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Understanding outcome selection, measurement and reporting for innovative invasive procedures

Use of multiple data sources to conceptualise outcome domains for an early-phase surgical intervention core outcome set

Shelley Potter, Kerry Avery, **Barry Main**, Nicholas Wilson, Rhiannon Macefield, Sian Cousins, Jez Zahra, Natalie Blencowe, Daisy Elliott, Rob Hinchliffe, Jane Blazeby

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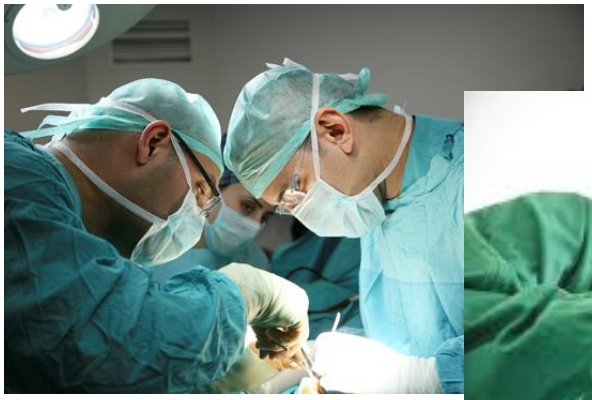
Rigorous testing of efficacy & effectiveness

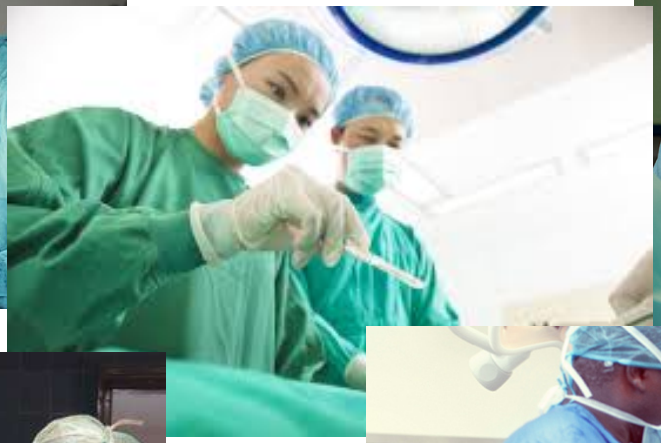
Highly regulated

New invasive devices less regulated:

- Large scale RCTs uncommon
- Rigorous evaluation after market approval granted not mandatory
- Reporting of early phase (pre RCT) studies not systematic

Lack of standardised reporting





Selective reporting

Exaggeration of benefits

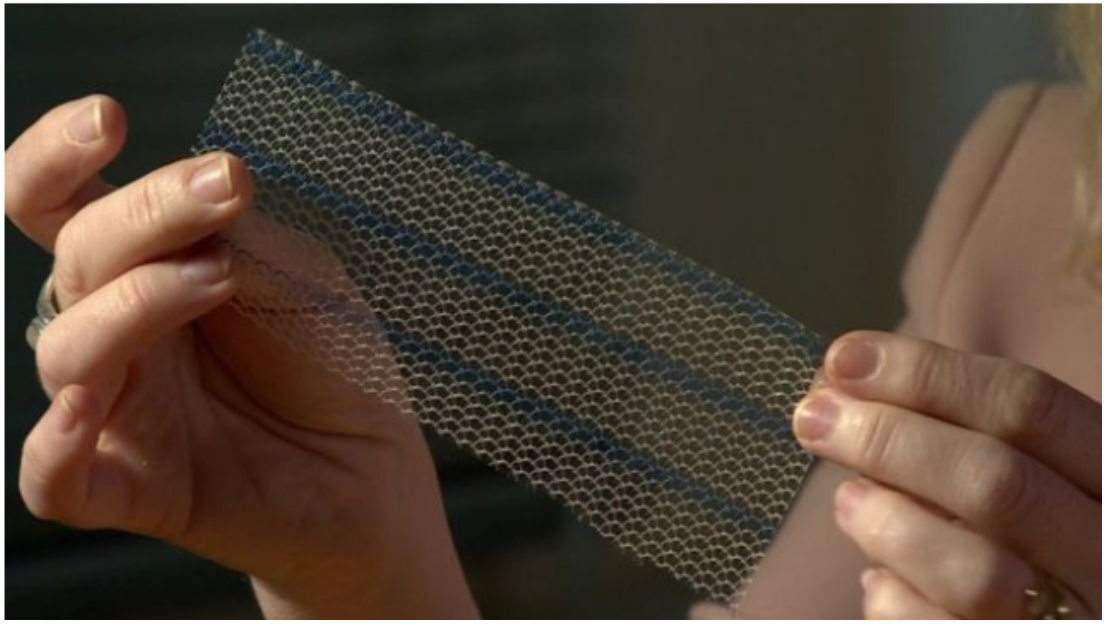
Under-estimation of harms

- Introduction of bias may **prevent early identification** of promising or harmful innovations

Unforeseen adverse events

"Vaginal mesh operations should be banned, says NICE"

BBC NEWS



"Life-changing consequences"

COS: a solution?

One…

COS: a solution?

One…

…or more (modular) COS

COS: a solution?

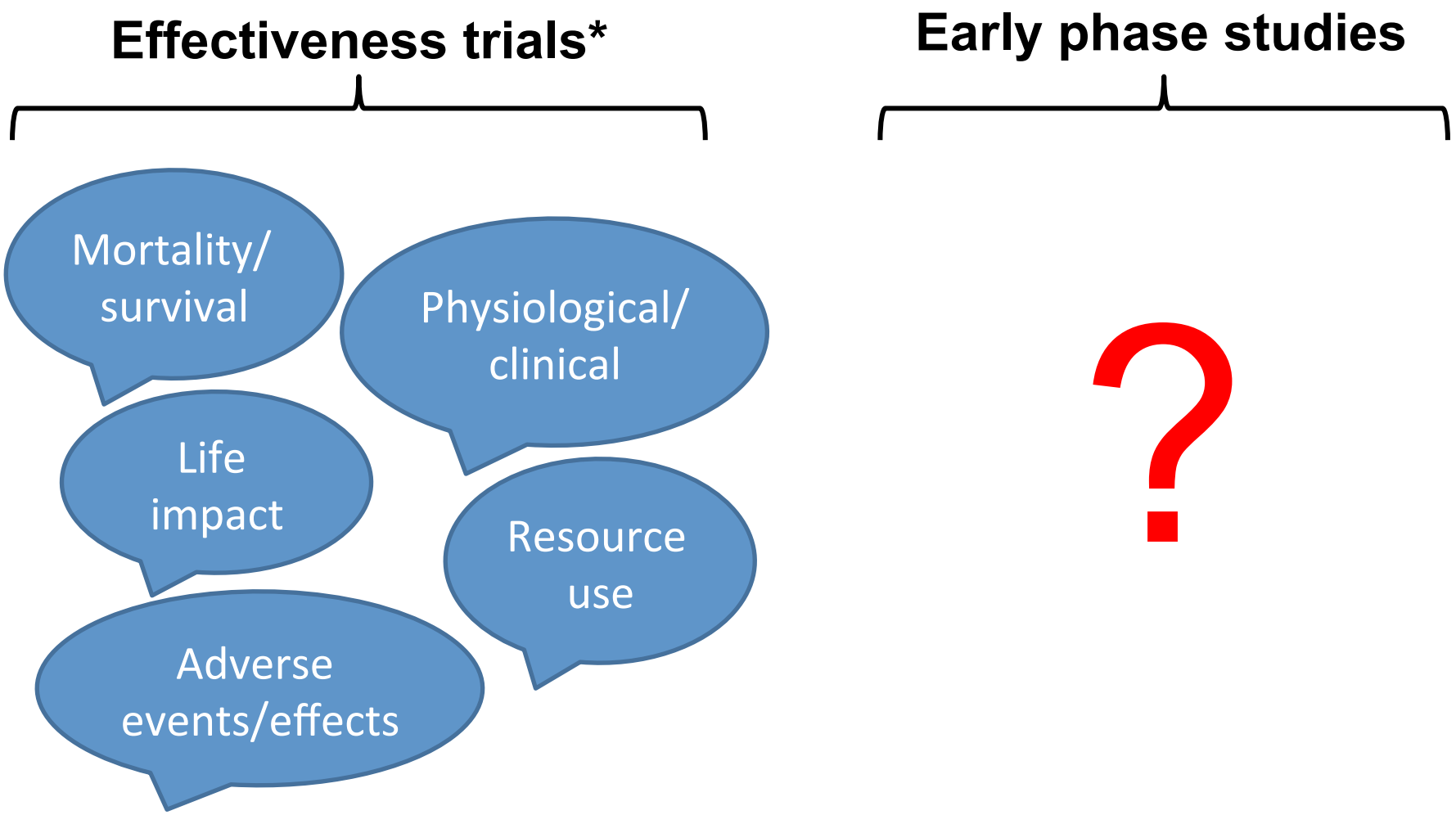
One…

…or more (modular) COS

but…

Core Outcome Measures in Effectiveness Trials

Conventional versus 'innovation' outcomes




COMET
INITIATIVE
Core Outcome Measures in
Effectiveness Trials

The COHESIVE Study

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CASESTUDIES

IDEAL
Collaboration

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CASESTUDIES

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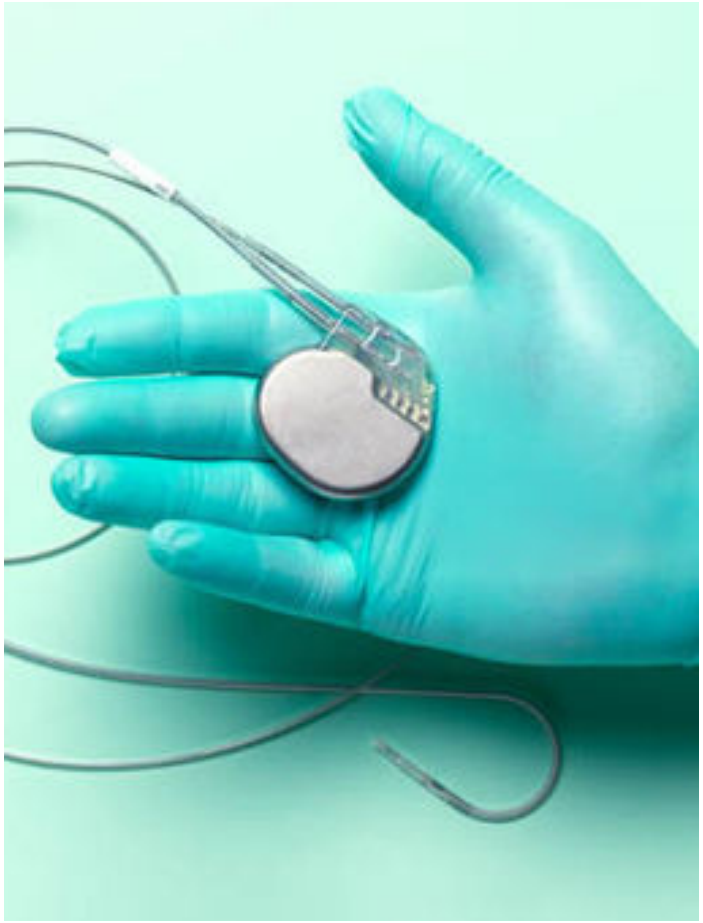
Outcome selection in 11 published case-studies

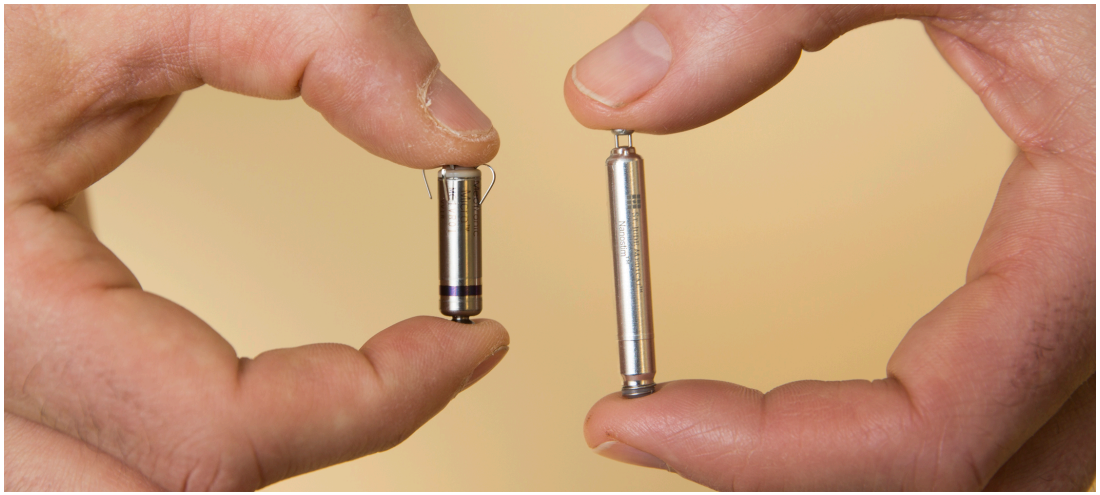
- UroLift
- Leadless pacemakers
- LINX reflux management system
- Magseed magnetic marker seeds
- ALIGN urethral support system
- Activa DBS
- LINX reflux management system
- Magseed magnetic marker seeds
- BRAXON matrix for reconstruction
- ALIGN urethral support system
- BioDesign fistula plug

Data extraction and analysis:

- Verbatim descriptions of outcomes reported
- Identify and compare ‘conventional’ versus ‘innovation’ outcomes

Case study: leadless pacemakers





Characteristics of published studies (n=42)*	n	%
Country		
Europe	16	38
North America	9	21
UK	2	5
Other (Malaysia, Hong Kong, Japan)	3	7
Multiple	12	29
Number of centres		
Single centre	28	67
Multicentre	14	33
Publication year		
2016-2017	36	86
2014-2015	6	14

*Acknowledgement: Barry Main, Matt Edmondson, et al

Characteristics of studies (n=42)

Study type, n	No. pts, mean (range)
Case report **(22)**	**1** (1-6)
Retro. cohort **(5)**	**225** (1-989)
Prosp. cohort **(15)**	**349** (1-795)

Characteristics of studies analysed (n=42)

Study type, n	No. pts, mean (range)	No. >1 centre
Case report **(22)**	**1** (1-6)	0
Retro. cohort **(5)**	**225** (1-989)	3
Prosp. cohort **(15)**	**349** (1-795)	11

Characteristics of studies analysed (n=42)

Study type, n	No. pts, mean (range)	No. >1 centre	Mean follow-up, months (range)
Case report **(22)**	**1** (1-6)	0	**4** (0-12)
Retro. cohort **(5)**	**225** (1-989)	3	**10** (6-12.6)
Prosp. cohort **(15)**	**349** (1-795)	11	**6** (1-16.4)

Outcomes cited (n=42)

Study type, n	Outcomes, mean (range)
Case report **(22)**	**41** (17-68)
Retro. cohort **(5)**	**57** (32-78)
Prosp. cohort **(15)**	**86** (46-136)
TOTAL	**2,469**

‘Effectiveness’ outcomes

Mortality/survival
- Device-related deaths
- Procedure-related deaths

Physiological/clinical
- Mean heart rate
- Pacing threshold
- Under/over-sensing
- Impedance
- R wave amplitude
- Cardiac failure

Life impact
- Time to ambulation
- Cosmetic appearance
- Level of activity

Resource use
- Additional cost
- Cost of closure method

Adverse events
- Complications
- Readmission
- Serious device-related
- Non-serious device-related
- Pain

Process-related
- Procedure time/prolonged procedure
- Time to discharge
- Additional time needed

Conceptualising ‘innovation’ outcomes

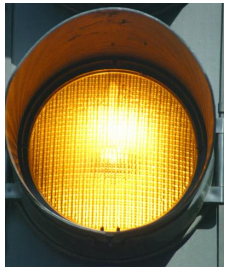
Innovation delivered as intended

- Implant success rate (%)
- Implant stability

Surgeons’ experiences

- Smoothness of implantation
- Convenience
- Overall impression

Conceptualising ‘innovation’ outcomes



Anticipated adverse effects

- Access site complications
- Interaction with adjacent structures
- Early battery depletion

Innovation delivered with unintended effect

- Number of redeployments
- Need for repositioning
- Remodelling

Conceptualising ‘innovation’ outcomes

Unanticipated adverse effects

- Injury
- Malfunctioning
- Displacement
- Device inadvertently placed in left ventricle
- Temporary pacing wire placed
- Detrimental electrical effects
- Changes in heart structure and function

Innovation abandoned

- Unsuccessful deployment
- Unsuccessful positioning
- Attachment point unsuccessful

Conclusions

- Typical effectiveness outcomes **do not include outcomes of relevance to surgical innovation**
- **Novel methods** are needed to conceptualise outcomes/outcome domains relevant to innovation
- Work is ongoing

Acknowledgements

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