Clinical Research
(and why you should do it!)

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No Conflicts of Interest
Clinical Research in UK Cardiology

• Too limited in number, scale and scope
  • Addressing very few questions
    • Much of our practice - no real evidence

• Limited engagement
  • Few institutions involved

• Recruit a tiny proportion of the true population
  • Affect ‘generalisation’ of results

• Often industry dominated
Local, Smaller-scale Research has a Place

- Local research - even small-scale - is important
  - Staff engagement and culture change
  - Training and development progression
  - Key element of higher degree process
Why is Research so Important?

- Define optimum evidence-based practice
Why is Research so Important?

• Define optimum evidence-based practice

• *Deliver* optimum evidence-based practice
  • The research active organisation:
    • Provides better ‘routine’ clinical care
    • Better systems of care
    • Better adherence to systems of care
  • Has more informed, engaged (satisfied) staff
  • Achieves better outcomes
Why is Research so Important?

• **Define** optimum evidence-based practice

• **Deliver** optimum evidence-based practice

• Stimulate and develop your career
  • Collaboration
  • Variety
  • Focus
  • Teaching
Why is Research so Important?

- Define optimum evidence-based practice
- Deliver optimum evidence-based practice
- Stimulate and develop your career
- The research active centre can ‘measure itself’
Examples from HEAT PPCI

THE LANCET

Unfractionated heparin versus bivalirudin in primary percutaneous coronary intervention (HEAT-PPCI): an open-label, single centre, randomised controlled trial

Adeel Shahzad, Ian Kemp, Christine Mars, Keith Wilson, Claire Roome, Rob Cooper, Mohammed Andron, Clare Appleby, Mike Fisher, Aleem Khand, Babu Kunadian, Joseph D Mills, John L Morris, William L Morrison, Shahzad Munir, Nick D Palmer, Raphael A Perry, David R Ramsdale, Pariaswamy Velavan, Rod H Stables, for the HEAT-PPCI trial investigators
HEAT-PPCI: D to B Time - The Weekend Effect?
HEAT-PPCI: Primary MACE Outcome by Operator

Primary Outcome MACE Event Rates (95%CI)
HEAT-PPCI Data: GPI Use and Bleeding

Scatter Plot Any Bleed v GP 2b/3a Use

Bleed Rate

GP 2b/3a Rate of Use
HEAT-PPCI: GPI use and MACE

6% v 16% = ↓ 10%
10% of 1000 = 100 cases per year
100 x £800 = £ 80 000
(and fewer bleeding complications)
HEAT-PPCI: Thrombus Aspiration and MACE

Thrombus Aspiration and MACE (%)

MACE% Asp%
HEAT-PPCI: Thrombus Aspiration and MACE

20% v 60% = ↓ 40%

40% of 1000 = 400 cases per year

400 x £300 = £ 120 000

(and fewer strokes 1.1% v 1.5%)
Common Problems with Local Research

- Small-scale, underpowered (unethical)
- Poor design - creating confounding of ‘results’
- Poor conduct - undermining the scientific validity
- Inadequate data handling
- Regulatory and trial conduct issues
- Limited, poor (or absent) eventual reporting
The Potential for Improvement

• Recapture control of the UK research agenda
• Engagement and commitment
• The ‘big and simple study’
  • Addresses an important question
  • In the context of routine practice
  • Easy to perform - “Why not?”
    • Every patient - Every time
Simplification and Myth-Busting

- The burden of follow-up
  - Simplify with automated national systems
    - Mortality tracking
    - NICOR registries (MI, PCI, Surgery)
    - HES data
Questions and Discussion