



ROYAL AUSTRALASIAN COLLEGE OF SURGEONS / ASERNIP-S

General Guidelines for Assessing, Approving & Introducing New Surgical Procedures into a Hospital or Health Service

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1. INTRODUCTION

1.1 Purpose

The purpose of this document is to provide general guidance to hospitals and health services on the assessment of new surgical procedures and the factors that should be considered prior to their introduction. In this document, a new surgical procedure will be defined as one that has not previously been used in that particular hospital or health service, and represents a significant departure from previous practice.

The use of formal processes for the introduction of new surgical procedures into hospitals or health services has the potential to improve the provision of healthcare, while protecting the interests of patients, clinicians and the organisation. In Australia, processes for the introduction of new surgical procedures into hospitals or health services have now been established at the state level. For example, in New South Wales the Department of Health has developed a model policy for the safe introduction of new interventional procedures into an Area Health Service or health facility.¹

1.2 Trade-offs

Often the decision regarding whether to introduce a new surgical technique is a balance between the desire to advance knowledge and increase experience, and the potential risks of new procedures. Even if new procedures have been thoroughly evaluated elsewhere, they may not have been assessed under particular local conditions. Any decision should also include an assessment of whether the new procedure is intended to replace or complement an older procedure, and the perceived advantages of the new versus the old procedure.

In addition, the introduction of a new procedure has an opportunity cost – it will consume resources that would have been used elsewhere. A judgement needs to be made about the benefits of the new procedure and the diversion of resources away from existing services.



2. ASSESSMENT

2.1 Prior evaluation

It is important to establish the safety and effectiveness of the new procedure. Many techniques new to Australia and New Zealand would have been evaluated or implemented elsewhere in the world first. Issues that should be considered include:

- *Has the technique been evaluated before?*

Hospitals/health services should establish whether an assessment has already been done through international or national systematic review (e.g. Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S)) or health technology assessment (see Appendix 1 for a list of relevant resources and their websites). If no systematic reviews or health technology assessments on the new procedure are available, then it may be useful to examine randomised controlled trials of the procedure. These could be identified using bibliographic databases such as PubMed (www.ncbi.nlm.nih.gov/pubmed/). However, for both logistical and ethical reasons there may be very few or no published randomised controlled trials on the procedure. Therefore, it may be necessary to assess the procedure based on available case series or case reports, as well as industry reports, laboratory studies, or reports of experiences of the technique in Australian and New Zealand facilities.

- *How reliable is the evaluation?*

Interpretation of assessments should take into consideration the likely robustness of the evidence, as indicated by the type of study design; whether studies were large enough to show reliable results for morbidity and mortality; and any possible confounding factors, such as the age of patients.

- *How wide-ranging or complex is the procedure?*

A procedure with a wide application or one that is highly technological is likely to require more intensive consideration and evaluation e.g. laparoscopic techniques.



2.2 Training and experience

Training requirements need to take into consideration all medical, nursing, allied health and support staff who will be involved in the new procedure.

- Individual – Has the staff member had any training and experience in the procedure at another institution?
- Institution – What previous experience does the institution have in similar procedures?



3. APPROVAL

3.1 Clinical governance

Who should assess applications for a new surgical procedure and decide whether it should be introduced?

- Whilst the primary role of a credentials committee is the credentialing of individuals, the committee also has a role in the maintenance of surgical standards, specifically to consider applications and provide guidelines for the performance of surgical procedures that are new or as yet of unproven value.² Most hospitals and health services will regard this as a natural extension of the functions of their credentials committees, although increasingly, specific clinical governance committees may also be involved. For example, in Victoria the Department of Human Services has developed guidance for health services to establish local Technology/Clinical Practice Committees to oversee the introduction of new technology/clinical practice.³
- An external representative (who is not a hospital employee) from the Royal Australasian College of Surgeons should be available for advice to the decision-making committee.
- Clearance from the hospital/health service/regional ethics committee may be required.

3.2 Application forms

An application form can serve as a checklist for both applicants and assessors, e.g. it could include the steps taken to check whether and how the procedure has been evaluated, and evidence that the hospital/health service has suitable facilities for the procedure.

An example of an application form (modified from NSW Health¹) is given in Appendix 2.



3.3 Conflict of interest/perceptions of bias

Individuals should declare to the hospital/health service decision-making body any involvement in prior assessment of the procedure and any financial involvement that could result in a conflict of interest.

3.4 Cost considerations and resource utilisation

- The present and future costs of the new procedure should be estimated as accurately as possible. For example, the initial high costs of a procedure may reduce over time.
- The published literature should be searched for studies that report on the cost-effectiveness of the new procedure. How do the costs of the new procedure compare with those of existing procedures and what additional benefits in terms of patient health outcomes are generated by its use?
- Is the new procedure sufficiently supported in the hospital or health facility by adequate resources and facilities?

3.5 Ethical and social considerations

It is important to consider whether there are any significant ethical, social, political or legal issues surrounding the use of the new procedure and, if so, how such issues should be addressed.

3.6 Predicted throughput

Consider whether the hospital or health service will be able to do enough procedures per year to maintain necessary skill levels.



3.7 Informed consent and patient information

If the procedure is experimental then the application should include draft patient information and informed consent forms for treatment. With respect to informed consent and patient information the application should conform to the National Privacy Principles (Australia).⁴ These principles outline the rights of an individual about whom information is collected. Valid consent requires that the individual knows and understands how the information will be used or disclosed and their rights in accessing that information. The National Privacy Principles, the Privacy Act 1988 (Commonwealth) and the Privacy Amendment (Private Sector) Act 2000, explanatory notes and other information can be obtained from the Office of the Federal Privacy Commissioner (Australia), which is located on the internet at www.privacy.gov.au. In New Zealand this information is described in the Code of Health and Disability Services Consumers' Rights [NZ]. Legislation also requires that providers are open about the fact of information collection and also their reason for collecting information. In New Zealand this is described in the Health Information Privacy Code. It is important that information in the application pertaining to informed consent and patient information also meets the specific requirements of the relevant hospital/health service human research ethics committee.

3.8 Conditional approval

Consider whether conditional approval should be given. Some of the conditions for carrying out a new procedure could be that it is performed:

- only by surgeons with a specified level of experience and expertise
- only for certain indications
- only for certain patient categories within a certain indication
- only under certain experimental conditions e.g. in the context of a controlled clinical trial.



4. INTRODUCTION AND MONITORING

4.1 Learning curve

There should be a general principle of more experienced practitioners undertaking new techniques, and avoiding the use of practitioners in the early stages of their learning curve for the new technique or similar techniques. The typical asymptote (flattening of the learning curve) for the new procedure may be available from published studies or the experience of other centres. This information could be used to establish a threshold, so that a surgeon may need to carry out a certain number of similar procedures or easier cases before fully undertaking the new procedure.

4.2 Informed consent

- The patient (and family) needs to be advised that the technique is new and/or experimental.
- Potential risks of the new procedure, including any areas of uncertainty, should be outlined to patients as accurately as possible.
- Information should be provided about the criteria for selection of patients for the new procedure, as well as alternative treatments which are available.
- Patients should be able to access information about how many of these procedures have been performed at the hospital and by the surgeon who will perform the procedure.

4.3 Monitoring

New surgical procedures should be monitored after their introduction. An example of a progress report (modified from NSW Health¹) is given in Appendix 3. The approval process should decide the type of monitoring to be undertaken and data collection systems should be established prior to the introduction of the procedure.



- As a minimum, an audit of indications and outcomes should be done.
- Access should be provided to reliable surgical data (local and global), organised in such a way that performance comparisons can be made.
- It is highly desirable to coordinate and standardise any study designs, e.g. outcomes should be measured in the same way for case series and audits across hospital services or as done in previous studies.
- If an audit or controlled clinical study is being contemplated, consider whether this can be done as part of a multi-centre study.
- Develop/amend internal processes for the reporting of any adverse events from new procedures and consider external processes e.g. participate in multicentre audits or advise the Therapeutic Goods Authority or the New Zealand New Technology Committee of problems with devices.



5. ROLE OF RESEARCH, AUDIT AND ACADEMIC SURGERY DIVISION

- The Research, Audit and Academic Surgery (RAAS) Division of the Royal Australasian College of Surgeons provides a variety of services for the evaluation of new and emerging surgical procedures and technologies.
- As part of the Division, the ASERNIP-S program uses a range of methodologies to assess the safety and effectiveness of new and emerging surgical procedures, including full and rapid systematic reviews, technology overviews, and horizon scanning summaries and reports. These assessments make clinical recommendations regarding a new procedure where required, and are disseminated to Fellows and Trainees of the College, Credentialing Committees of all hospitals, practitioners, consumers, health care providers and government agencies.
- The Division also establishes and manages both clinical and research audits of surgical procedures.



6. REFERENCES AND BIBLIOGRAPHY

References

1. NSW Health, November 2003. *Model Policy for the Safe Introduction of New Interventional Procedures*. Available at:
www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_333.pdf
2. Royal Australasian College of Surgeons. *Credentials committees, Surgical Appointments and Complaints Procedures: a guide by the Royal Australasian College of Surgeons*. Melbourne 2000. Available at:
www.surgeons.org/Content/NavigationMenu/WhoWeAre/ReportsandPublications/Publications/Guidelinesandpositionpapers/Credentials_Committees.pdf
3. Department of Human Services, Victoria, 2006. *Guidance for Victorian public health services to establish Technology/Clinical Practice Committees*. Available at: www.health.vic.gov.au/newtech/comguide.htm
4. *National Privacy Principles*. Available at:
www.privacy.gov.au/publications/npps01.pdf

Bibliography

- *Code of health and disability services consumers' rights 1996*. Available at: www.hdc.org.nz
- Darzi A, Smith S, Taffinder N. Assessing operative skill. *BMJ* 1999; 318:887-888.
- *Guidelines on privacy in the private health sector* (December 2001). Available at: www.privacy.gov.au/publications/hg_01.pdf
- *Health Information Privacy Code 1994* (NZ). Available at: www.privacy.org.nz



- McNeil John. *Draft procedures for the assessment of new and innovative procedures*, November 2000. Alfred Hospital. Melbourne, Victoria.
- *Minimal access surgery: A report of the Australian Health Technology Advisory Committee*, December 1996. Canberra: NHMRC, 1997.
- *Privacy Act 1988 [Commonwealth] and Privacy Amendment (Private Sector) 2000 [Commonwealth]*. Available at: www.privacy.gov.au/act/index.html
- Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF, Russell IT. Statistical assessment of the learning curves of health technologies: a systematic review, April 2001. *Health Technol Assess* 2001; 5(12).
- Royal Australasian College of Surgeons. *The implications of new technology for surgical practice, quality assurance, accreditation and the delineation of responsibilities*, 1994. Melbourne.



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8. APPENDIX 1

Relevant resources and their websites

SYSTEMATIC REVIEWS

Australian and New Zealand resources

- *ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures – Surgical)*. Available at:
www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm

Selected international resources

- *Cochrane Collaboration*. Available at:
www.thecochranelibrary.org/
- *PubMed Clinical Queries*. Available at:
www.nlm.nih.gov/bsd/special_queries.html
- *TRIP*. Available at:
www.tripdatabase.com

HEALTH TECHNOLOGY ASSESSMENTS

Australian and New Zealand resources

- *MSAC (Medical Services Advisory Committee)*. Available at:
www.msac.gov.au/
- *Australia and New Zealand Horizon Scanning Network*. Available at:
www.horizonscanning.gov.au/
- *Centre for Clinical Effectiveness, Monash University*. Available at:
www.mihsr.monash.org/cce/



- *New Zealand Health Technology Assessment (NZHTA)*. Available at: <http://nzhta.chmeds.ac.nz>

Selected international resources

- *Agence d’Evaluation des Technologies et des Modes d’Intervention en Santé (AETMIS)*. Available at: www.aetmis.gouv.qc.ca/site/home.phtml
- *Canadian Agency for Drugs and Technologies in Health*. Available at: www.cadth.ca/index.php/en/home
- *INAHTA (The International Network of Agencies for Health Technology Assessment)*. Available at: www.inahta.org/
- *International Information Network on New and Changing Health Technologies (Euroscan)*. Available at: www.euroscan.bham.ac.uk/
- *National Horizon Scanning Centre (NHSC)*. Available at: www.pcpoh.bham.ac.uk/publichealth/horizon/
- *National Institute for Clinical Excellence (NICE)*. Available at: www.nice.org.uk
- *NHS Centre for Reviews and Dissemination University of York (NHS CRD)*. Available at: www.york.ac.uk/inst/crd/
- *NHS Quality Improvement Scotland (NHS QIS)*. Available at: www.nhshealthquality.org/nhsqis/CCC_FirstPage.jsp

OTHER RESOURCES

- *TGA (Therapeutic Goods Administration)*. Available at: www.tga.gov.au/
- *The Office of The Federal Privacy Commissioner (Australia)*. Available at: www.privacy.gov.au



9. APPENDIX 2

Application form/checklist for the introduction of a new interventional procedure

Date: / /

Name of procedure:

Name of individual or group making the application:

1. Has the procedure been used elsewhere?
 YES NO
If YES, please attach details.

2. Does this new procedure replace current procedures?
 YES NO

3. If YES, does this new procedure have advantages over current procedures?
 YES NO
If YES, please attach details.

4. Has this procedure been evaluated elsewhere?
 YES NO

for example: INHATA, Cochrane Collaboration, ASERNIP-S, Medical Services Advisory Committee, NICE, Professional College or Sections thereof, publications, clinical trials, information from internal and/or external peers.

If YES, please attach details.



5. If the procedure involves the use of a new medical device, has the device been approved for this purpose by the Therapeutic Goods Administration (Commonwealth Department of Health and Ageing)?
 YES NO

6. Are there discrete training requirements for the proposed procedure?
 YES NO

If YES, please attach details.

On a separate sheet please list:

- the name/s
- qualifications
- evidence of relevant training and courses attended

of those individuals who wish to be credentialed for this procedure.

7. Has the patient information sheet been developed?
 YES NO

If YES, please attach.

(the patient must indicate their understanding of the procedure by signing and dating the patient information sheet)

8. Have specific risks arising from the procedure been considered and will patients be explicitly informed about these?
 YES NO

9. Will outcomes be monitored by a database/register?
 YES NO

If YES, please attach details.

10. Will outcomes be reviewed regularly?
 YES NO

If YES, please attach details.



11. If the procedure carries with it a risk for adverse events are there criteria for reviewing outcomes before any further procedures are performed?
 YES NO

If YES, please attach details.

12. Have direct and indirect costs been considered?
 YES NO

If YES, please attach details.

13. Have staffing requirements been considered?
 YES NO

If YES, please attach details.

14. Has the impact on other departments been considered?
 YES NO

If YES, please attach details.

15. Have occupational Health & Safety requirements been addressed?
 YES NO

If YES, please attach details.

16. Please indicate the number of cases anticipated to be performed per year
_____ cases.

Please note that approval will only be granted when questions 7 – 15 are answered by ticking the YES box



10. APPENDIX 3

Progress report for a new interventional procedure

Name of procedure:

Reference number: _____

Date: _____

1. Has the procedure been introduced?

YES

NO

If yes, please give commencement date.....

If no, please give reasons:

2. Is it continuing?

YES

NO

3. How many procedures have been performed? _____

4. Have outcomes been measured?

YES

NO

Please list a summary of progress and key outcomes on a separate page.



5. Have there been any adverse outcomes or significant problems?

YES

NO

If yes, please list details on a separate page.

6. Is the procedure to continue to be employed?

YES

NO

This Progress Report was:

Completed by (*name*):

.....

Reviewed by (*name & date*):

.....

