IDEAL Cardiovascular Group

Discussion on 4th May 2017
TAVR — Transcatheter Aortic Valve Replacement

• US entry very late
• Comprehensive register fundamental: only possible with CME funding

Lessons
• Engage early in planning for next devices – mitral
• Iterations of device – evidence/IDEAL Stage depends on type of change
• Outcome measures may change with use in lower risk patients
• Team working vital
• International harmonisation an important aim
• Data linkage a good method for long term FU of cardiovasc devices
• Importance of introducing UDI
ECMO — Extra Corporeal Membrane Oxygenation

• A range of techniques/devices – methods unstable and evolving
• A *rescue therapy* applied to patients who are dying
• Many different IDEAL stages simultaneously – typically 2b – need evidence on *indications*
• Needs mandated international register (*collaborations*)
• Evidence gap – patients who are *not* treated missed by registers
• **Manufacturers’ registries**
  • Big potential
  • Reliability
  • Good for label expansion >>>> training for new indication
TEVAR (Thoracic EndoVascular Aortic Repair) for aortic dissections

• One RCT so “Stage 4” but patient selection uncertainties >>> IDEAL 2b
• Collaboration better than little case series (SVS, FDA, industry…)
• Now Stage for some indications but questions still arise
• FDA could draw on other relevant data (use in aneurysms, transections)

.... What about untreated patients?
Practical steps for dissemination and adoption of IDEAL

- **Start using the name** – FDA using “IDEAL approach” for ages
- **Professional Societies** pivotal. International collaborations.
- **Journal editors** must be informed and influenced
- **Industry**: big companies already use IDEAL approach – need educate small companies
- Need **money** for good data collection
- Bring IDEAL influence to bear on **linking** electronic records, UDI …