

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 &/or efficacy of a procedure then recommendations will be given suggesting the most appropriate method for doing this.

EVIDENCE RATING

- ◇ Poor
- ◇ Average
- ◇ Good

This gives an idea of the strength, quality, precision and magnitude (where appropriate) of the evidence-base.

SAFETY

- ◇ Safe compared to comparator* procedure(s)
- ◇ Safety cannot be determined
- ◇ Unsafe compared to comparator* procedure(s)

EFFICACY

- ◇ Efficacious compared to comparator* procedure(s)
- ◇ Efficacy cannot be determined
- ◇ Not efficacious compared to comparator* procedure(s)

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

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, is 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.

July 2001

Audit for the endoluminal repair of abdominal aortic aneurysms

An Australian audit of the endoluminal repair of abdominal aortic aneurysms is being conducted by ASERNIP-S on behalf of the Medical Services Advisory Committee (MSAC) of the Commonwealth Department of Health and Aged Care. Vascular surgeons from around Australia registered patients who received the endoluminal graft between 1 November 1999 and 16 May 2001. Follow-up data for these patients is submitted annually for a period of up to 5 years.

Reportage on the audit takes place at 6-month intervals to MSAC. A copy of the report is also made available on the ASERNIP-S web site. Surgeons are notified at yearly intervals of their results as well as the national aggregate.



Further Information

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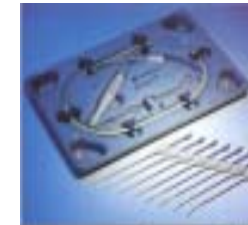
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ASERNIP / S



**Australian Safety
and Efficacy
Register of New
Interventional
Procedures -
Surgical**



Introduction

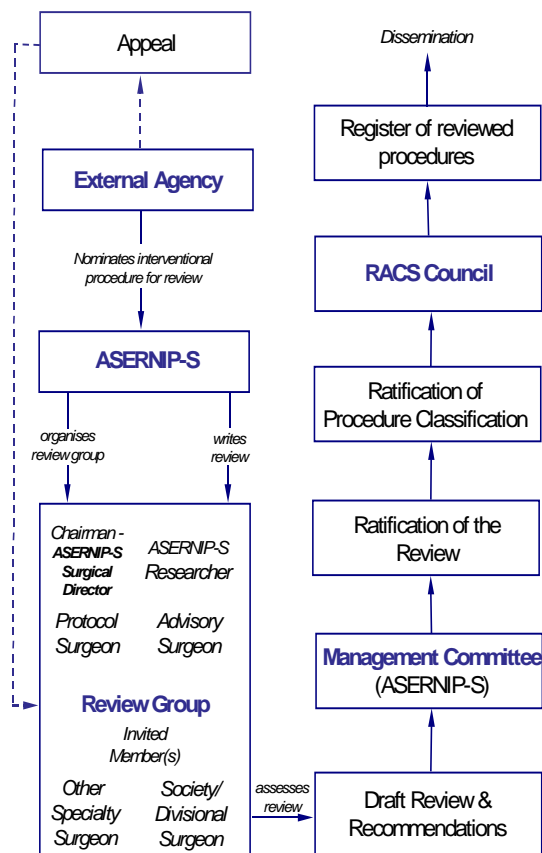
The increasing rate of introduction of new surgical technologies and techniques has highlighted the need for initial clinical assessment and validation. The Royal Australasian College of Surgeons (RACS) established ASERNIP-S, The Australian Safety and Efficacy Register of New Interventional Procedures - Surgical, in January 1998.

Professor Guy Maddern is the Surgical Director of ASERNIP-S. A Management Committee comprising several College Fellows and representatives from the Consumers' Health Forum, the National Centre for Classification in Health, the Australasian Cochrane Centre, the Australian Council on Healthcare Standards and the Medical Services Advisory Committee (MSAC) oversees the operation of ASERNIP-S.

The ASERNIP-S process

The flow chart illustrates the process adopted by ASERNIP-S to assess new surgical procedures. The process commences with nomination of procedures from a variety of sources including the Divisions and Sections of RACS, specialist societies, Consumers' Health Forum, Consumer Complaints Commission, medical indemnity organisations, and any other individuals or organisations. The ASERNIP-S Management Committee endorses the procedures for review and when time becomes available procedure assessment commences. A protocol of the systematic review, with recommendations and a safety and efficacy classification, are submitted to the ASERNIP-S Management Committee for ratification. The review documentation is presented to the Council of RACS for endorsement and becomes part of a register of reviewed procedures before being disseminated.

ASERNIP-S Process



The procedures are initially assessed by a systematic literature review and, where appropriate, followed by the collection of available data from surgeons currently performing the procedure within Australia. ASERNIP-S is at present collecting data on Laparoscopic Live Donor Nephrectomy and Minimally Invasive Parathyroidectomy.

Composition of Review Groups

Each Review Group consists of the members as outlined below. In addition, other people deemed suitable for inclusion in the Review Group may be invited to become a member.

ASERNIP-S Surgical Director

The chairperson of the Review Group.

Protocol Surgeon

Assists the ASERNIP-S Researcher to draft the protocol of the systematic review.

ASERNIP-S Researcher

Prepares the protocol and writes the systematic review. Relevant outcomes and other data are extracted from the articles and tabulated. The systematic review is a synthesis of this information.

Advisory Surgeon

Is available to assist the ASERNIP-S Researcher in preparing the systematic review (when necessary).

Surgeon(s) Nominated by a Society or Division/Section of the College

A representative of the relevant specialty.

Surgeon from Another Specialty

A surgeon from another specialty.

Each member of the group receives a copy of the systematic review and critiques the document according to their particular expertise. The Review Group meets and discusses any concerns, reaches a consensus on the classification concerning the safety and efficacy of the procedure and produces clinical and research recommendations.