

# **IDEAL Evidence: an Australian perspective**

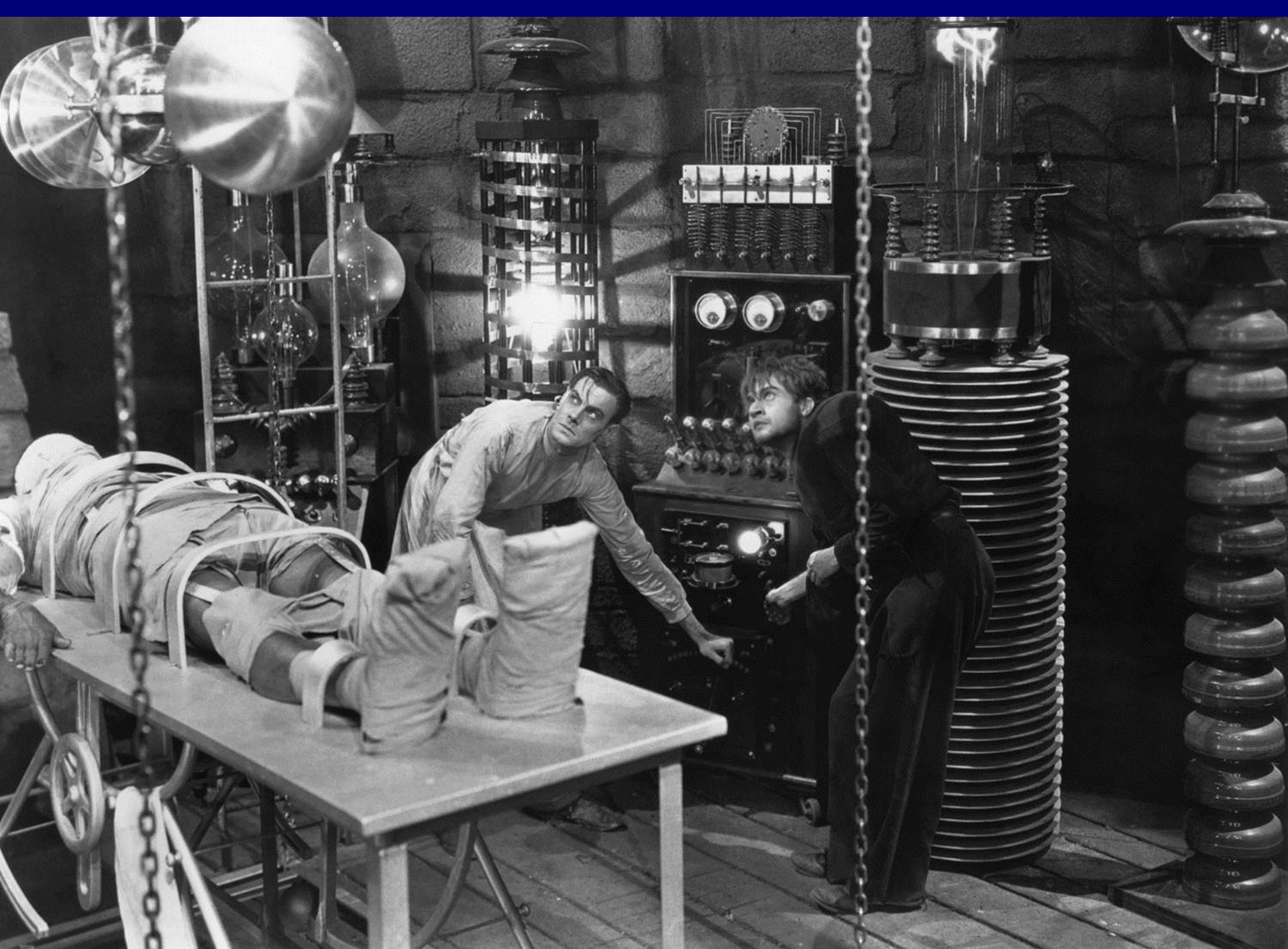
**Guy Maddern**

**RP Jepson Professor of Surgery  
University of Adelaide  
Surgical Director ASERNIP-S**



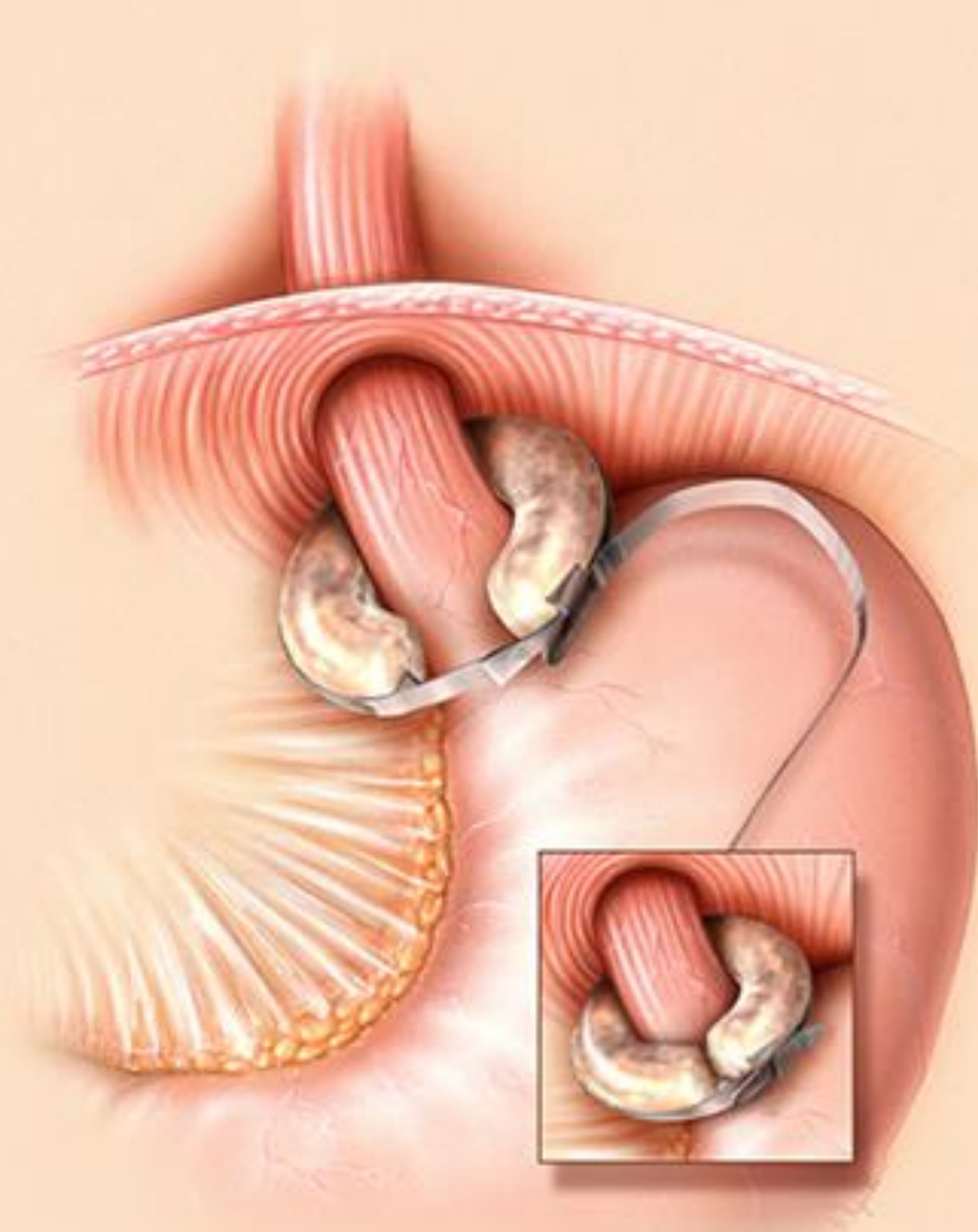
**THE UNIVERSITY  
of ADELAIDE**













# ASR Joint

## Johnson & Johnson DePuy ASR Hip Implant

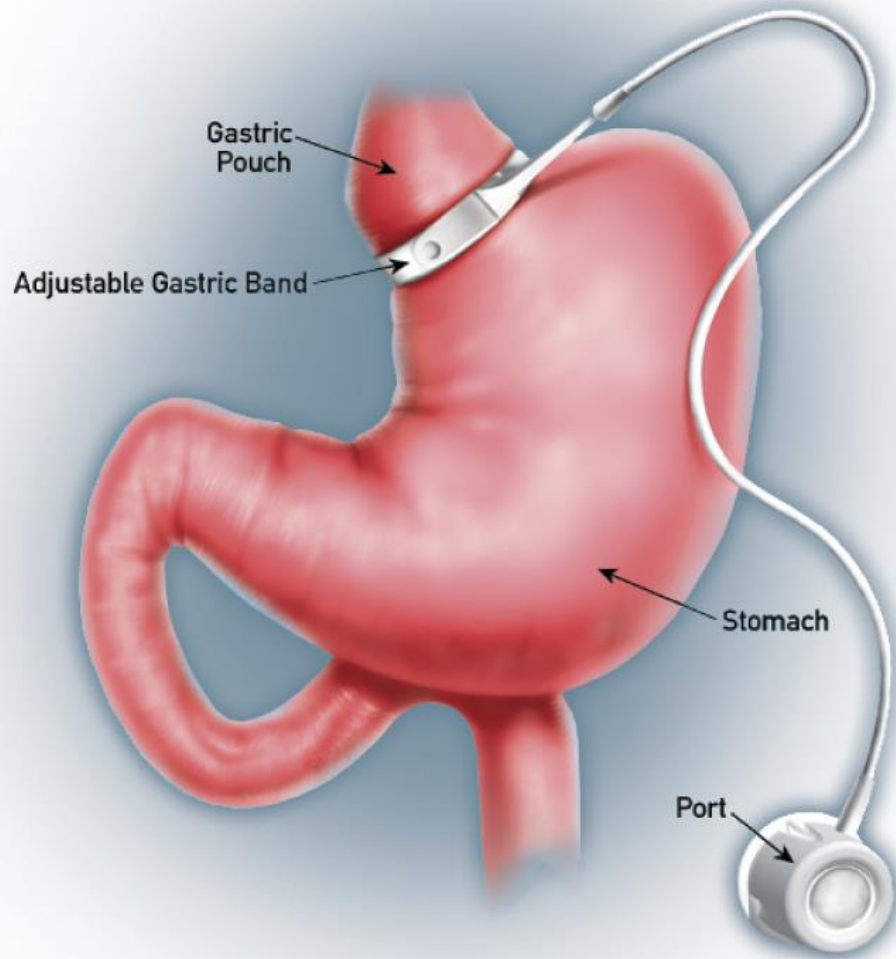
The DePuy ASR hip implant, meant to last approximately 15 years, can fail within only a few years of surgery. Victims of faulty DePuy ASR hip implants experience excruciating pain, and often have to undergo complicated and expensive replacement surgery.



# MitraClip® System

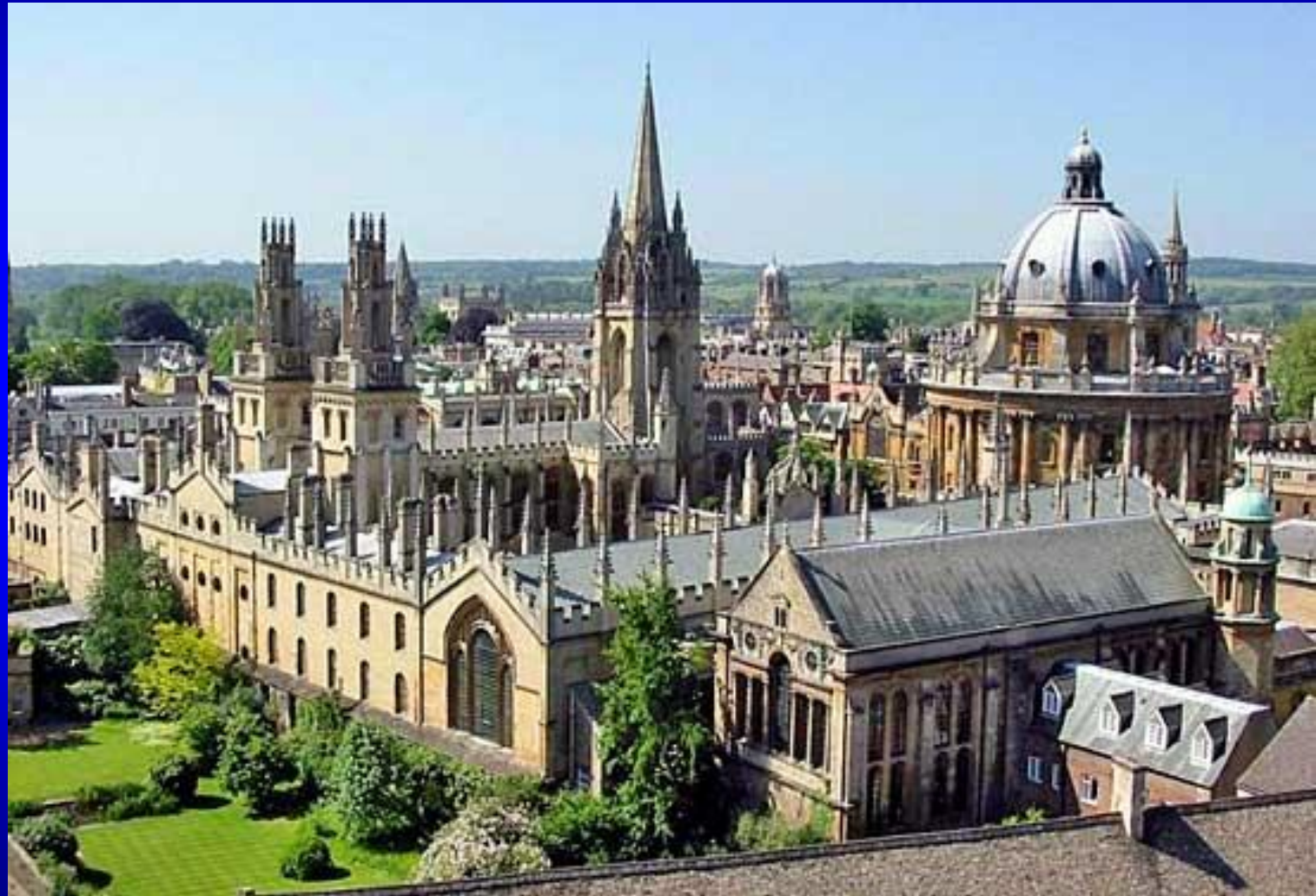








# Ideal Collaboration



# 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

## **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



## FEATURE

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# Right Portal Vein Ligation Combined With In Situ Splitting Induces Rapid Left Lateral Liver Lobe Hypertrophy Enabling 2-Stage 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\**

# IDEAL Framework

## Stage 2b: Exploration

### Question

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

### Aim

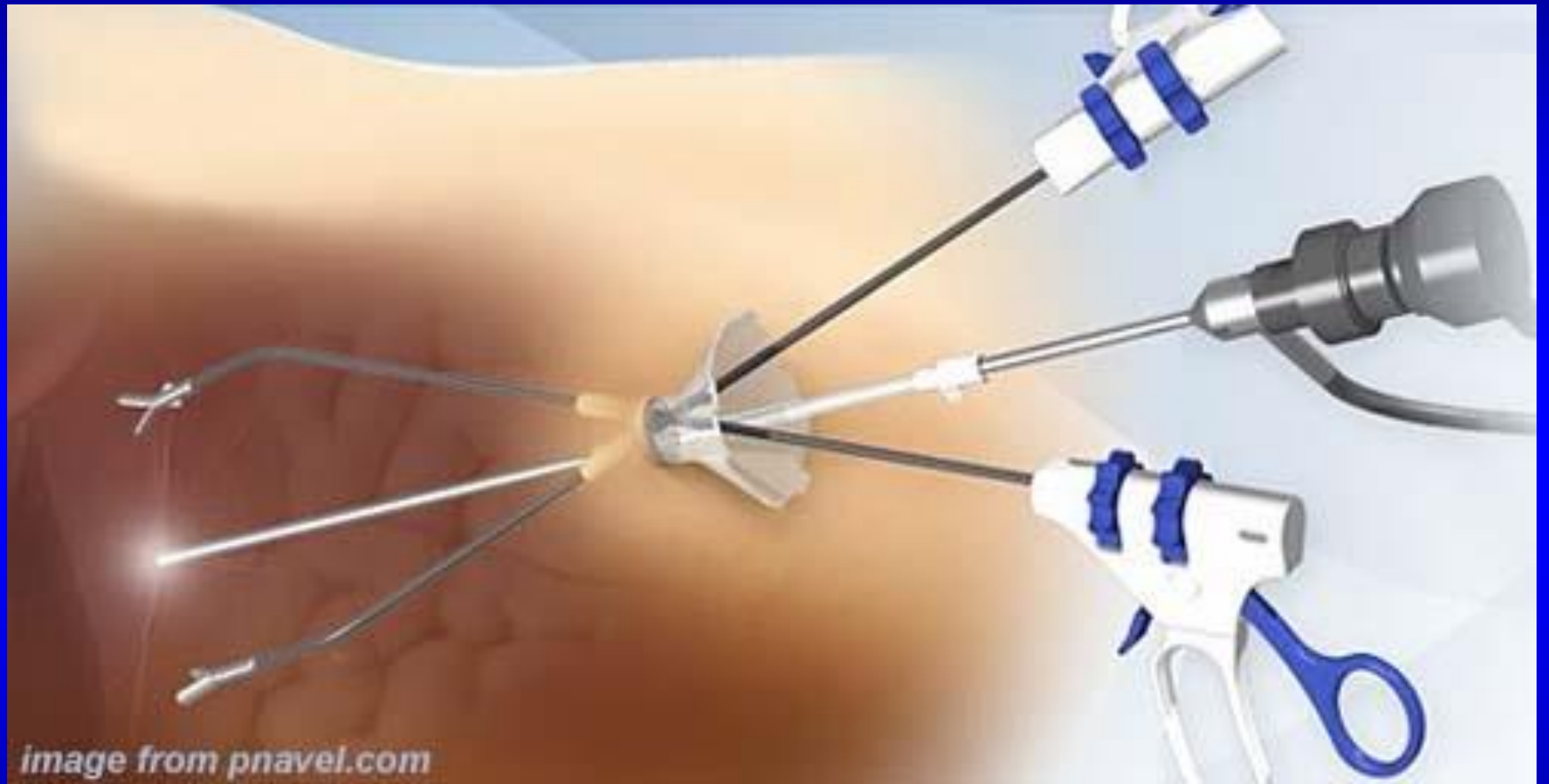
- Efficacy

### Patient Base

- 100s

### Optimal Study Design(s)

- Prospective collaborative observational study (Phase IIS) or feasibility randomised controlled trial (or both)



*image from pnavel.com*

# 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



# 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



# Laparoscopic Liver Surgery



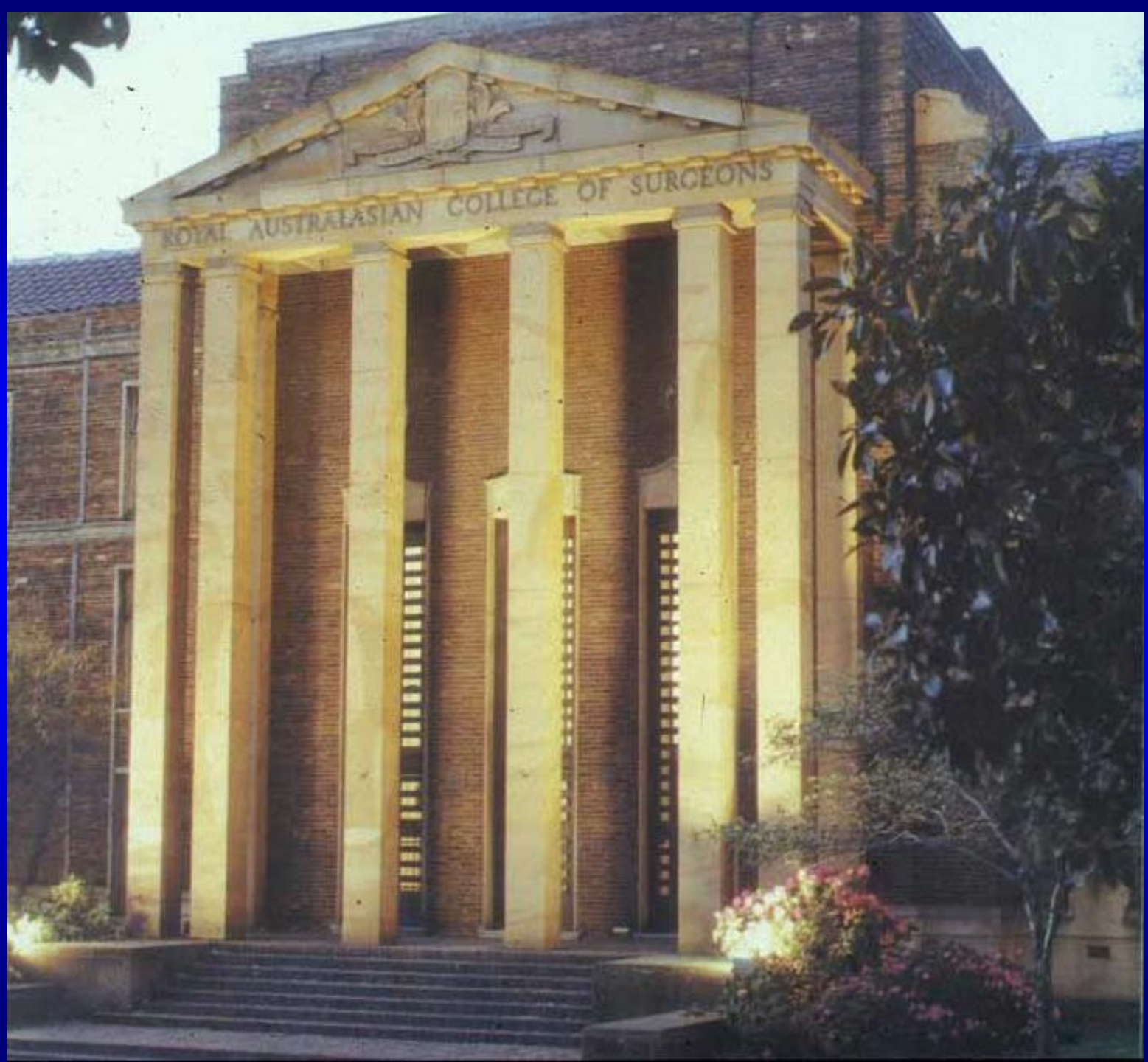
# Intraluminal Aortic Grafts

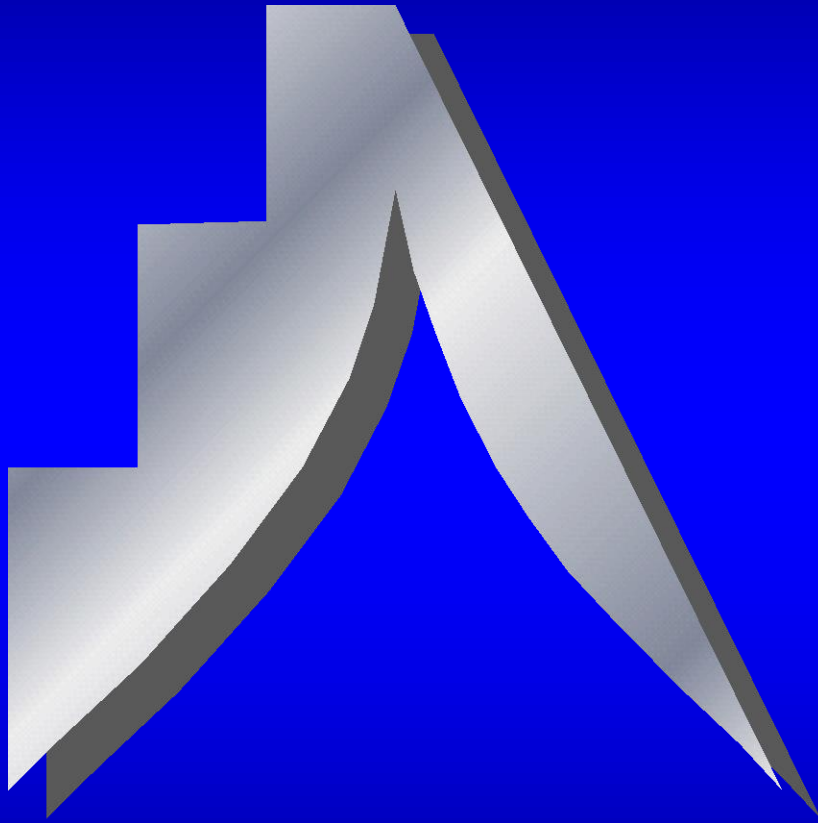


# Malignant Gastric Surgery







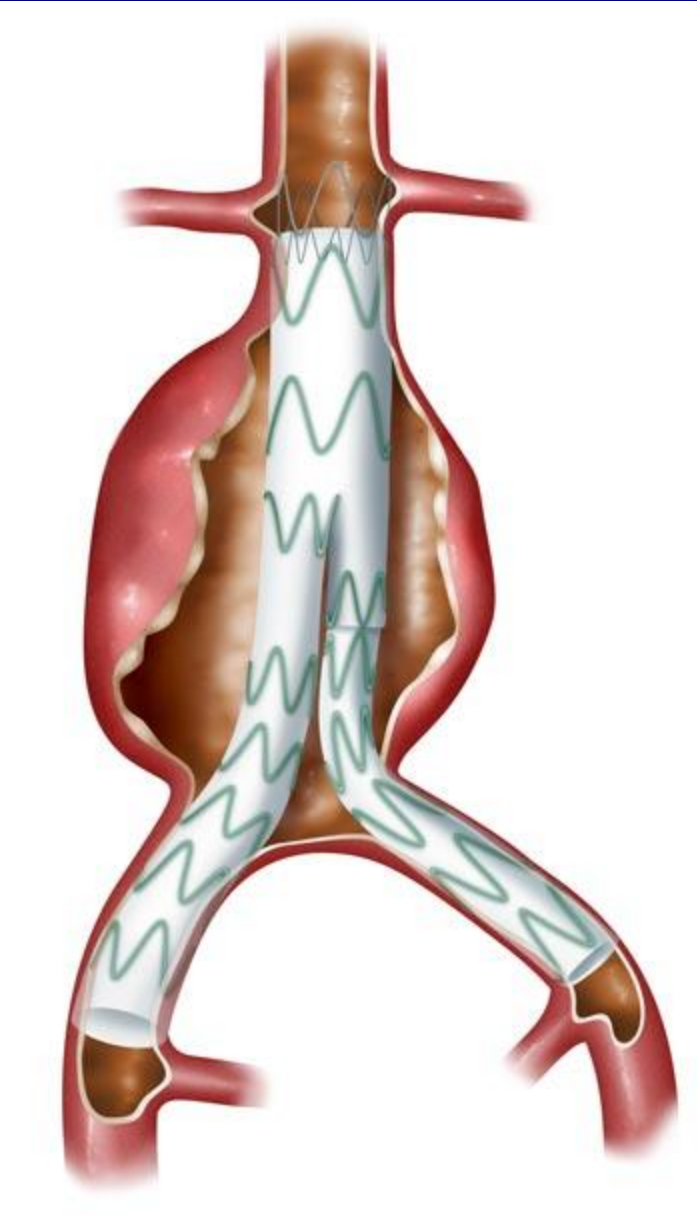


**A**ustralian  
**S**afety and  
**E**fficacy  
**R**egister of  
**N**ew  
**I**nterventional  
**P**rocedures –  
**S**urgical

# Staff









# Laparoscopic Donor Nephrectomy







Australian Government  
Productivity Commission

# 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.





Australian Government  
Department of Health and Ageing

REVIEW OF  
Health Technology Assessment  
in Australia

DECEMBER 2009





**ROYAL AUSTRALASIAN  
COLLEGE OF SURGEONS /  
ASERNIP-S**

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

RACS  
RACS  
RACS



# ASERNIP-S Publications

1. Atukorale, Y.N., Church, J.L., Hoggan, B.L., Lambert, R.S., Gurgacz, S.L., Goodall, S., Maddern, G.J. Self-Expanding Metallic Stents for the Management of Emergency Malignant Large Bowel Obstruction: a Systematic Review; *Journal of Gastrointestinal Surgery* 2016, 20 (2): 455-462.
2. Vreugdenburg, T.D., Lambert, R.S., Atukorale, Y.N., Cameron, A.L. Stereotactic anatomical localization in complex sinus surgery: A systematic review and meta-analysis. *Laryngoscope* 2016, 126 (1): 51-59.
3. Chong, C., Walters, D., de Silva, P., Taylor, C., Spillane, A., Kollias, J., Pyke, C., Campbell, I., Maddern, G. Initial axillary surgery: Results from the BreastSurgANZ Quality Audit (2015); *ANZ Journal of Surgery* 2015, 85 (10): 777-782.
4. Pena, G., Altree, M., Field, J., Sainsbury, D., Babidge, W., Hewett, P., Maddern, G. Nontechnical skills training for the operating room: A prospective study using simulation and didactic workshop (2015) *Surgery (United States)*, . Article in Press.
5. Pena, G., Altree, M., Field, J., Thomas, M.J.W., Hewett, P., Babidge, W., Maddern, G.J. Surgeons' and trainees' perceived self-efficacy in operating theatre non-technical skills (2015); *British Journal of Surgery*, 102 (6): 708-715.
6. Pena, G., Altree, M., Babidge, W., Field, J., Hewett, P., Maddern, G. Mobile simulation unit: Taking simulation to the surgical trainee. *ANZ Journal of Surgery* 2015; 85 (5): 339-343.
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10. Pena, G.N., Altree, M., Babidge, W., Maddern, G.J. Surgical simulation training: Mobile and anywhere. *Medical Journal of Australia* (2014), 200 (3), pp. 180-181.
11. Hoggan, B.L., Cameron, A.L. Systematic review of hyperbaric oxygen therapy for the treatment of non-neurological soft tissue radiation-related injuries. *Supportive Care in Cancer* (2014), 22 (6), pp. 1715-1726.
12. Gurgacz, S., Zamora, L., Scott, N.A. Percutaneous sclerotherapy for vascular malformations: A systematic review. *Annals of Vascular Surgery* (2014), 28 (5), pp. 1335-1349
13. Marlow, N., Altree, M., Babidge, W., Field, J., Hewett, P., Maddern, G.J. Laparoscopic skills acquisition: A study of simulation and traditional training. *ANZ Journal of Surgery* (2014), 84(12), pp. 976-980.
14. Tan, S.B., Pena, G., Altree, M., Maddern, G.J. Multidisciplinary team simulation for the operating theatre: A review of the literature. *ANZ Journal of Surgery* (2014), 84 (7-8), pp. 515-522.
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16. Leopardi, D., Thavaneswaran, P., Mutimer, K.L.A., Olbourne, N.A., Maddern, G.J. Autologous fat transfer for breast augmentation: A systematic review. *ANZ Journal of Surgery* (2014), 84 (4), pp. 225-230.



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17. Khan, M.W., Lin, D., Marlow, N., Altree, M., Babidge, W., Field, J., Hewett, P., Maddern, G. Laparoscopic skills maintenance: A randomized trial of virtual reality and box trainer simulators. *Journal of Surgical Education* (2014), 71 (1), pp. 79-84.
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# ASERNIP-S Publications

33. Lauder, C.I.W., Marlow, N.E., Maddern, G.J., Barraclough, B., Collier, N.A., Dickinson, I.C., Fawcett, J., Graham, J.C. Systematic review of the impact of volume of oesophagectomy on patient outcome. *ANZ Journal of Surgery* (2010), 80 (5), pp. 317-323.
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# ASERNIP-S Publications

50. Boulton, M., Babidge, W., Maddern, G., Barnes, M., Fitridge, R. Predictors of success following endovascular aneurysm repair: Mid-term results. *European Journal of Vascular and Endovascular Surgery* (2006), 31 (2), pp. 123-129.
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# ASERNIP-S Reports

## 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. 23 - Holmium Laser Prostatectomy for Benign Prostatic Hyperplasia, June 2003

ASERNIP-S Report No. 35 - Laparoscopic Live-donor Nephrectomy: Second update and re-appraisal, June 2003

ASERNIP-S Report No. 43 - Spinal Cord Stimulation/Neurostimulation: Accelerated systematic review, June 2003

ASERNIP-S Report No. 29 - Surgical Simulation, December 2003

ASERNIP-S Report No. 37 - Vacuum-assisted Closure of Wounds: Accelerated systematic review, December 2003

ASERNIP-S Report No. 39 - Post-vasectomy Testing to Confirm Sterility, December 2003

## 2004

ASERNIP-S Report No. 45 - Da Vinci Surgical Robotic System: A Technology Overview, July 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

ASERNIP-S Report No. 41 - Laparoscopic Ventral Hernia Repair: An Accelerated Systematic Review, 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 transluminal 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

ASERNIP-S Rapid Review - Centralisation of Bariatric Surgery: Policy implications, July 2014

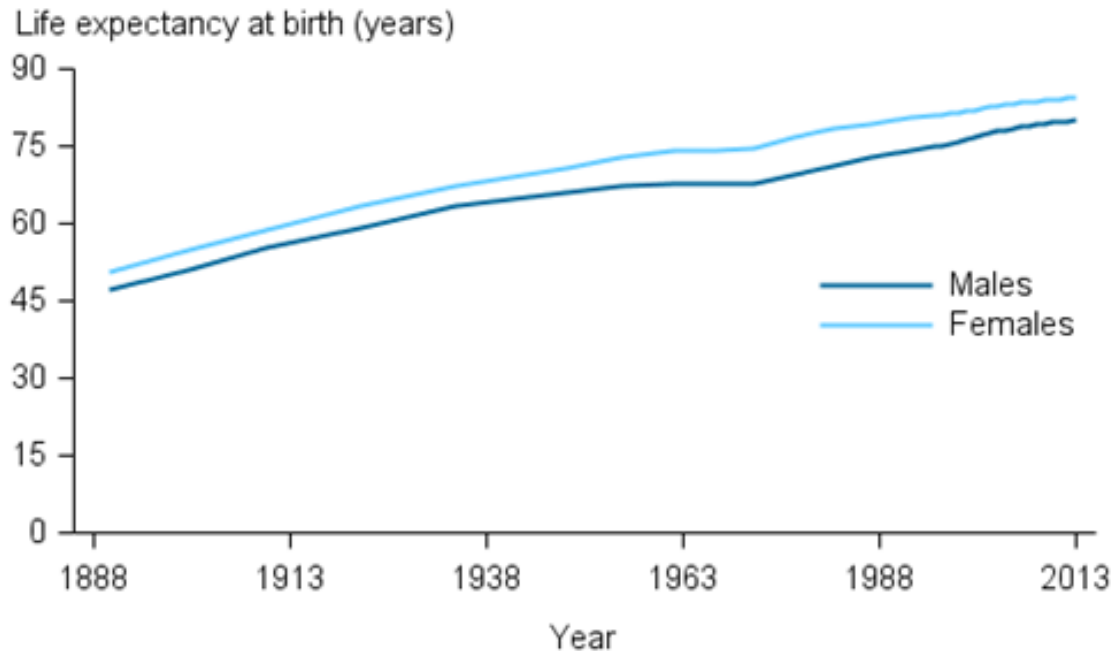
ASERNIP-S Rapid Review - Spinal Surgery for Chronic Low Back Pain: Review of clinical evidence and guidelines, July 2014

## 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.

# Australian Life Expectancy

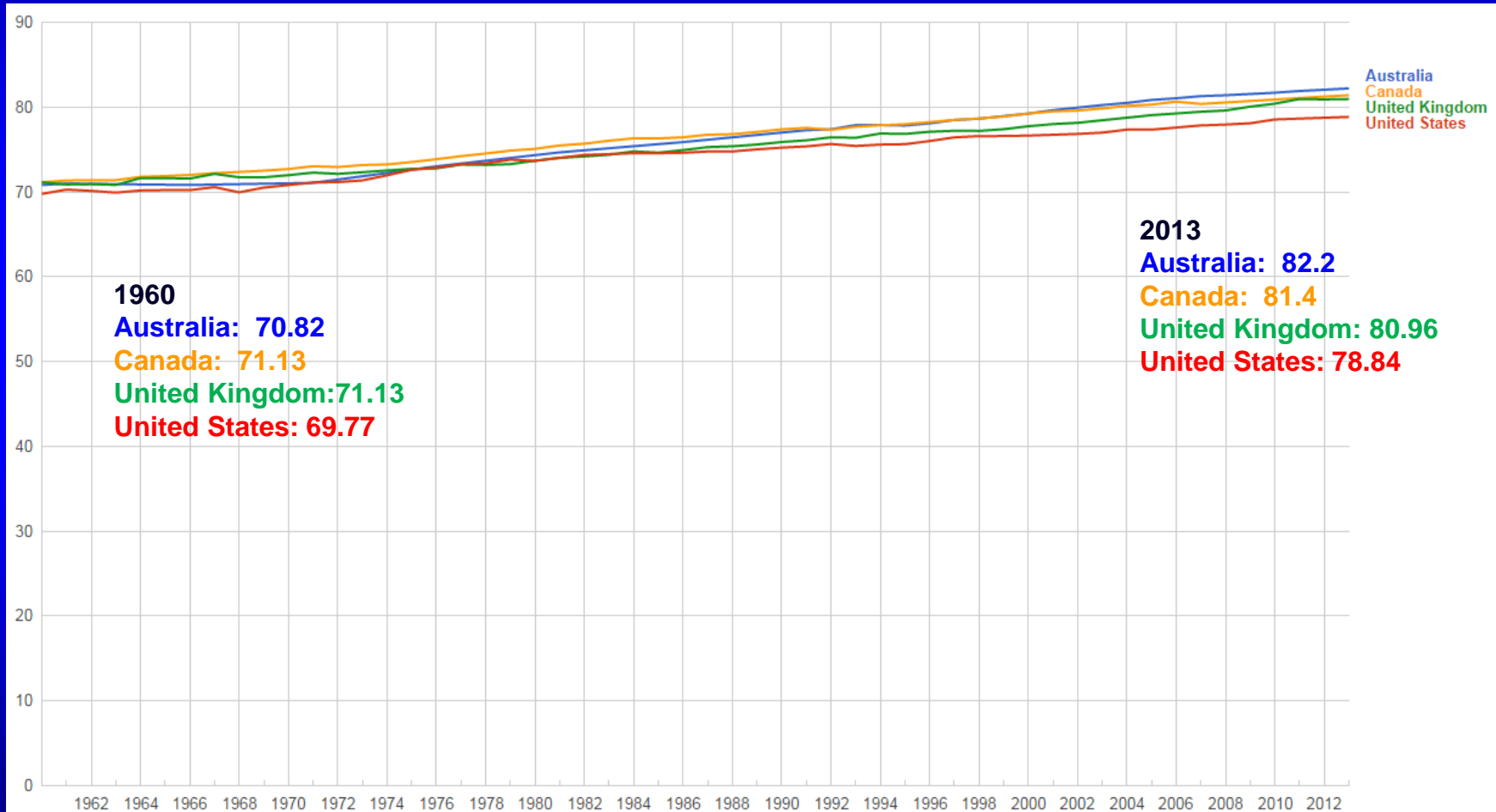
**Figure 1: Life expectancy (years) at birth by sex, 1881–1890 to 2011–2013**



Sources: ABS 2014a; ABS 2014b (Table S1).

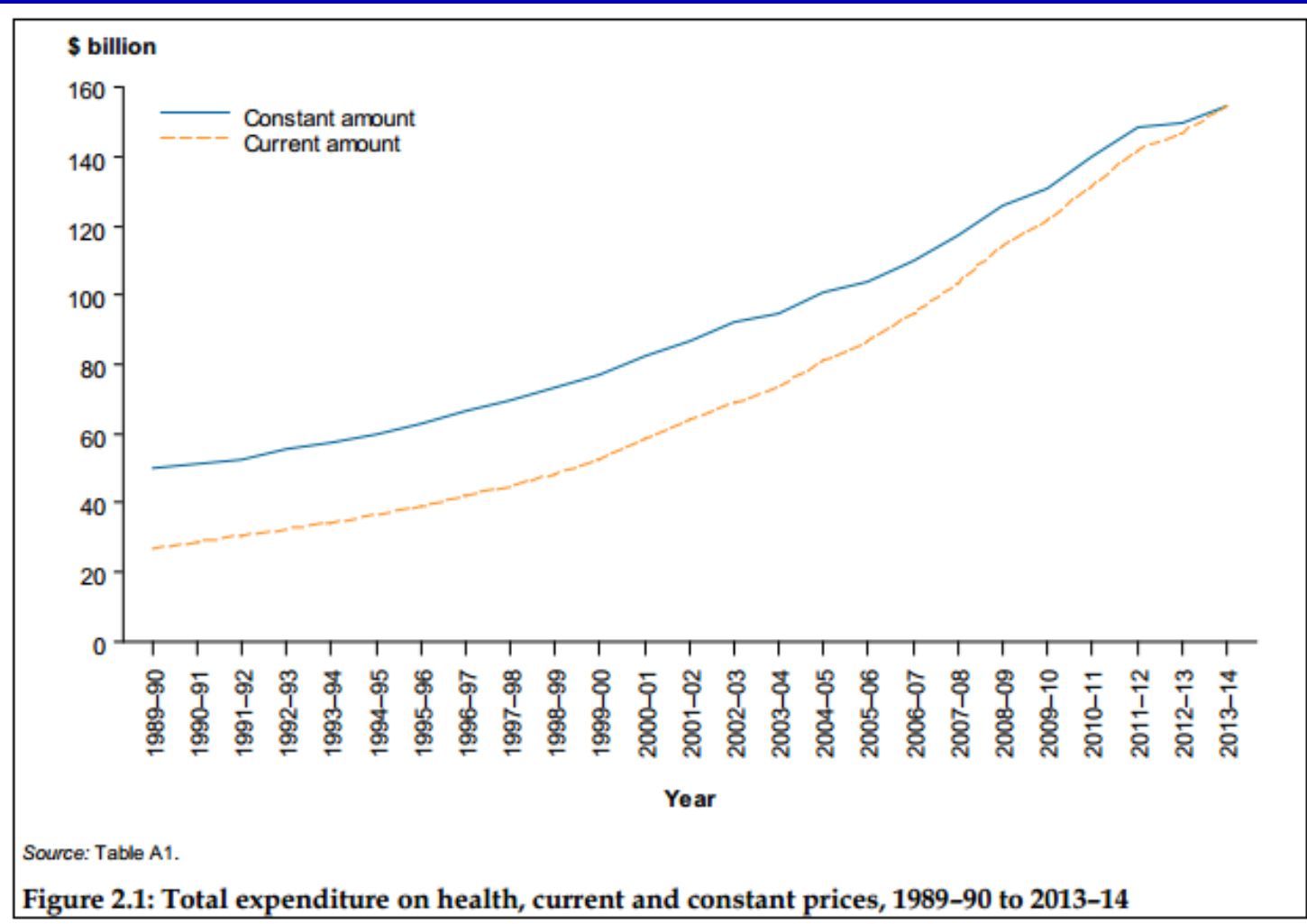
# First World Life Expectancy 1960 - 2013

Life Expectancy at birth (Years)



Year

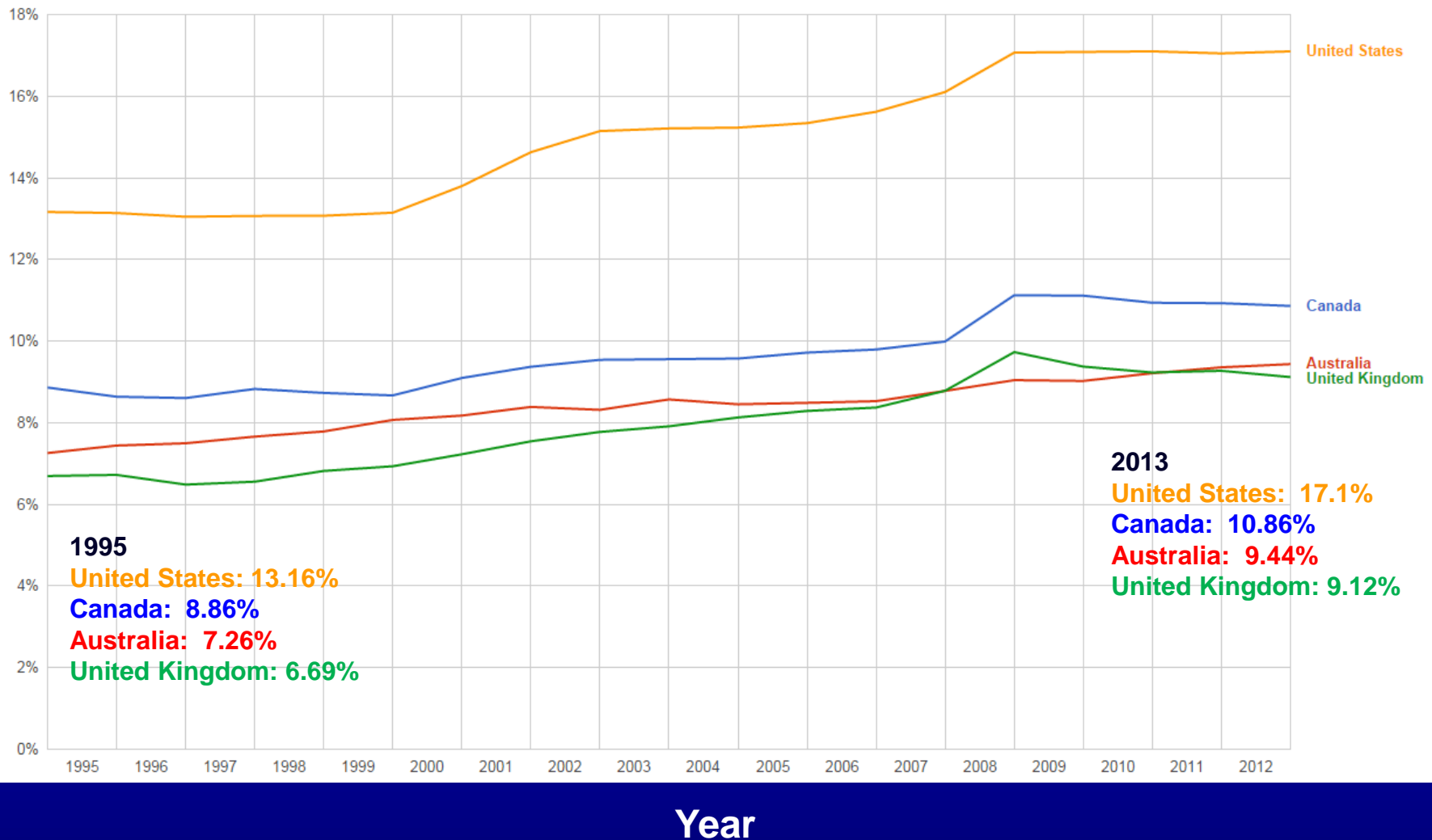
# Australian National Health Expenditure





# First World Health Expenditure (% of GDP)

Health Expenditure (% of GDP)





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