

# The use of Stepped Wedge cluster randomized trials: Systematic Review

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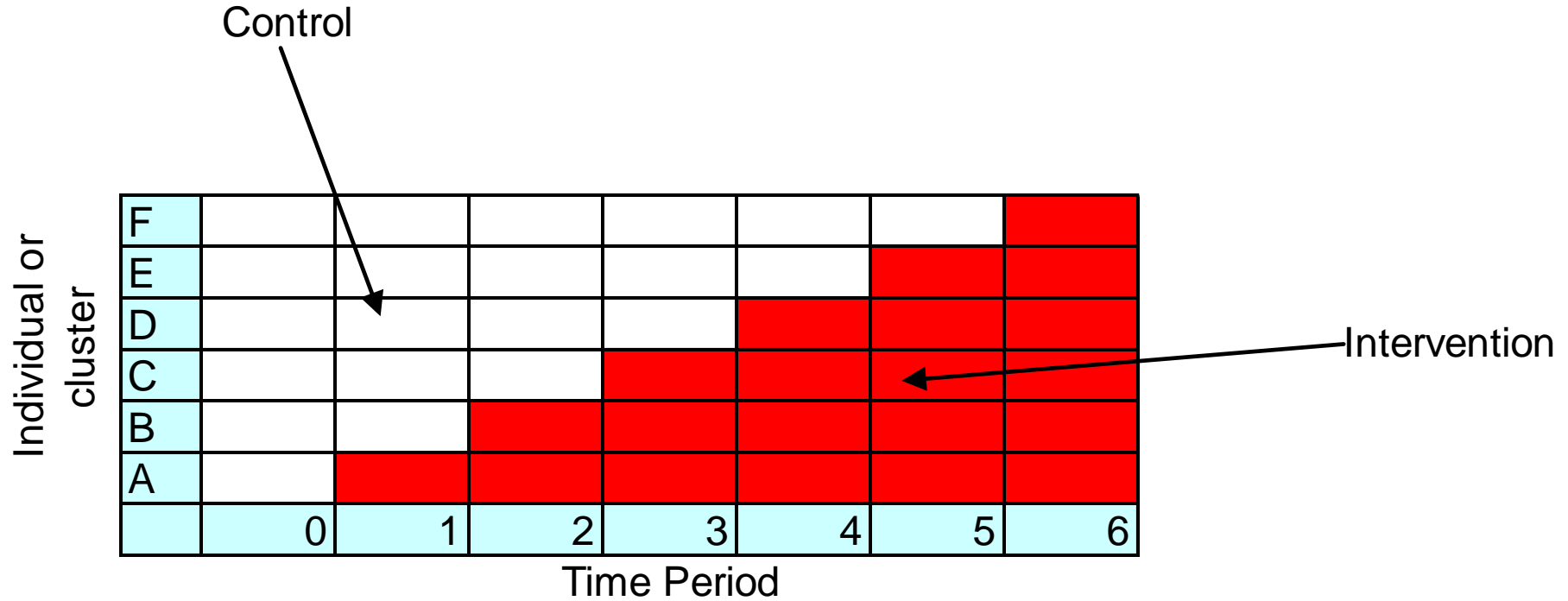
The University of Birmingham

On behalf of my co-authors: Noreen Mdege, Mei-See  
Man and David Torgerson (University of York)

# Today's presentation

- What is a stepped wedge design?
- What are the advantages and disadvantages of using a SW design?
- Aims of systematic review
- Results of systematic review
- Conclusions

# Stepped Wedge designs

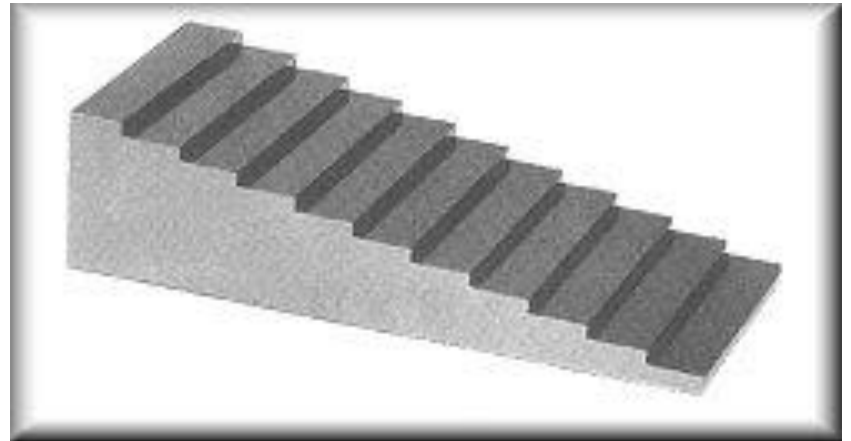


# A stepped wedge design can be...

- (and should be, wherever possible) randomised
- Used with individuals or with clusters as the 'steps'

# But isn't...

- A step wedge
- A cross-over trial
- A multiple baseline study



# Advantages

- Solves ethical dilemma of withholding the intervention when not in equipoise
- Solves logistical and financial problems associated with simultaneous implementation
- Can detect trends
- Increases statistical power (within and between comparisons)
- Can study the effect of context as intervention is implemented in multiple settings



# Disadvantages

- Can require a lengthy trial – so best if short time between intervention and outcome
- Multiple data collection points required – so best if using routinely collected data
- Data analysis is fairly complicated (see paper by Hussey and Hughes)



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Design and analysis of stepped wedge cluster randomized trials

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# Example SW study

Comparison of standard therapy with home-based therapy with 'ready to use therapeutic food' (RUTF) to treat malnourishment of children in Malawi (Ciliberto et al., 2005).

SW design used as 'full' randomisation not possible due to resource constraints and cultural beliefs; SW allows control for bias introduced by seasons

7 centres were randomised, 1 every 3 weeks 'stepped' from control to RUTF

Primary outcome: recovery defined as WHO weight for height z-score  $> -2$

Results: recovery rate in intervention group 79% vs. control group 46%,  $p < 0.001$

Why successful?

1. Inpatient care as part of standard therapy increases risk of infection
2. Standard therapy food provided on discharge needs preparation 7 times/day over an open fire

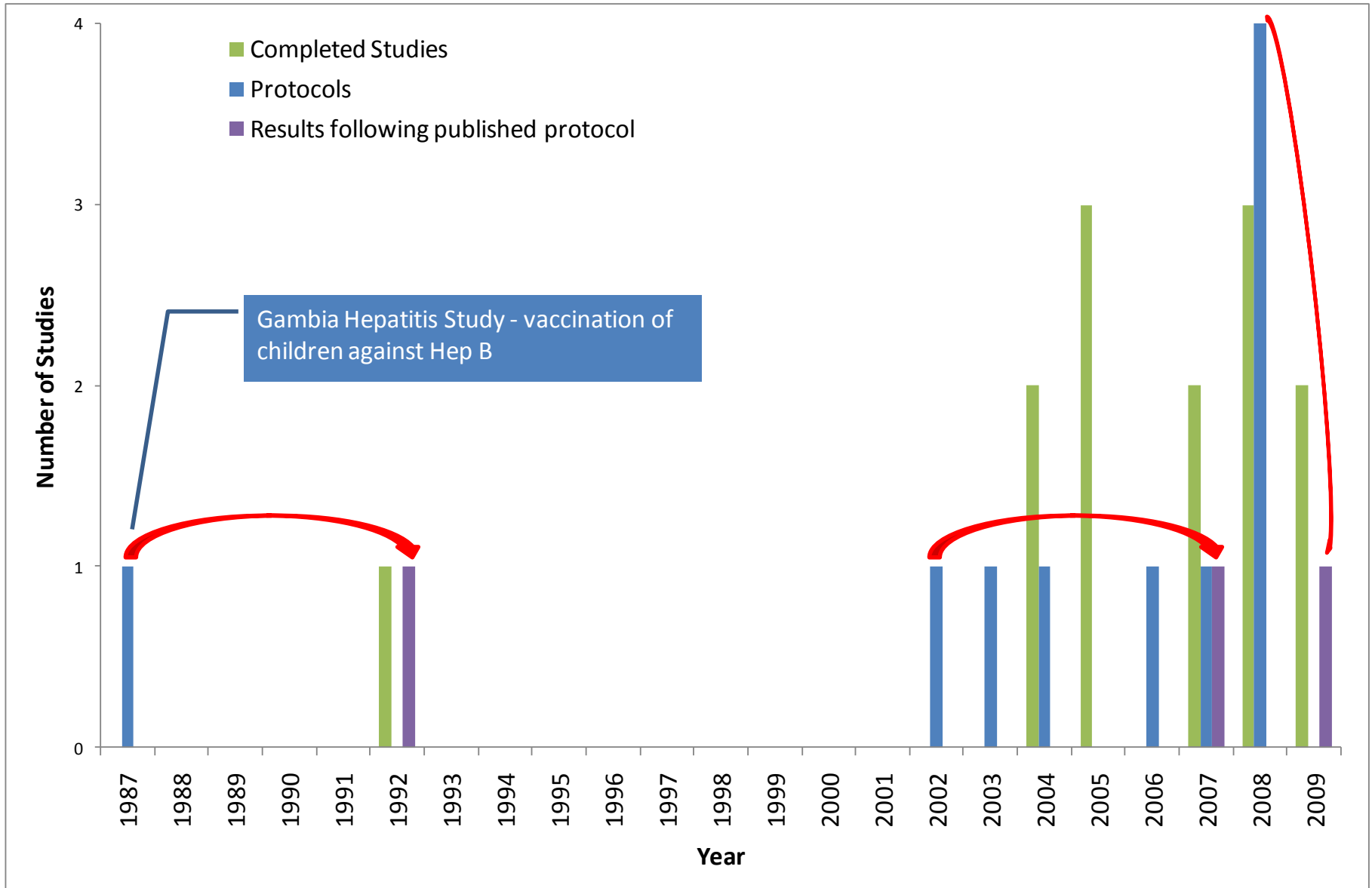




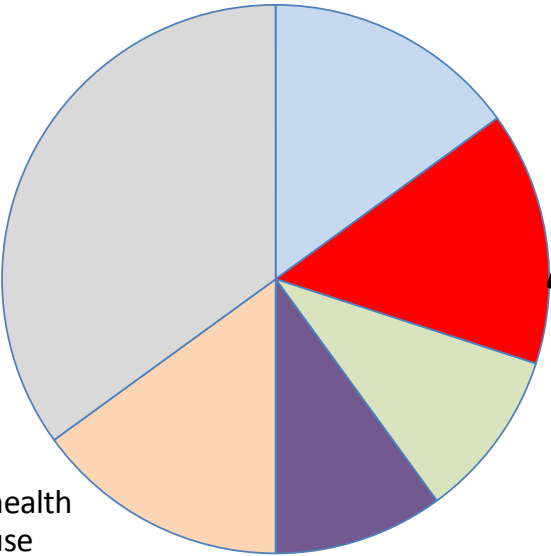
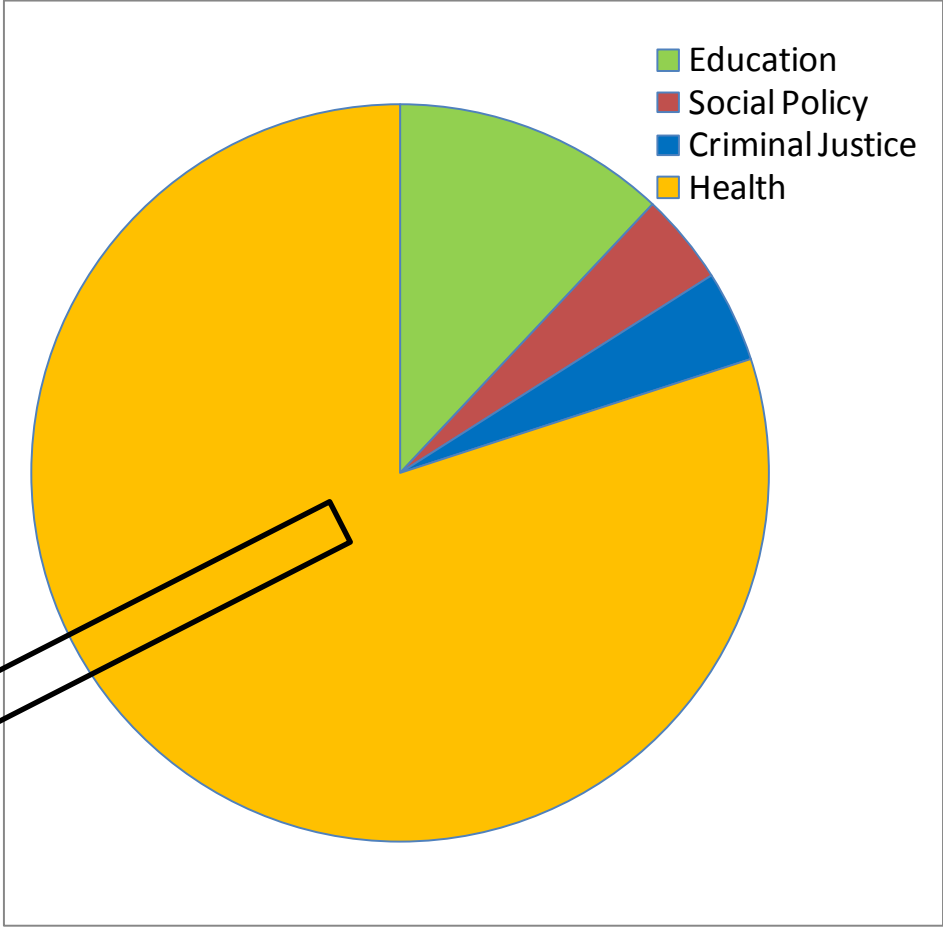
# Aims of systematic review

- To describe the application of the cluster randomised stepped wedge design:
  - Change in use over time
  - Areas of research where design used
  - Motivations for using design
  - Methods of data analysis
  - Quality of reporting
- 25 Studies included up to January 2010
- 15 completed studies and 10 protocols

# Results 1: Increasing use over time

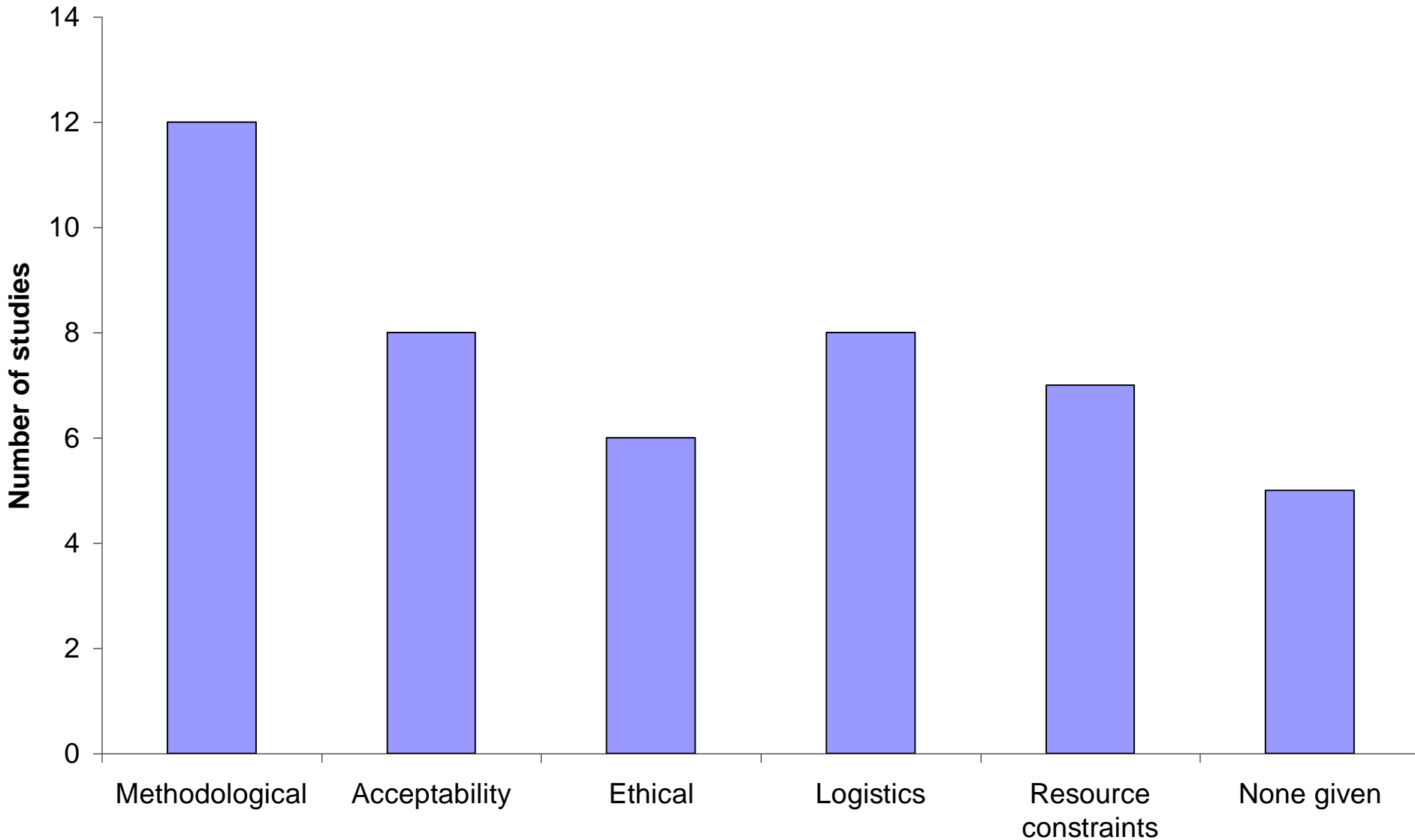


# Results 2: Areas where design used

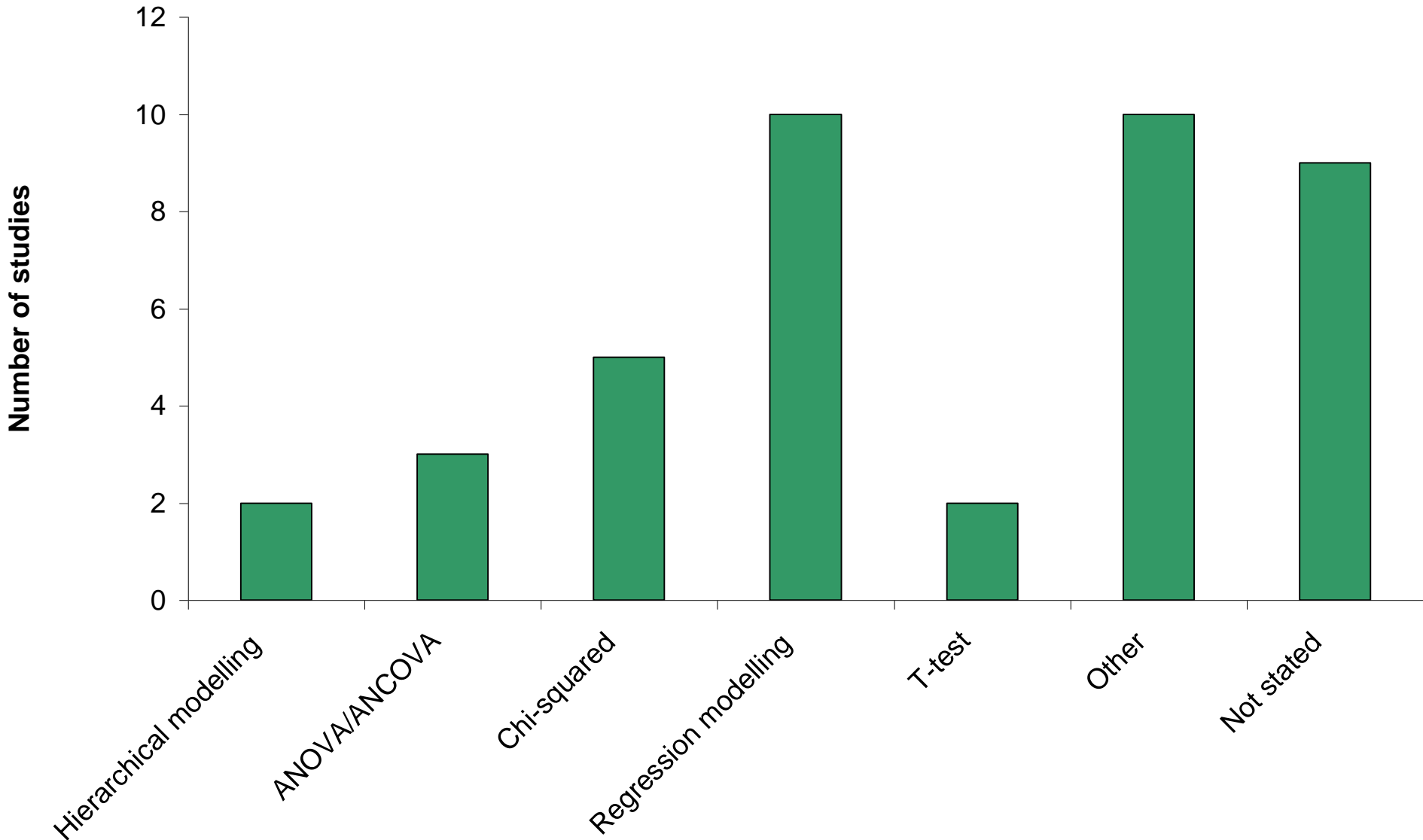


- Nutrition
- STDs/HIV
- Maternal health
- Resource use
- Other
- Cancer/CVS/Hypertension/Respiratory

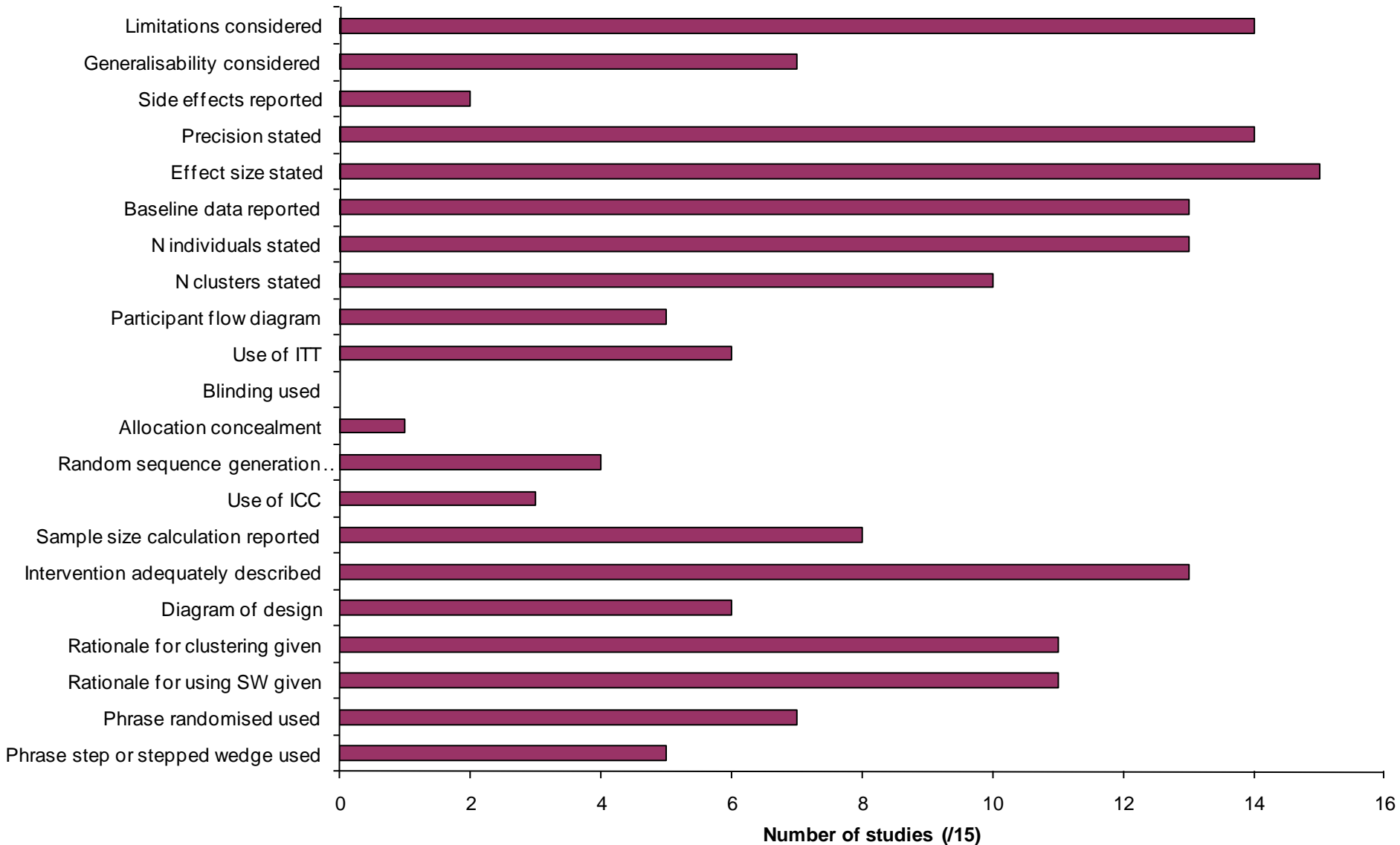
# Results 3: Motivations for using SW



# Results 4: Methods of analysis



# Results 5: Quality of Reporting



# Conclusions

- Increasing use of design over time
- Design used for a variety of reasons
- Most studies in health
  - Most RCTs of any type in health
  - Design can overcome ethical constraints often cited in other areas (e.g. education)
- Lack of consistency in describing the design as a “stepped wedge” (so we may have missed some)
- Other problems with the quality of reporting
  - Adaptation of CONSORT statement required?

# Thank you

- And thank you to my co-authors
- Questions?
- Comments?