

# Workshop C – Evaluation

Rod Taylor

Complex Interventions Research Framework Masterclass 2010

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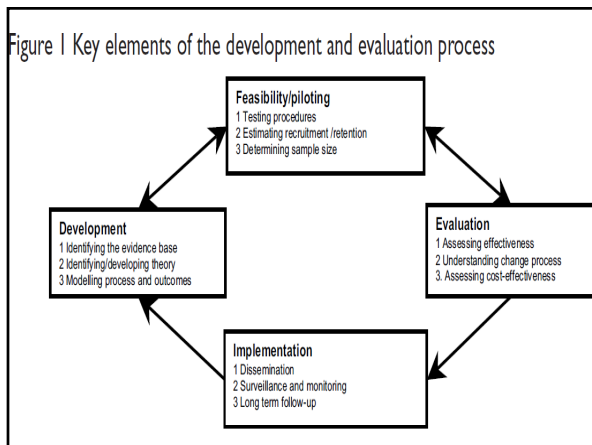
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## Background

- Biostatistician & trialist
- Scientific Director of Peninsula Clinical Trials Unit (PenCTU)
- Research interest - exercise/physical activity community-based interventions & trial design to evaluate medical devices/surgical procedures

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## Is collaborative care effective in the treatment of depression?

- Collaborative care is a complex combination of clinician and patient education, consultation-liaison between primary and secondary care clinicians and case management, translated into practice by the introduction of a new case manager role into primary care who liaises between primary care clinicians and mental health specialists, collects and shares information on the clinical care of individual patients and delivers and manages aspects of their care.

Bower et al. *BMJ* 2005;330:839-842.



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## Efficacy vs Effectiveness

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|--|---|
| <ul style="list-style-type: none"><li>■ <b>Efficacy</b><ul style="list-style-type: none"><li>□ explanatory trials</li><li>□ highly selected populations</li><li>□ comparator: often placebo</li><li>□ outcomes: often surrogate, focus on adverse effects</li><li>□ 'does the therapy work?'</li></ul></li></ul> | <ul style="list-style-type: none"><li>■ <b>Effectiveness</b><ul style="list-style-type: none"><li>□ pragmatic trials</li><li>□ few exclusions</li><li>□ comparator: 'current (best) practice'</li><li>□ outcomes: patient-focused, plus down-stream resources</li><li>□ 'what's the real world added value of the therapy?'</li></ul></li></ul> |
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Taylor R.S. *Value in Health* 2001;4:8-11



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## 1. Assessing Effectiveness

- Choosing an appropriate trial design
- There ARE alternatives to the classical RCT, e.g:
  1. Cluster randomisation
  2. Stepped wedge designs
  3. Preference designs
  4. Randomised consent
  5. N-of-1 studies



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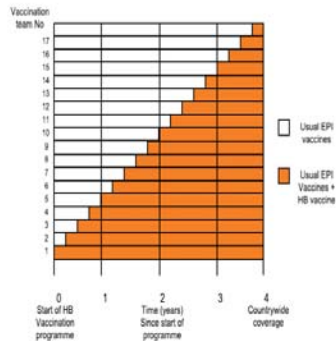
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## Two rarely used designs...



WORLD AFFORDERS

The existing vaccination programme in the Gambia was administered by 17 area-based teams. HBV vaccine was added to the vaccination schedule of each team in a random sequence, at 3 monthly intervals over a four-year period, until countrywide coverage was achieved (see figure).



Source<sup>18</sup>



International Journal of Cardiology xx (2006) xxx–xxx

International Journal of  
Cardiology

www.elsevier.com/locate/ijcard

### Home-based versus hospital-based rehabilitation after myocardial infarction: A randomized trial with preference arms — Cornwall Heart Attack Rehabilitation Management Study (CHARMS)<sup>1,2</sup>

H.M. Dalal<sup>a,\*</sup>, P.H. Evans<sup>b</sup>, J.L. Campbell<sup>b</sup>, R.S. Taylor<sup>b</sup>, A. Watt<sup>a</sup>, K.L.Q. Read<sup>c</sup>,  
A.J. Mourant<sup>d</sup>, J. Wingham<sup>a</sup>, D.R. Thompson<sup>d</sup>, D.J. Pereira Gray<sup>c</sup>

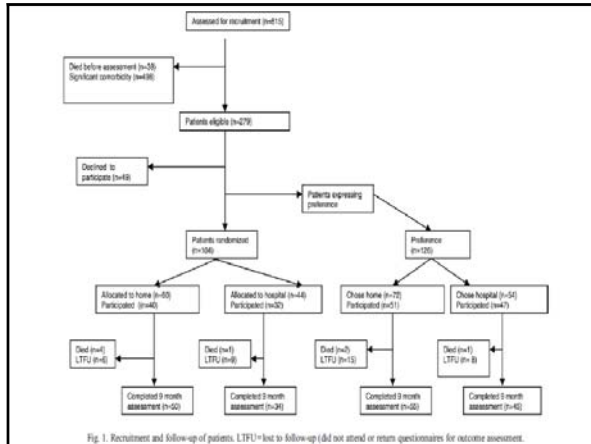
<sup>a</sup> Royal Cornwall Hospital, Truro, Cornwall, UK

<sup>b</sup> Peninsula Medical School, Exeter, UK

<sup>c</sup> University of Exeter, Exeter, UK

<sup>d</sup> University of Leicester, UK

Received 25 July 2006; received in revised form 6 October 2006; accepted 2 November 2006




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## Use of non-randomised designs

- Randomisation is occasionally unnecessary or inappropriate
- Randomisation is quite often impossible, e.g. if the intervention has already been implemented
- Observational studies can provide important data – and are often better than nothing

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## Use of non-randomised designs

**An example: Does air pollution kill people?**

- This question unlikely to be answered by a classical RCT
- Two observational studies of air pollution controls
  - Clancy et al., Lancet 2002 – looked at death rates before and after Dublin banned coal sales
  - Hedley et al., Lancet 2002 – studied death rates before and after Hong Kong switched to low sulphur fuels

Less air pollution DOES reduce death rates

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## 2. Understanding the change process

- Failure or unanticipated outcomes are common with complex interventions
- Process evaluation can help understand such outcomes
  - Assess intervention fidelity
  - Identify contextual factors
  - Moderators and mediators of intervention effect
  - Often mixed methods




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## 3. Assessing cost-effectiveness

- Definition: the difference in cost of two or more health care interventions relative to their difference in health outcomes




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## Types of Economic Studies

		Are Costs and Outcome Examined?		
		No, examines only outcomes	No, examines only costs	Yes
Comparison of two alternatives?	No	Outcome description	Cost description	Cost-outcome description
	Yes	Effectiveness evaluation	Cost-analysis	Full economic evaluation




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## Incremental Cost Effectiveness Ratio (ICER)

$$\text{ICER} = \frac{\text{cost [complex intervention - usual care]}}{\text{outcome [complex intervention - usual care]}}$$

Quality adjusted life years (QALYs)



mood disorders

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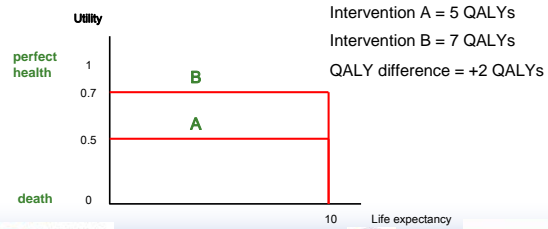
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## Cost utility analysis (CUA)



mood disorders

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## EQ-5D

- **Mobility**
  - I have no problems in walking about
  - I have some problems in walking about
  - I am confined to bed
- **Self-Care**
  - I have no problems with self-care
  - I have some problems washing or dressing myself
  - I am unable to wash or dress myself
- **Usual Activities**
  - I have no problems with performing my usual activities
  - I have some problems with performing my usual activities
  - I am unable to perform my usual activities
- **Pain/Discomfort**
  - I have no pain or discomfort
  - I have moderate pain or discomfort
  - I have extreme pain or discomfort
- **Anxiety/Depression**
  - I am not anxious or depressed
  - I am moderately anxious or depressed
  - I am extremely anxious or depressed

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Table 2: EuroQol Scoring Formula based on UK Coefficients (Weights)

DIMENSION	COEFFICIENT (Weight)
Constant	0.081
Mobility	
Level 1	0
Level 2	0.069
Level 3	0.314
Self-care	
Level 1	0
Level 2	0.104
Level 3	0.214
Usual activities	
Level 1	0
Level 2	0.036
Level 3	0.094
Pain/discomfort	
Level 1	0
Level 2	0.123
Level 3	0.386
Anxiety/depression	
Level 1	0
Level 2	0.071
Level 3	0.236
N3	0.269

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### Cost-effectiveness of what?

- Including an economic evaluation should make the results of an evaluation study much more useful for decision-makers, but you should also ask the question, 'Is this study worth doing?'
- For large, expensive trials, a formal approach to assessing the 'expected value of information' from the study should be included in the planning process.




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### References

- Richards D et al. Collaborative Depression Trial (CADET): multi-centre randomised controlled trial of collaborative care for depression - study protocol. *BMC Health Services Research* 2009, 9:188
- Shiell A et al Complex interventions or complex systems? Implications for health economic evaluation. *BMJ*. 2008;336:1281-3.
- See references in objectives handout




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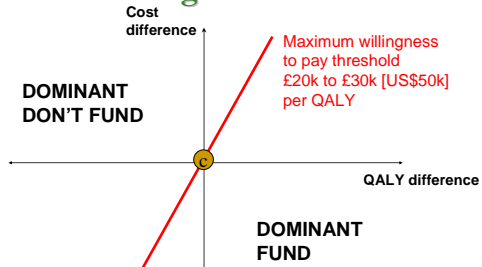
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## CEA Rationale Framework for Decision Making



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