

**Trial based economic
evaluation: prompt
publication and mixed
messages**

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**Timely and complete
publication of economic
evaluations alongside RCTs
(work in progress)**

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Economic evaluations

- Publication bias – well known problem for clinical effectiveness results
- Are economic evaluations
 - ❖ as likely to be published?
 - ❖ published as promptly?
 - ❖ published in journals with equivalent impact factors?

Methods

- ISRCTN database: “cost” or “economic”
- Exclude where
 - ❖ unfinished or recently finished
 - ❖ no plan to conduct an economic evaluation
- Find clinical and economic articles for a random 100 trials (360 met inclusion criteria)
- Contact PIs of unpublished results

Preliminary results

Please email joanna.thorn@bristol.ac.uk
for further details

PI responses

- Contacted 45 PIs – 34 responded (76%)
- 23 will not be published
- Variety of reasons given
 - ❖ Health economist left the group
 - ❖ Intervention was not effective
 - ❖ Ran out of time
 - ❖ Not interested in financial calculations

Preliminary conclusions

- Publication rate is poor
- Economic results are subject to longer delays than clinical results
- Economic results are published in journals with lower impact factors
- Trial registration is not a complete solution

Clinical versus economic design and interpretations of RCT results - Mixed messages?

Work in Progress

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Background

- Sample size formulas for cost-effectiveness have been available for many years - but may not be used in practice.
- Therefore recruitment may cease too soon or continue too long in relation to cost effectiveness
- It is often assumed that RCTs are underpowered on economic outcomes (QALY too crude, costs too variable or missing cost data)

Objectives

- Review of literature of cost per QALY analysis (CUAs) conducted alongside RCTs to determine:
 - ❖ Extent to which cost-effectiveness is considered in sample size calculations
 - ❖ The frequency with which economic conclusions conflict with clinical conclusions
 - ❖ Whether economic evaluations are underpowered and so more likely to come to indeterminate results

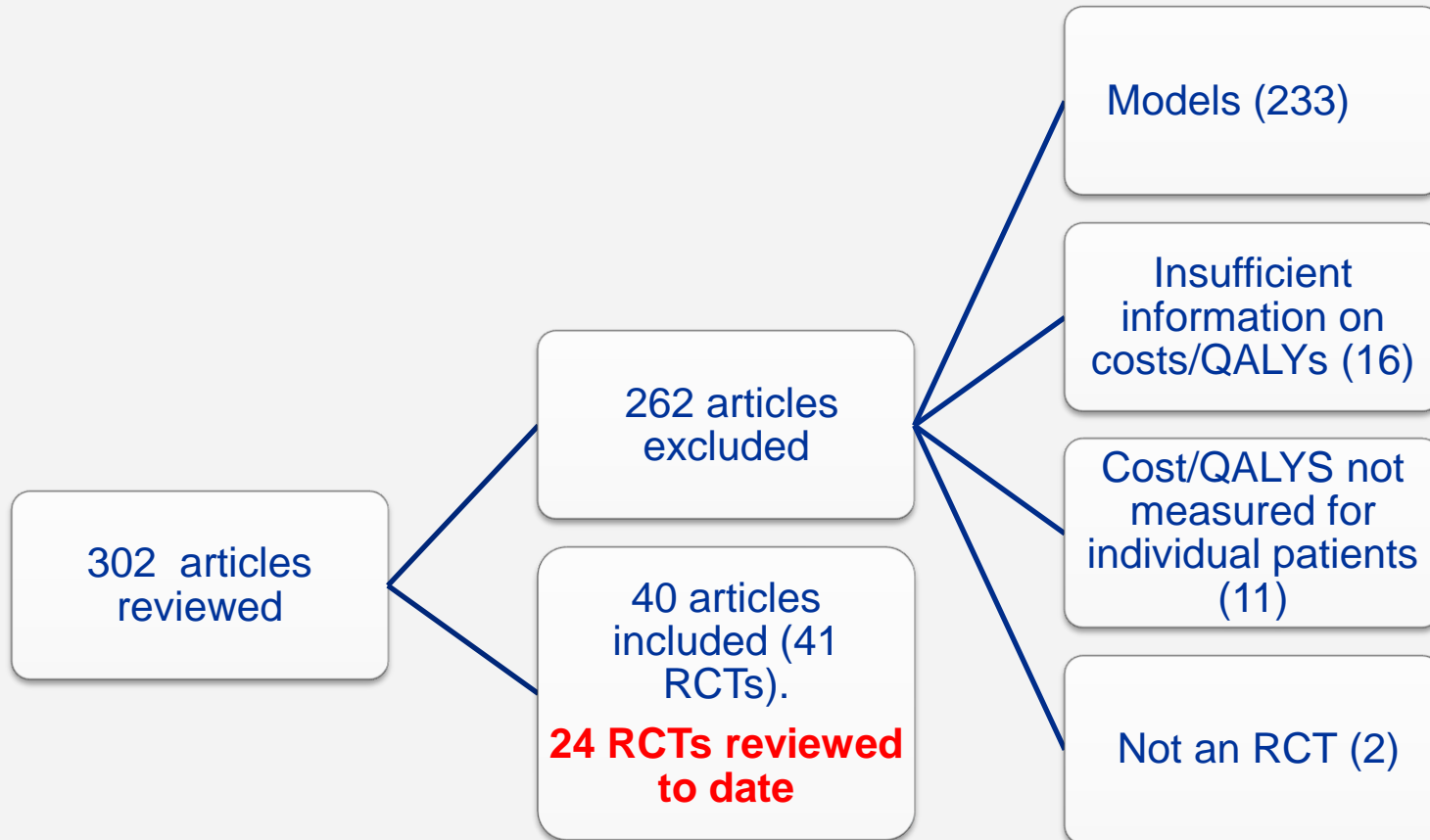
Methods 1 – Search strategy

- Searched NHS Economic Evaluation Database to identify RCTs using Cost per QALY Analysis
 - ❖ 717 articles in 293 journals identified.

We selected:

- ❖ Initially selected 4 high impact journals (BMJ, NEJM, Lancet, JAMA) and 5 high volume journals (Pharmacoecon, Value Health, Int J Technol Assess, Ann Intern Med, Med Res & Curr Opin)
- ❖ 50% random sample of the remaining journals that published 3 or more CUAs

Methods 2 - Flow chart



Methods 3 – Data Extracted

- **Study Characteristics** e.g. year of publication, funding source, number of patients in each arm, sample size calculation
- **Outcome Data:**
 - Primary clinical outcomes (SE, SD & CI)
 - QALY gain (SE, SD & CI)
 - Incremental costs (SE, SD & CI)
- **Interpretation of Data:**
 - Costs and Outcome- categorised as definitely/probably/ probably not/ definitely not effective
 - Cost per QALY- definitely/ probably/ probably not/definitely not efficient

Preliminary Key Findings:

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