IDEAL Evidence: an Australian perspective

Guy Maddern
RP Jepson Professor of Surgery
University of Adelaide
Surgical Director ASERNIP-S
Johnson & Johnson
DePuy ASR Hip Implant

The DePuy ASR hip implant, meant to last approximately 15 years, can fail within only a few years of surgery. Victims of faulty DePuy ASR hip implants experience excruciating pain, and often have to undergo complicated and expensive replacement surgery.
MitraClip® System
Ideal Collaboration
IDEAL Framework

Stage 1: Idea

Question
• Can the procedure or device achieve a specific physical or physiological goal?

Aim
• Proof of concept

Patient Base
• Single to few

Optimal Study Design(s)
• First-in-man study, structured case report

Cook JA et al. BMJ 2013; 346: f2820
Example of procedure at this stage

• Stem cell based tracheal transplant for tracheal stenosis
IDEAL Framework

Stage 2a: Development

Question
• What is the optimal technique or design, and for which patients does it work best?

Aim
• Safety, efficacy

Patient Base
• 10s

Optimal Study Design(s)
• Prospective development study

Cook JA et al. BMJ 2013; 346: f2820
Right Portal Vein Ligation Combined With In Situ Splitting Induces Rapid Left Lateral Liver Lobe Hypertrophy Enabling 2-Staged Extended Right Hepatic Resection in Small-for-Size Settings

Andreas A. Schnitzbauer, MD,* Sven A. Lang, MD,* Holger Goessmann, MD,† Silvio Nadalin, MD,§ Janine Baumgart, MD,|| Stefan A. Farkas, MD,* Stefan Fichtner-Feigl, MD,* Thomas Lorf, MD,¶ Armin Goralcyk, MD,¶ Rüdiger Hörbelt, MD,# Alexander Kroemer, MD,* Martin Loss, MD,* Petra Rümmele, MD,† Marcus N. Scherer, MD,* Winfried Padberg, MD,# Alfred Königsrainer, MD,§ Hauke Lang, MD,|| Aiman Obed, MD,¶ and Hans J. Schlitt, MD*
Stage 2b: Exploration

Question
• What are the outcomes of more widespread use? Can consensus equipoise be reached on a trial question?

Aim
• Efficacy

Patient Base
• 100s

Optimal Study Design(s)
• Prospective collaborative observational study (Phase IIS) or feasibility randomised controlled trial (or both)

Cook JA et al. BMJ 2013; 346: f2820
IDEAL Framework

Stage 3: Assessment

Question
• How well does this procedure work compared with current standards of care?

Aim
• Comparative effectiveness

Patient Base
• 100s+

Optimal Study Design(s)
• Randomised controlled trial

Cook JA et al. BMJ 2013; 346: f2820
Robotic Pancreatectomy
IDEAL Framework

Stage 4: Long term study

Question
• What are the long term effects and outcomes of the procedure?

Aim
• Quality assurance

Patient Base
• 100s+

Optimal Study Design(s)
• Observational study or randomised trial nested within a comprehensive disease based registry

Cook JA et al. BMJ 2013; 346: f2820
Intraluminal Aortic Grafts

Malignant Gastric Surgery
Australian Safety and Efficacy Register of New Interventional Procedures - Surgical
Laparoscopic Donor Nephrectomy
Impacts of Medical Technology in Australia

Productivity Commission Progress Report

This is a progress report prepared for further public consultation and input.

The Commission will finalise its report after these processes have taken place.
General Guidelines for Assessing, Approving & Introducing New Surgical Procedures into a Hospital or Health Service
ASERNIP-S Publications


ASERNIP-S Publications


ASERNIP-S Publications


ASERNIP-S Publications


2003
ASERNIP-S Report No. 32 - Transanal Endoscopic Microsurgery (MSAC), March 2003
ASERNIP-S Report No. 36 - Radiofrequency Ablation of Liver Tumours (MSAC), May 2003
ASERNIP-S Report No. 42 - Implantable Spinal Infusion Devices for Chronic Pain and Spasticity: Accelerated systematic review, May 2003
ASERNIP-S Report No. 29 - Surgical Simulation, December 2003
ASERNIP-S Report No. 39 - Post-vasectomy Testing to Confirm Sterility, December 2003

2004
ASERNIP-S Report No. 22 - Live-Donor Liver Transplantation – Adult Donor Outcomes, October 2004
ASERNIP-S Report No. 34 - Live-Donor Liver Transplantation – Adult Recipient Outcomes, October 2004
ASERNIP-S Report No. 33 - Comparison of lung volume reduction surgery with medical management of emphysema (CCOHTA), December 2004
ASERNIP-S Report No. 38 - Intraoperative Ablation for the Treatment of Atrial Fibrillation, July 2004

2005
ASERNIP-S Report No. 30 - Sentinel Lymph Node Biopsy in Breast Cancer – Diagnostic (MSAC), March 2005
ASERNIP-S Report No. 40 - Carotid Percutaneous Transluminal Angioplasty with Stenting (MSAC), March 2005
ASERNIP-S Report No. 44 - Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis, June 2005
ASERNIP-S Report No. 48 - Laparoscopic radical prostatectomy, June 2005
ASERNIP-S Report No. 50 - Sentinel Lymph Node Biopsy in Breast Cancer – Safety and efficacy (MSAC), March 2005
ASERNIP-S Report No. 51 - Lung volume reduction surgery for emphysema: systematic review of studies comparing different procedures (CCOHTA), August 2005
ASERNIP-S Reports

2006
ASERNIP-S Report No. 46 - Bioengineered skin substitutes for the management of burns, August 2006
ASERNIP-S Report No. 49 - Self-expanding metallic stents for relieving malignant colorectal obstruction, August 2006
ASERNIP-S Report No. 52 - Bioengineered skin substitutes for the management of wounds, August 2006
ASERNIP-S Report No. 53 - Surgical simulation (update), August 2006
ASERNIP-S Report No. 54 - Endoscopic treatments for gastro-oesophageal reflux disease: an accelerated systematic review, August 2006
ASERNIP-S Report No. 56 - Radiofrequency ablation for the treatment of liver tumours (update), August 2006

2007
ASERNIP-S Report no. 57 - Centralisation of selected surgical procedures: implications for Australia, July 2007
ASERNIP-S Report no. 58 - A review of policies and processes for the introduction of new interventional procedures, July 2007
ASERNIP-S Report no. 59 - Scalpel safety in the operative setting, July 2007
ASERNIP-S Report no. 60 - Rapid versus full systematic reviews: an inventory of current methods and practice in Health Technology Assessment, July 2007
ASERNIP-S Report no. 61 - Surgical simulation for training: skills transfer to the operating room, July 2007
ASERNIP-S Report no. 62 - Natural orifice translumenal endoscopic surgery (NOTES) ™ for intra-abdominal surgery, July 2007

2008
ASERNIP-S Report no. 63 - Clinical treatments for wrist ganglia (rapid review), October 2008
ASERNIP-S Report no. 64 - Diagnostic arthroscopy for conditions of the knee (rapid review), October 2008
ASERNIP-S Report no. 65 - Non-therapeutic male circumcision (rapid review), October 2008
ASERNIP-S Report no. 66 - Treatments for varicose veins (rapid review), October 2008
ASERNIP-S Report no. 67 - Upper airway surgery for the treatment of adult obstructive sleep apnoea (rapid review), October 2008
ASERNIP-S Report no. 69 - Treatments for varicose veins, October 2008

2009
ASERNIP-S Report no 55 - Permanent and semi-permanent dermal fillers, February 2009
ASERNIP-S Report no. 68 - The effect of fatigue on surgeon performance and surgical outcomes, August 2009
ASERNIP-S Report no. 71 - Endoscopic thoracic sympathectomy (evidence essential), August 2009
ASERNIP-S Report no. 72 - Neoadjuvant radiochemotherapy for rectal cancer (evidence essential), August 2009
ASERNIP-S Report no. 73 - Radiofrequency ablation for the treatment of renal tumours (evidence essential), March 2010
ASERNIP-S Reports

2010
ASERNIP-S Report no. 70 - Autologous fat transfer for cosmetic and reconstructive breast augmentation, September 2010
ASERNIP-S Report no. 73 - Radiofrequency ablation for the treatment of renal tumours (evidence essential), March 2010
ASERNIP-S Report no. 76 - Veress needle laparoscopic entry technique (evidence essential), September 2010

2011
ASERNIP-S Report no. 78 - Credentialing in surgery: a systematic literature review, October 2011

2012
ASERNIP-S Report no. 80 - Surgical simulation for training: skills transfer to the operating room, November 2012
ASERNIP-S Report no. 79: Bariatric surgery for the treatment of obesity: a rapid review
ASERNIP-S Report no. 77: Percutaneous sclerotherapy for vascular malformations: a rapid review,

2013
ASERNIP-S Report no 81 - Needs for medical devices for older people, February 2013
ASERNIP-S Report no 82 - Breast prosthesis implantation for reconstructive and cosmetic surgery (rapid review), December 2013

2014

2015
ASERNIP-S Report no 83 - Survey of needs for assistive and medical devices for older people in six countries of the WHO Western Pacific Region, July 2015.
Figure 1: Life expectancy (years) at birth by sex, 1881–1890 to 2011–2013

Sources: ABS 2014a; ABS 2014b (Table S1).
First World Life Expectancy
1960 - 2013

Life Expectancy at birth (Years)

1960
Australia: 70.82
Canada: 71.13
United Kingdom: 71.13
United States: 69.77

2013
Australia: 82.2
Canada: 81.4
United Kingdom: 80.96
United States: 78.84

Data from World Bank Last updated: Jan 12, 2016
First World Health Expenditure (% of GDP)

Year | Health Expenditure (% of GDP)
--- | ---
1995 | United States: 13.16%, Canada: 8.86%, Australia: 7.26%, United Kingdom: 6.69%
2013 | United States: 17.1%, Canada: 10.86%, Australia: 9.44%, United Kingdom: 9.12%

Data from World Bank Last updated: Jan 12, 2016