Assessing the sustainability of treatment effects: is data linkage the answer?

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CHaRT is jointly supported by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates and the University of Aberdeen. The author accepts full responsibility for this talk.
RCTs are often referred to as the ‘gold standard’

Conducting RCTs are costly

Originally funded for short follow-up periods

Need for extended follow-up to assess the sustainability of treatment effects
Knee Arthroplasty Trial

- Total knee replacement (TKR) is a well established surgical procedure
- Examined three key aspects of TKR design
  - Patellar resurfacing
  - Mobile bearings
  - Metal backed tibial components
- Primary knee replacements survive 13-15 years
- Initially funded for a median of 10 years follow-up
- Extended follow-up required to assess the sustainability of the observed outcomes
• Routinely collected data
  - Hospital re-admission data, GP records

• Participant reported outcomes
  - Administration of postal questionnaires

• Combination of both
  - Routinely collected data and patient reported outcomes important
Postal questionnaires

- Functional status as measured with the Oxford Knee Score (OKS)
- Quality of life as measured with two standard tools (SF-12 and EQ-5D)

Routine data

- Intra- and post-operative complications
- Need for additional knee surgery
Advantages

• Better evaluation of the key clinical question
  – 16% of relevant hospital readmissions identified through routine data only

• Overcomes issues with participant retention
  – No participant involvement required
  – Data also collected for participants who had declined further follow-up
Routine data

Disadvantages

• Consent process
• Lengthy application processes
• Extensive data security checks
• Data classification
• Inconsistencies
Summary

- Extended follow-up often required to access sustainability of treatment effects
- Clinical outcomes (hospital readmissions) can be collected through record linkage
- Better evaluation of outcome/overcomes retention issues
- Time consuming in terms of the application process and resolving inconsistencies
Thank for your attention.

If you have any further questions please contact:

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