesophageal stenoses, fistulas and leakages
- Radiofrequency assisted liver resection
- Sentinel lymph node mapping for colorectal cancer
- Supplemental perioperative oxygen to reduce surgical wound infection
- SprayGel™ adhesion barrier system
- Totally endoscopic coronary artery bypass surgery
- Vacuum-assisted closure for enterocutaneous fistulas
- Versajet™ hydrosurgery system for wound debridement.

There are 5 new horizon scanning reports available:

- Autologous bone marrow transplantation for myocardial infarction
- Proton beam therapy for the treatment of neoplasms involving (or adjacent to) cranial structures
- Proton beam therapy for the treatment of uveal melanoma
- Genetic screening for familial hypercholesterolaemia
- Intraoperative ultrasonography for breast conserving surgery.

Project activities

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



Consumer information

ASERNIP-S continues to inform patients and surgeons worldwide of the latest in evidence-based research on new surgeries. Plain English summaries of our reports are available on the consumer information and publications pages of our website (<http://www.surgeons.org/asernip-s.htm>). The summaries can be used in consulting rooms when patients and doctors discuss the advantages and risks of a new surgical treatment. Some summaries are targeted at busy surgeons and healthcare workers who may not have time to read the full systematic review.

This year we produced consumer information on scalpel safety in the operative setting; transfer to the operating room of skills gained through surgical simulation training; and natural orifice transluminal endoscopic surgery (NOTES)[™] for intra-abdominal surgery. Articles advising of these publications appeared in the newsletters of the Royal Australasian College of Surgeons and HealthInsite. We sent copies of our consumer summaries to specialty surgical societies, and healthcare and consumer groups.

A vast amount of medical information is available to consumers on the internet, of variable quality. The ASERNIP-S consumer summaries are prepared in collaboration with Fellows of the College and consumer representatives, and have the accreditation of both HealthInsite and HONcode. To further improve the summaries, we sought feedback through a web-based survey of readers. In 2007 the number of consumers visiting the consumer information page on our website increased by more than a quarter, with many more accessing the information through direct links.

At ASERNIP-S we work closely with two consumer representatives, Jane Doyle, professional communicator, and Margaret Charlton, from the Health Consumers Alliance of South Australia and member of the Consumers' Health Forum. As members of our Advisory Committee, Jane and Margaret are invited to provide comments at any stage of the review process, and we thank them for their invaluable help in the preparation of our consumer information. Globally, we are working with Health Technology Assessment International (HTAi) on the effective involvement of patients and the public in medical research. This group is compiling an international consumer glossary of medical terms, using the in-house glossaries of ASERNIP-S and others as a starting point.

For more information please visit the consumer information page of our website at <http://www.surgeons.org/asernip-s/consumer.htm> or contact us at asernipsconsumer@surgeons.org.

Promotional activities

Peer-reviewed publications 2007

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

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

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

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

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

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

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

Hutton J, Trueman P, Henshall C. Coverage with evidence development: an examination of conceptual and policy issues. *International Journal of Technology Assessment in Health Care* 2007; 23(4): 425-435. Maddern G participant in workshop.

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

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

Other publications 2007

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Endoscopic treatments for gastroesophageal reflux disease. *Surgical News*, Vol.8 No 3, April 2007

New Surgery, Centralisation, Safe Surgery – What next from ASERNIP-S. *Surgical News*, Vol 8 No 4 May 2007

Robotic surgery: will it be evidence-based or just 'toys for boys'. *Surgical News*, Vol 8 No 4, May 2007

Radiofrequency ablation for the treatment of liver tumours. *Surgical News*, Vol 8 No 5, June 2007

ASERNIP-S Update. *Surgical News*, Vol 8 No 8, September 2007

Surgery in the abdominal cavity through natural openings. *Surgical News*, Vol 8 No 8, September 2007

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

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

Surgical simulation training: skills transfer to the clinical setting. *Surgical News*, Vol. 8 No10, November-December 2007

Radio 2007

Seamless surgery. *Science Show on ABC Radio National* 1 December 2007. Maddern G interviewed.

2007 Presentations

Maddern G. *How to assess new surgical technologies in the 21st century*. Sims Travelling Fellowship, South Africa, January 2007

Maddern G. *Surgical audits*. Sims Travelling Fellowship, South Africa, January 2007

Boulton M. *Pilot audit of peripheral stenting procedures*. Vascular Interventions 2007, Newcastle, February 2007

Anderson J, Fitridge R, Boulton M, Barnes M, Maddern G. *A predictive model for endovascular aneurysm repair*. Annual Scientific Congress of the Royal Australasian College of Surgeons, Christchurch, New Zealand, May 2007

Maddern G. *Evaluation of medical devices*. Australian Society of Gynaecologic Oncologists Annual Scientific Meeting, Glenelg, South Australia, May 2007

Maddern G. *Evaluation of surgical interventions*. ASERNIP-S and how this works. Surgical Research Society Annual Scientific Meeting, Christchurch, New Zealand May 2007

Babidge W, Cameron AL, Watt A, Norderhaug I, Blamey S, Facey K, Gaucher M, Hailey D, Maddern G. *Rapid health technology assessments compared with full systematic reviews*. 4th Annual HTAi meeting, Barcelona, Spain, June 2007

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Fitridge R, Boult M, Barnes M, Maddern G. *Mid term results of endovascular aneurysm repair based on ASERNIP-S audit*. Vascular 2007, Melbourne, August 2007

Maddern G. *What is the evidence for new surgical procedures?* American College of Surgeons Clinical Congress, New Orleans, USA, October 2007

Maddern G. *New surgical technologies in the 21st century*. American College of Surgeons Clinical Congress, New Orleans, USA, October 2007

Maddern G. *Health technology assessment challenges for new technology – panel discussion*. Medical Industry Association of Australia Annual Conference, Sydney, October 2007

Maddern G. (key note speaker) *New surgical technology - Star Trek or star struck?* Cabrini Research Day, Cabrini Institute, Melbourne, November 2007

Severin V, Buranyi-Trevarton D. *Research and Audit Activities, Support, Education and Networks*. Clinical Oncological Society of Australia, 34th Annual Scientific Meeting, Adelaide, November 2007

Ahern E. *How ASERNIP-S has made a difference to surgery in Australia*. New Health Technologies and Medical Devices Workshop, Consumers' Health Forum of Australia, Canberra, December 2007.

Externally-commissioned projects

ASERNIP-S has been commissioned to work on:

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



ASERNIP-S website

The ASERNIP-S website (<http://www.surgeons.org/asernip-s/>) has continued to provide site users with detailed information regarding our work. The website, which is accessible directly or via links from the College homepage, is regularly updated with systematic reviews, accelerated systematic reviews and consumer summaries produced by ASERNIP-S. The full text of these reports can be downloaded free of charge from the site. A comprehensive archive of previous work is also maintained.

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

In the past year the total number of visits to the ASERNIP-S website increased. Figures ranged from 1200 to over 2000 hits per month, up from the maximum of 1300 hits per month recorded in the previous year. Overall there was a 30% increase in the number of visits to the main page, with a similar increase in the number of consumers visiting the consumer information page and many more accessing the information through direct links.

ASERNIP-S remains a HealthInsite information partner site, with ASERNIP-S reports appearing as key search results when consumers utilise the HealthInsite search portal. The website also continues to comply with the HONcode standard for health trustworthy information, an accreditation that is prominently displayed on the homepage to inform users of the status of the site.



ASERNIP-S Advisory Committee 2007

The members of the ASERNIP-S Advisory Committee are:

Dr Andrew Sutherland	Chairman, and College President (from June 2007)
Dr Russell Stitz	Chairman, and College President (to May 2007)
Professor Bruce Barraclough	College Fellow (to November 2007)
Ms Margaret Charlton	Consumer Representative, Health Consumers Alliance
Ms Jane Doyle	Consumer Representative
Professor Kingsley Faulkner	College Fellow
A/Professor Sally Green	Director, Australasian Cochrane Centre (to November 2007)
Dr Denise O'Connor	Australasian Cochrane Centre (from Nov 2007)
Dr David Hailey	Health Technology Assessment Expert
Dr David Hillis	College Chief Executive Officer
Mr Brian Johnston	Chief Executive, Australian Council on Healthcare Standards
Professor Brendon Kearney	MSAC Representative
Professor Guy Maddern	ASERNIP-S Surgical Director
Dr John Quinn	College Executive Director for Surgical Affairs (Australia)

In May 2007 Dr Russell Stitz resigned from the committee due to the completion of his term as College President. We thank him for his excellent contribution while Chairman of the committee. In November 2007 A/Professor Sally Green resigned from the committee, and has been replaced by Dr Denise O'Connor of the Australasian Cochrane Centre. In November Professor Bruce Barraclough also resigned from the committee. We thank them both for their outstanding work with ASERNIP-S.

Representation on external committees

ASERNIP-S staff were represented on the following committees:

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



Education and Training

Students

This year ASERNIP-S has supervised research proposal development for two students. Clara Tan, a fourth year medical student, worked with the audit staff of the National Breast Cancer Audit, examining data to assess the practice pattern in relation to the clinical guideline recommendations. Alexandra Waddell, a fourth year medical student, is working on the development of a research proposal for a systematic review examining the financial impact of centralisation for oesophagectomy in Australia. The purpose of this work is twofold: it will enable Ms Waddell to complete a compulsory component of her course, and provide ASERNIP-S with a preliminary protocol for a future systematic review. This work is due for completion in late 2007. In addition, Chloe Weir, a vacation scholarship student from the University of South Australia, completed a research project on how the public access and utilise health information.

Training opportunities for staff

Courses and conferences attended by staff members in 2007 included:

- Editing for science communicators, Australian Science Communicators, Biotext, Adelaide, March
- Annual Scientific Congress of the Royal Australasian College of Surgeons, Christchurch, New Zealand, May
- Australian Patient Safety Foundation workshop – Standards-Protocols-Algorithms: Human factors and work practice in health care, Adelaide, May
- Australasian Cochrane Centre workshop – Developing a protocol for a systematic review, Adelaide, May
- Australasian Cochrane Centre workshop – Introduction to analysis, Adelaide, June
- National Quality and Safety Indicators workshop, Canberra, June
- Health Technology Assessment International (HTAi) conference, Barcelona, Spain, July
- 15th Annual Meeting of the International Network of Agencies for Health Technology Assessment (INAHTA), Barcelona, Spain, July
- Australian Centre for Evidence Based Clinical Practice – Evidence-based clinical practice, Adelaide, July
- 5th Australasian Conference on Safety and Quality in Health Care, Brisbane, August
- Science on the radio, Australian Science Communicators, Soundbite Series, Adelaide, August
- Making sense of communication, Adelaide, September
- ISO 9001:2000 Quality Assurance Management Systems, WEA, Adelaide, November
- Dissemination for knowledge and change, Department of General Practice, Primary Health Care Research Evaluation & Development Program, Adelaide, November
- New Health Technologies and Medical Devices Workshop, Consumers' Health Forum, Canberra, December.

Personnel

During 2007 we welcomed new Research Officers Amelia Russin, Ben Hoggan, Cliona O'Donovan, Tim Lathlean, Vendra Severin, Caryn Perera, Deanne Leopardi and Karen Humphreys. The following staff left ASERNIP-S: Sarah Tyson, Amelia Russin, Cliona O'Donovan and Eliana Della Flora. Lana Sturm left to go overseas but continues to work on ASERNIP-S reviews. Chris Barber moved to take up another position in the Royal Australasian College of Surgeons.

In 2007 we benefited from the expertise of three consultants and a consultancy group.

- **Dr Ann Scott**

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

- **Dr Karen Facey**

Dr Karen Facey worked with ASERNIP-S as a consultant for 4 weeks in 2004 and provided advice virtually from her home in Scotland during 2006 and 2007, reviewing HTAs and horizon scanning reports. Karen is a Certified Statistician with a PhD related to interim analyses in clinical trials. She is an Honorary Member of the UK Faculty of Public Health and a Fellow of the Royal Society of Medicine. She is a visiting Research Fellow at the University of Glasgow and is an independent evidence-based health policy consultant with a wide variety of experience in industry, HTA Agency and government.

- **Ms Brita Pekarsky**

Brita Pekarsky is a Senior Research Fellow at the Centre for Regulation and Market Analysis at the University of South Australia. Brita is an experienced analyst of the Australian healthcare system. She was a member of the National Evaluation Team for the Coordinated Care Trials (1997 to 2000). In the last 10 years she has worked on more than 40 consultancies in the area of health care evaluation. Brita has been a member of the Economic Subcommittee of

the PBAC since May 1997. Since March 2006 Brita has worked as a senior consultant for ASERNIP-S on projects for the Medical Services Advisory Commission, primarily in relation to economic evaluation.

- **CHERE**

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

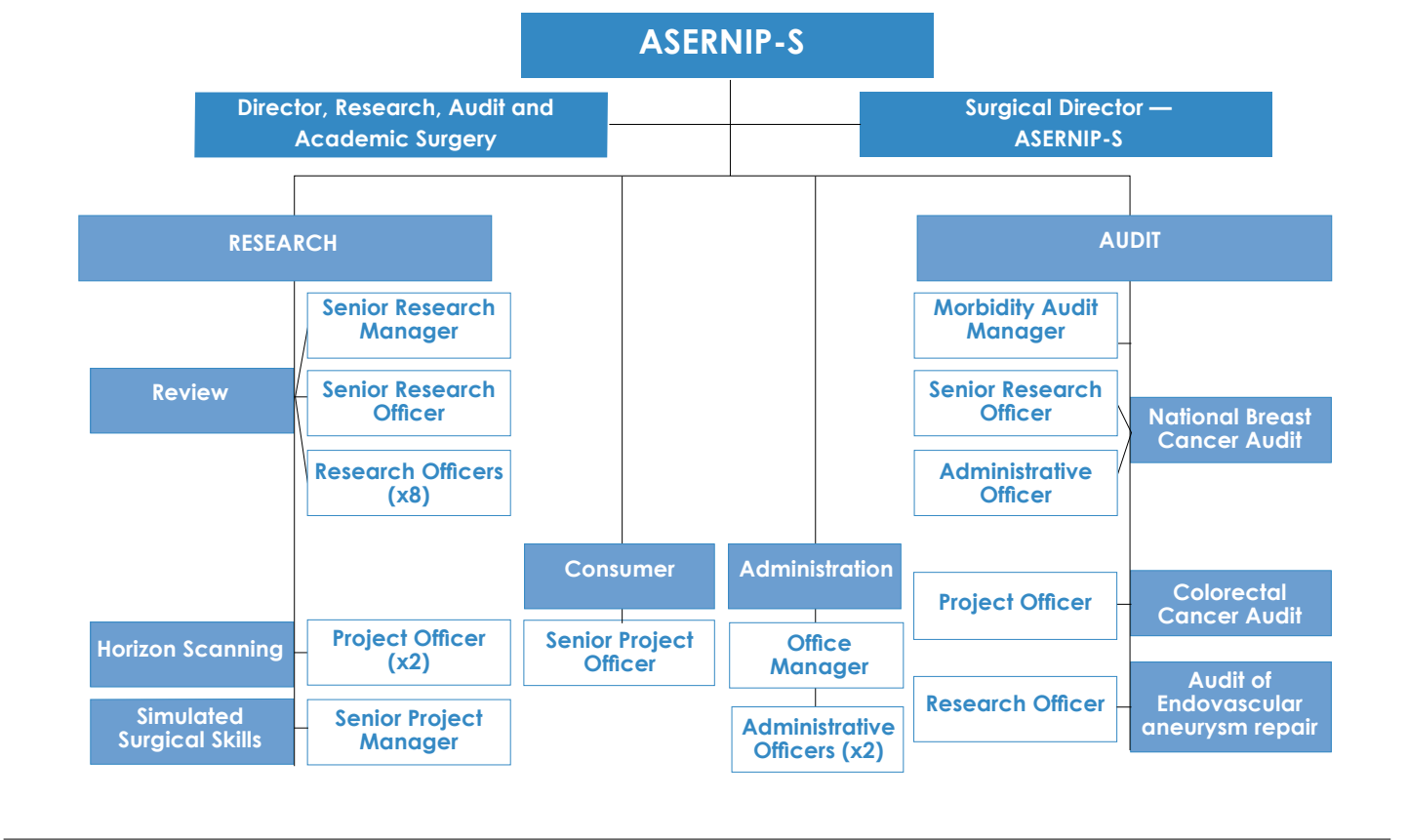


A magnifying glass with a black handle and frame is positioned over a white, textured surgical drape. The background is a solid teal color. The magnifying glass is angled, with the lens pointing towards the top left. The drape has a fine, woven texture. The overall image has a clinical and professional feel.

Staff profiles

- Professor Guy Maddern
- Dr Wendy Babidge
- Dr Alun Cameron
- Dr Prema Thavaneswaran
- Eleanor Ahern
- Christine Barber
- Maggi Boulton
- Deborah Clapp
- Eliana Della Flora
- Dr Michael Duffield
- Jane Franklin
- Ben Hoggan
- Karen Humphreys
- Louise Kennedy
- Tim Lathlean
- Irving Lee
- Deanne Leopardi
- Nicholas Marlow
- Claire Marsh
- Cliona O'Donovan
- Caryn Perera
- Amelia Russin
- Vendra Severin
- Lana Sturm
- Belinda Tarca
- Sarah Tyson
- Dr Jim Wang
- Amber Watt
- Luis Zamora

Research, Audit and Academic Surgery Division – Royal Australasian College of Surgeons
ASERNIP-S organisational chart, December 2007



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



Director, Research, Audit and Academic Surgery Division, Royal Australasian College of Surgeons
Dr Wendy Babidge
Dr Wendy Babidge became a Director of the Royal Australasian College of Surgeons (the College) in June 2005 and is responsible for the Division of Research, Audit and Academic Surgery. This Division currently supports 47 staff members, working in the areas of ASERNIP-S, Audits and Scholarships. As well as directing the ASERNIP-S program, Wendy oversees the College morbidity and mortality audits, the provision of scholarships for surgical research and the fundraising activities associated with this. Another major focus of the Division is to establish a secure web-based system at the College for the purpose of training. Wendy has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business.



ASERNIP-S Senior Research Manager

Dr Alun Cameron

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

ASERNIP-S Senior Research Officer

Dr Prema Thavaneswaran

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

ASERNIP-S Senior Project Officer - Consumer

Eleanor Ahern

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

ASERNIP-S Research Officer

Christine Barber

Chris Barber joined ASERNIP-S in August 2005 to conduct systematic reviews. She previously worked as a researcher at the Institute of Medical and Veterinary Science investigating the relationship between the intervertebral disc and the vertebral body in osteoporosis of the human lumbar spine. She has a Bachelor of Science degree majoring in molecular biology and genetics from Flinders University and a Bachelor of Health Sciences, Honours in Pathology from the University of Adelaide, focusing on the assessment of osteoporosis and bone quality in the human lumbar spine. Chris left ASERNIP-S in 2007 to take up another position in the Royal Australasian College of Surgeons.

ASERNIP-S Morbidity Audit Manager

Maggi Boulton

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

ASERNIP-S Administrative Officer

Deborah Clapp

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



ASERNIP-S Research Officer

[Eliana Della Flora](#)

Eliana joined ASERNIP-S in November 2006 to conduct systematic reviews. She has a Bachelor of Medical and Pharmaceutical Biotechnology Degree with Honours from the University of South Australia. Her Honours project was conducted at the Hanson Institute, where she investigated the role of a novel gene in angiogenesis and apoptosis. Eliana left ASERNIP-S in December 2007 to travel overseas.

ASERNIP-S Research Officer

[Dr Michael Duffield](#)

Dr Michael Duffield joined ASERNIP-S in September 2003 to conduct systematic reviews. He has a Bachelor of Science degree, with Honours, from the University of Adelaide, and has completed his PhD, which involved a molecular biological and electrophysiological investigation of ion channel gating. In 2005 Michael commenced studies in medicine at Flinders University, but he still works at ASERNIP-S on a part-time basis.

ASERNIP-S Administrative Officer

[Jane Franklin](#)

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

ASERNIP-S Research Officer

[Ben Hoggan](#)

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

ASERNIP-S Research Officer

[Karen Humphreys](#)

Karen Humphreys joined ASERNIP-S in November 2007 to conduct systematic reviews. She has a Bachelor of Medical Science degree, Nutrition and Dietetics degree, and recently completed Honours in Nutrition and Dietetics. She has commenced a PhD in the Rehabilitation and Aging Studies Unit of Flinders University, investigating the nature of weight loss post proximal femoral fracture and the effectiveness of nutrition therapy for preventing weight loss and poor functional outcomes in the population.

ASERNIP-S Administrative Officer

[Louise Kennedy](#)

Louise Kennedy joined ASERNIP-S in December 2002. She has a Certificate III in Business (Office Administration) and has studied several Information Technology subjects. Louise previously worked in clerical positions for the Commonwealth Public Service. At ASERNIP-S, Louise provides assistance to the administrative officers and audit projects.



ASERNIP-S Research Officer

Tim Lathlean

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

ASERNIP-S Project Officer – Horizon Reporting

Irving Lee

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

ASERNIP-S Research Officer

Deanne Leopardi

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

ASERNIP-S Research Officer

Nicholas Marlow

Nicholas Marlow joined ASERNIP-S in November 2005. Nicholas holds a Bachelor of Arts majoring in Anthropology and Japanese, an Honours degree in Anthropology and a Graduate Diploma in Public Health, all from the University of Adelaide. At ASERNIP-S, Nicholas conducts systematic reviews. He has also provided design assistance for internal and external presentations.

ASERNIP-S Research Officer

Claire Marsh

Claire Marsh joined ASERNIP-S in August 2005. She has a Bachelor of Health Sciences Honours degree from the University of Adelaide, and majored in public health and psychology throughout her undergraduate course. Her Honours thesis focused on health behaviours and attitudes around self-administered cancer screening techniques. At ASERNIP-S Claire has been involved with the National Breast Cancer Audit and is now dividing her time between this project and the Audit for Endovascular Aneurysm Repair.

ASERNIP-S Research Officer

Cliona O'Donovan

Cliona O'Donovan joined ASERNIP-S in April 2007 from a background in clinical trials, where she focused on data management of multinational trial data. She has an honours degree in Pharmacology and Biochemistry and is currently studying for a Masters in Epidemiology. At ASERNIP-S Cliona was involved in the National Breast Cancer Audit. Cliona left ASERNIP-S in October 2007 to live overseas.



ASERNIP-S Research Officer

Caryn Perera

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

ASERNIP-S Research Officer

Amelia Russin

Amelia Russin joined ASERNIP-S in January 2007. She holds a Bachelor of Arts with a major in Psychology, a Bachelor of Law and a Bachelor of Health Science with Honours, all from the University of Adelaide. Her thesis explored the South Korean therapeutic cloning fraud and the media representations of stakeholders involved in the fraud, as presented in stakeholder talk and text. At ASERNIP-S Amelia was employed as a Research Officer. Amelia left ASERNIP-S in 2007 to take up further study.

ASERNIP-S Project Officer – Bi-National Colorectal Cancer Audit

Vendra Severin

Vendra Severin joined ASERNIP-S in July 2007 as the Bi-National Colorectal Cancer Audit Project Officer. She has worked extensively in a diverse range of registry and audit environments, specialising in cancer data, specifically colorectal and urological. She is currently undertaking post-graduate studies in Health Management, Flinders University South Australia and she is a representative for the recently established Research and Audit Group, established as part of the Clinical Research Professionals Group affiliated with COSA.

ASERNIP-S Research Officer

Lana Sturm

Lana joined ASERNIP-S in May 2006. She has a Bachelor of Applied Science (Env Hlth) and a Bachelor of Science (Hons) from Flinders University. She has a Grad Dip Comms (PR) from Uni SA. Lana has spent the last five years working as an Environmental Health Officer in local government. At ASERNIP-S she conducts systematic literature reviews. Lana left ASERNIP-S in 2007 to live in Canada; however, she continues to work for ASERNIP-S on a casual basis.

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

Belinda Tarca

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

ASERNIP-S Senior Research Officer

Sarah Tyson

Sarah Tyson joined ASERNIP-S as a researcher in November 2002 after operating the RACS Breast Audit as a separate project since March 1998. She has a science degree from the University of Adelaide majoring in Clinical and Experimental Pharmacology and Toxicology, and Biochemistry. Prior to her appointment Sarah was engaged in several other complex projects in the health and disability sectors. Sarah left ASERNIP-S in 2007 to take up another position.



ASERNIP-S Research Officer

Dr Jim Wang

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

ASERNIP-S Research Officer

Amber Watt

Amber Watt joined ASERNIP-S in August 2005. She holds a Bachelor of Medical Science from Flinders University, with majors in Physiology and Neuroscience, and is currently undertaking studies in Public Health at The University of Adelaide. At ASERNIP-S, Amber conducts systematic literature reviews and undertakes a variety of other project work.

ASERNIP-S Project Officer – Horizon Reporting

Luis Zamora

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



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 prior to 2007



Appendix A

Hierarchy of evidence

Designation of levels of evidence¹

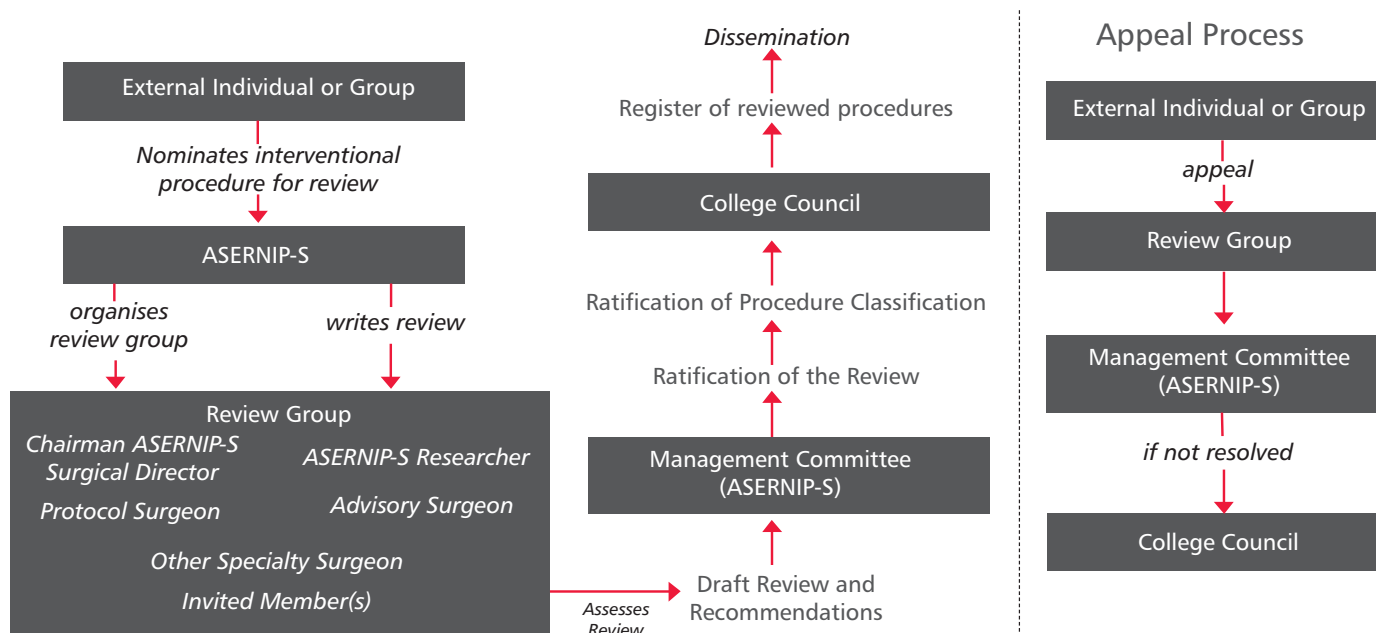
Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation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

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

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

Appendix B

ASERNIP-S review process



Appendix C

ASERNIP-S classification system

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

Evidence rating

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

Good

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

Average

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

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

Poor

Most of the evidence is from case series, or studies of the above designs with significant flaws or a high risk of bias. A poor rating may also be given if there is insufficient evidence.

Safety

At least as safe compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is at least as safe as the comparator.

Safety cannot be determined

This grading is given if the evidence is insufficient to determine the safety of the new intervention.

Less safe compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as safe as the comparator.

Efficacy

At least as efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is at least as efficacious as the comparator.

Efficacy cannot be determined

This grading is given if the evidence is insufficient to determine the efficacy of the new intervention.

Less efficacious compared to comparator* procedure(s)

This grading is based on the systematic review showing that the new intervention is not as efficacious as the comparator.

Recommendations regarding the need for further research

In order to strengthen the evidence base regarding the procedure it may be recommended that either:

- an audit be undertaken, or
- a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The Royal Australasian College of Surgeons recognises that it may not always be possible to undertake a controlled clinical trial. Under such circumstances, it is recommended that, at the very least, data be contributed to an audit for further assessment, in collaboration with ASERNIP-S, until such time as a controlled clinical trial is undertaken.

**A comparator may be the current "gold standard" procedure, an alternative procedure, a non-surgical procedure or no treatment (natural history).*

Appendix D

Reports and Publications prior to 2007

1998

Maddern G. Surgery and evidence-based medicine. A new Australian registry promises to strengthen the push towards evidence-based surgery. *Medical Journal of Australia* 1998; 169: 348–349

1999

ASERNIP-S Report No. 1
Minimally Invasive Parathyroidectomy, June 1999

ASERNIP-S Report No. 2
Lung Volume Reduction Surgery, June 1999

ASERNIP-S Report No. 3
Laparoscopic Live Donor Nephrectomy, June 1999

ASERNIP-S Report No. 4
Ultrasound-Assisted Lipoplasty, October 1999

Introducing ASERNIP-S: The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (1999). Keeping You Informed (*New Zealand Health Technology Assessment newsletter*) December 1999; Issue No. 5

2000

ASERNIP-S Report No. 5
Percutaneous Endoscopic Laser Disectomy: Update & re-appraisal, February 2000

ASERNIP-S Report No. 6
Arthroscopic Subacromial Decompression using the Holmium: YAG Laser: Update & re-appraisal, February 2000

ASERNIP-S Report No. 7
Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction, February 2000

ASERNIP-S Report No. 8
Laparoscopic-Assisted Resection of Colorectal Malignancies, February 2000

ASERNIP-S Report No. 15
Laparoscopic Live-donor Nephrectomy: Update & re-appraisal, May 2000

ASERNIP-S Report No. 18
Lung Volume Reduction Surgery: Update & re-appraisal, May 2000

ASERNIP-S Report No. 9
Laparoscopic Adjustable Gastric Banding in the Treatment of Obesity, June 2000

ASERNIP-S Report No. 17
Ultrasound-Assisted Lipoplasty: Update & re-appraisal, July 2000

ASERNIP-S Report No. 10
Off-Pump Coronary Artery Bypass Surgery with the Aid of Octopus Tissue Stabilisers, November 2000

ASERNIP-S Report No. 16
Minimally Invasive Techniques for Relief of Bladder Outflow Obstruction: Update & re-appraisal, November 2000

Babidge WJ, Maddern GJ. Evidence-based surgery at ASERNIP-S. Can this improve quality in surgical practice? *Journal of Quality in Clinical Practice* 2000; 20(4):164–166

Boult M, Fraser R, Jones N, Osti O, Liddell J, Dohrmann P, Donnelly P, Maddern G. Percutaneous endoscopic laser disectomy: a systematic review. *Australian and New Zealand Journal of Surgery* 2000; 70(7): 475–479

EU Hernia Trialists Collaboration. Mesh compared with non-mesh methods of open groin hernia repair — systematic review of randomised controlled trials. *British Journal of Surgery* 2000; 87: 854–859

EU Hernia Trialists Collaboration. Laparoscopic compared with open methods of groin hernia repair — systematic review of randomised controlled trials. *British Journal of Surgery* 2000; 87: 860–867

Maddern GJ. Evidence-based surgical research – consumers to benefit. The Australian Health Consumer. *The Consumers' Health Forum of Australia newsletter* Summer 2000; (1): 12–13

Maddern GJ. This is ASERNIP-S. International Network of Agencies for Health Technology Assessment (INAHTA) *Newsletter* 2000; VIII(1): 3

Maddern GJ, Babidge WJ. Improving quality in surgery. The Australian Health Consumer. *The Consumers' Health Forum of Australia newsletter* Spring 2000; (3): 9–10

Merlin T, Scott D, Rao M, Wall D, Francis D, Bridgewater F, Maddern G. The safety and efficacy of laparoscopic live-donor nephrectomy: a systematic review. *Transplantation* 2000; 70(12): 1659–1666

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