

Observational data used in Health Technology Assessment by the National Institute of Health and Clinical Excellence

Dr Hannah Patrick
Consultant Clinical Adviser to the Interventional Procedures Programme

Interventional Procedures Guidance on safety and efficacy

- Procedures used for treatment or diagnosis that involve:
 - incision, puncture or entry into body cavity
 - ionising, electromagnetic, acoustic energy
- First use in the NHS (or private sector)
- New concerns about efficacy or safety

Procedures not specific devices

Evidence used by the Interventional Procedures Advisory Committee (IPAC)

- Published studies
- Specialist Medical Advisers (questionnaires)
- Patient Commentators (questionnaires)
- Committee Members' knowledge
- *Public consultation*

What to recommend when evidence for IP is inadequate?

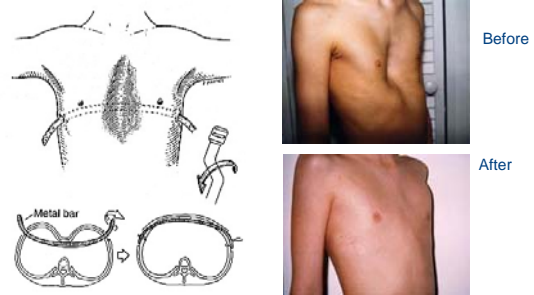
Possible recommendations:

- *Do not use* - very rare
- *Only in research* - many problems
- “Special Arrangements” :
 - Governance – tell the hospital
 - Consent - tell the patients
 - Audit/research – review outcomes

Registers for new procedures our aspiration.....

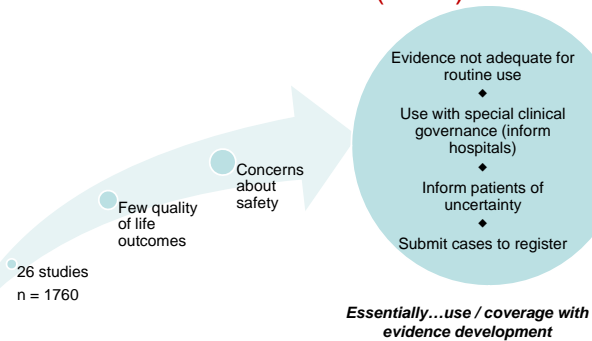
- Procedures with inadequate evidence
- Small relevant dataset
- To address explicit uncertainties
- Time-limited to answer questions (exceptions)
- Data on all patients treated (link to funding)
- Timely analysis and review of data

Case study 1: the Nuss procedure – minimally invasive repair



Acknowledgement: www.nussprocedure.com

First assessment (2003)



Re-assessment of the Nuss procedure - evidence available

Register	Published evidence
n = 260 From 13 hospitals 2000-2008	n = 5400 From 88 studies - mostly case series (published since 2003)

Substantial increase in the published evidence base from 2003

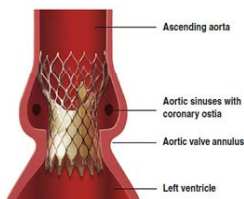
Safety

Outcome	Register	Published evidence *
Wound infection (major)	5% (13/260)	1-3%
Pleural effusion	2% (4/260)	1-3%
Bar displacement	2% (5/260)	1-7%
Pneumothorax	2% (4/260)	3-4%

Efficacy

Outcome	Register	Published evidence *
Cosmetic appearance	Pre-procedure: 3.1 Post procedure: 8.4	Excellent: 59-91% Good: 2-33% Fair: 1-19% Failed repair : 4% (1 paper)
Assessment method	<i>Patient-rated cosmetic appearance score from 1 to 10</i>	<i>Assessment methods poorly described (often clinician-not patient-rated)</i>

Case study 2 : Transcatheter Aortic Valve Implantation

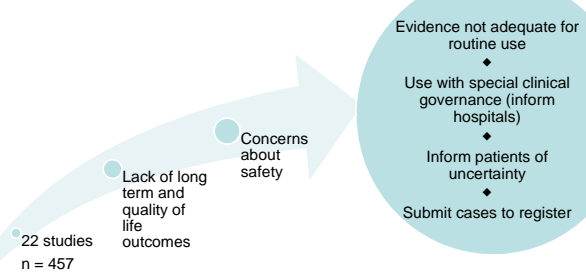


Medtronic



Edwards lifesciences

First assessment (2008)



Essentially...use / coverage with evidence development

Collaboration on evidence development

National commissioning framework and joint statement

Funding linked to data submission

Active surveillance using manufacturer's data

UK TAVI register and a research protocol

Aim: to facilitate the early clinical implementation of promising technology whilst developing the evidence base.

UK TAVI Registry

- 100% of consecutive UK TAVI implants from 1st Jan 2007 to 31st Dec 2009
- Mortality tracking by linkage of central TAVI database with the Office of National Statistics (ONS)
- 877 TAVI procedures (10 unsuccessful)
- 28.6% 2 year mortality,
- 4% stroke (in hospital)

Others for the future

- National audit of the management of the open abdomen
- Bronchial thermoplasty for severe asthma
- Renal artery denervation for resistant hypertension
- Temporo-mandibular joint replacement