SA114

Development of a Tool To Assist in Identifying Study Designs for the Purposes of HTA

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INTRODUCTION

As the most internally rigorous designs, randomised controlled trials (RCTs) are the gold standard for assessing the efficacy and safety profile of interventions. Increasingly, health technology assessment (HTA) considers evidence from non-randomised studies. Guidance recommends synthesising different study designs separately due to their different inherent biases/limitations. However, when authors or reviewers misclassify studies, this can affect which studies are included in a review and, therefore, the review results.

METHODS

This methods study aimed to:

1. Develop a clear study design classification system for studies evaluating pharmaceutical treatments.
2. Explore whether the use of such a system produces consistent study design categorisations amongst reviewers of all levels of experience.
3. Iteratively improve the classification system.

The tool was developed by review of existing algorithms (identified by pragmatic web-based search) and by reviewer testing on 18 published papers (median 7 reviewers, range 4 to 8). Improvements included clarifications to wording prompts, re-ordering and adding study designs (single-arm trials, interrupted time series studies, and different RCT designs).

This poster summarises the next phase of testing, in which the revised tool was piloted for consistency and user experience by web-based survey of reviewers external to our organisation. Reviewers were asked to use the system to categorise 16 published studies.

RESULTS

14 people responded, of which 7 labelled ≥1 study. These 7 responders:

- Worked in HEOR consultancies (4), academia (2), or did not report this detail (1)
- Had a median of 5 years' experience conducting reviews (range 3 to 20+)
- Had completed a median of 10 reviews (range 0 to 100+)
- Had a median of 1.7 years' experience designing studies (range 0 to 6).

A median of 3 responders (range 2 to 7) categorised each study.
Consistency (100% agreement) was achieved for only 5 (31%) studies: 2 RCTs, 1 cross-over RCT, 1 single arm trial (SAT), 1 case series.
Between-responder agreement for the remaining 11 studies was 50% to 67%.

Considering YHEC reference labels:

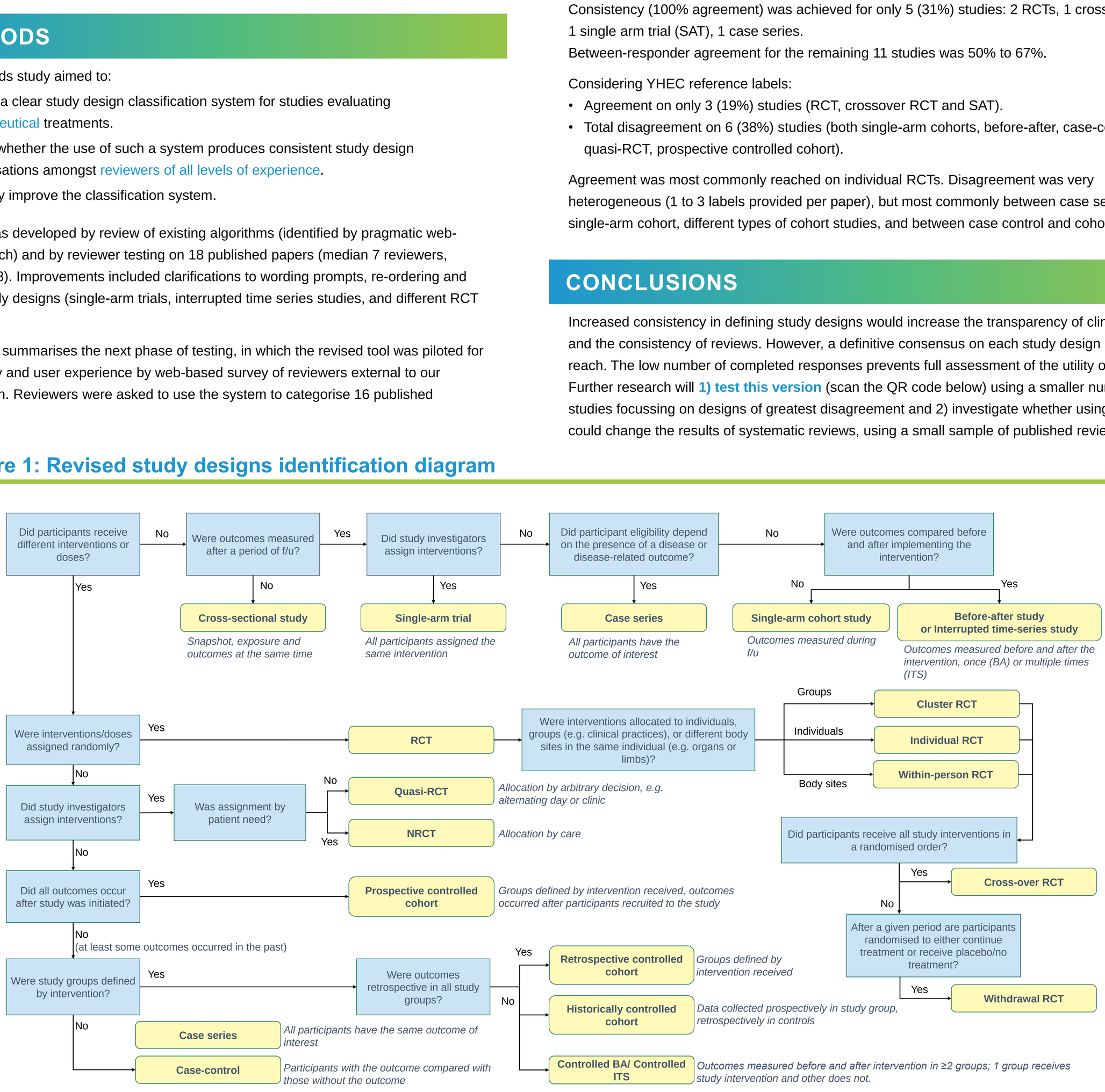
- Agreement on only 3 (19%) studies (RCT, crossover RCT and SAT).
- Total disagreement on 6 (38%) studies (both single-arm cohorts, before-after, case-control, quasi-RCT, prospective controlled cohort).

Agreement was most commonly reached on individual RCTs. Disagreement was very heterogeneous (1 to 3 labels provided per paper), but most commonly between case series and single-arm cohort, different types of cohort studies, and between case control and cohort studies.

CONCLUSIONS

Increased consistency in defining study designs would increase the transparency of clinical studies and the consistency of reviews. However, a definitive consensus on each study design is hard to reach. The low number of completed responses prevents full assessment of the utility of this tool. Further research will **1) test this version** (scan the QR code below) using a smaller number of studies focussing on designs of greatest disagreement and 2) investigate whether using the tool could change the results of systematic reviews, using a small sample of published reviews.

Figure 1: Revised study designs identification diagram



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