An Audit of Evidence Review Group Criticisms of Systematic Literature Reviews Conducted to Inform Manufacturers' Submissions to the National Institute for Health and Care Excellence

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Objectives

 To review the feedback that Evidence Review Groups have provided on systematic literature reviews presented in manufacturers' single technology appraisal submissions to NICE, identify the methodological and reporting approaches most likely to be criticised, and make recommendations for manufacturers on avoiding these criticisms.

Background

- The single technology appraisal (STA) template for manufacturer submissions to the National Institute for Health and Care Excellence (NICE) requests systematic literature reviews (SLRs) on both clinical and health economic topics.
- As SLRs can be time-consuming and resource-intensive to conduct, it is important to maximise their impact within the manufacturer's submission by avoiding Evidence Review Group (ERG) criticism if possible.

Methods

- Manufacturer submissions to NICE (STAs using the January 2015 STA submission template only) and associated ERG reports published on the NICE website between 1 January 2015 and 14 August 2017 were downloaded from the NICE website.
- Key information was extracted regarding the methodological and reporting approach taken by the manufacturer with respect to the SLRs and any relevant ERG comments.

Results

- 56 manufacturers' submissions and associated ERG reports were reviewed.
- In the 56 submissions, 59 SLRs were conducted to inform the clinical sections. All submissions reported an SLR designed to identify evidence from randomised controlled

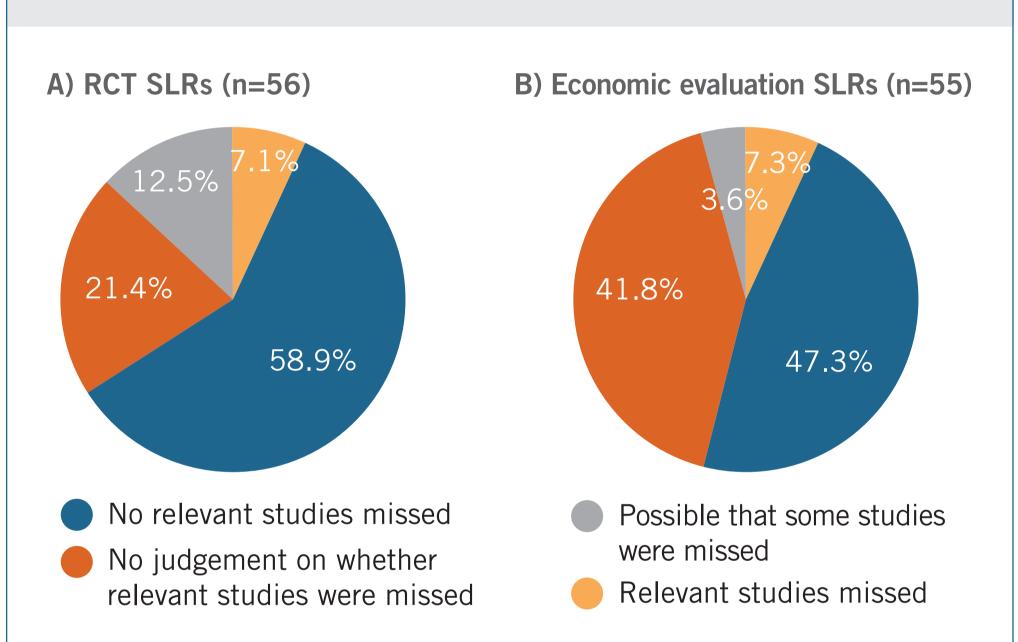
trials (RCTs), while 25 (45%) also presented SLRs designed to capture evidence from non-RCTs.

• 55 submissions (98%) presented an SLR on economic evaluations; 53 submissions (95%) on health-related quality of life (HRQoL); and 45 submissions (80%) on cost and resource use (CRU) data. In most submissions, each topic was investigated independently of any other.

ERG Criticism of RCT and Economic Evaluation SLRs

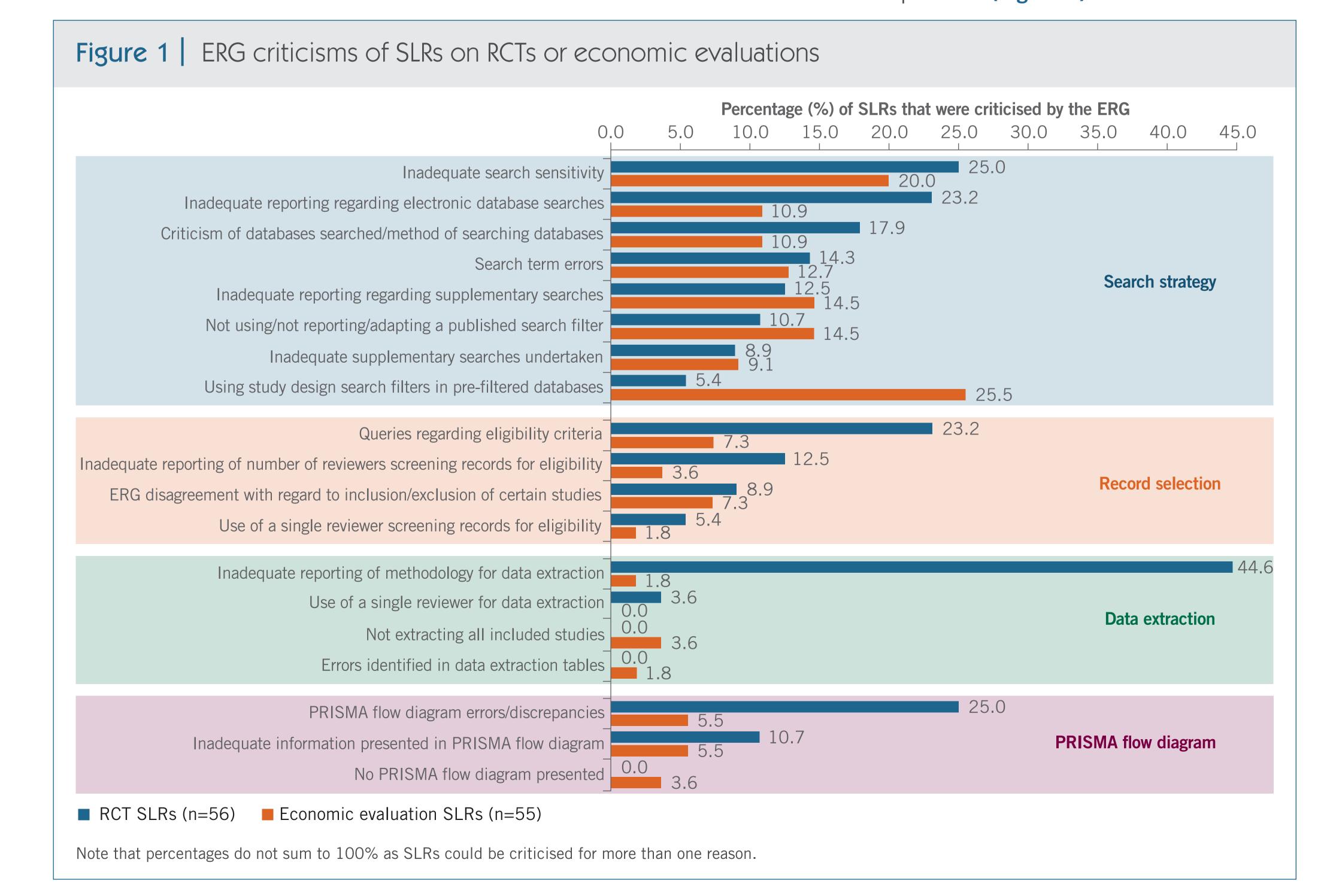
- Criticism was provided by the ERGs on each RCT and economic evaluation SLR presented in these submissions (Figure 1).
- Despite criticism being common, it was unusual for the ERG to identify relevant studies that the SLR had missed (Figure 2).

Percentage of SLRs on RCTs and economic Figure 2 evaluations in which the ERG believed that relevant studies had been missed

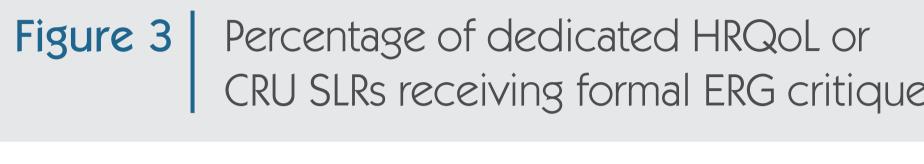


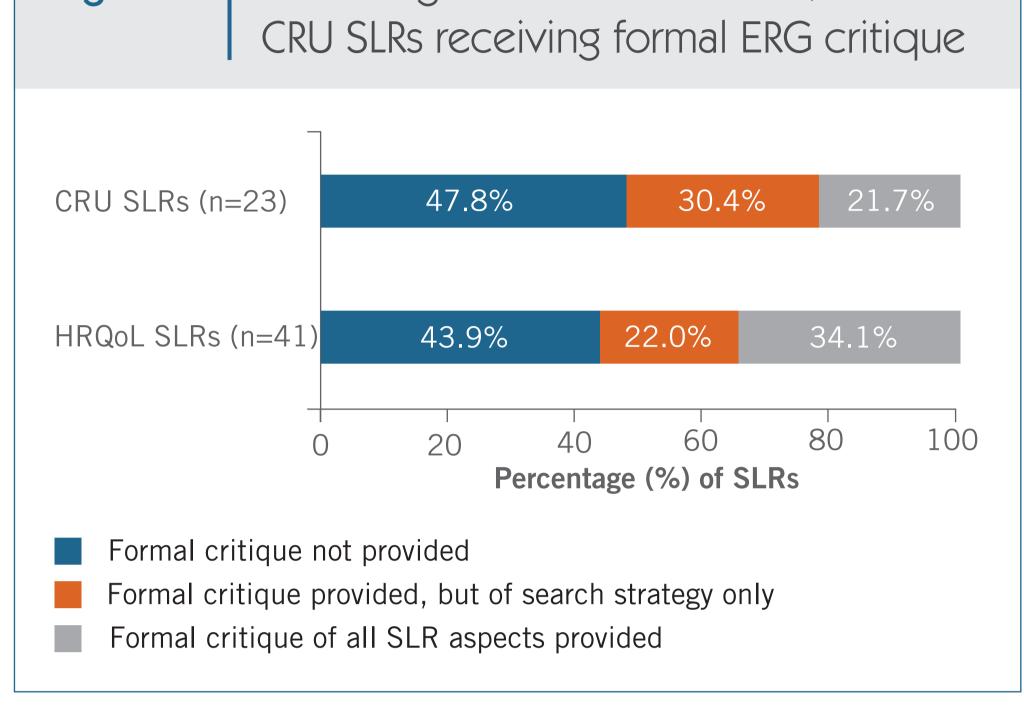
ERG Criticism of HRQoL and CRU SLRs

 When manufacturers conducted SLRs on the HRQoL or CRU topics in isolation (i.e. independently of other topics), detailed ERG critique across all aspects of the SLR was often not provided (Figure 3).



• There was inconsistency between ERGs, and individual ERGs were also inconsistent within themselves between submissions in terms of whether they provided critique on these SLRs as standard (data not presented).





Key Recommendations to Avoid ERG Criticism

- Methodology:
- Constructing error-free and adequately sensitive search strategies, tailored to the individual databases (e.g. use of MeSH and Emtree terms; using unmodified, validated search filters when appropriate; not using study design search filters in the Cochrane Library).
- Performing adequate supplementary searches (e.g. of congresses and resources such as the Tufts Cost-Effectiveness Analysis Registry).
- Reporting:
- Reporting full details of all searches conducted, including search filters used, search dates and spans, and numbers of results per search string.
- Providing rationales for the use of date limits or other eligibility criteria, especially if these deviate from the NICE scope.
- Reporting the approach to record screening and data extraction.
- Ensuring the PRISMA flow diagram is maximally informative and free from errors or discrepancies with the surrounding text.

Conclusions

- Implementing the recommendations presented here would be most impactful on ERG feedback regarding RCT and economic evaluation SLRs, as SLRs on HRQoL or CRU data alone are not always subject to such rigorous critique.
- It is reassuring that, in this analysis, SLR limitations identified by ERGs only rarely led to assertions by ERGs that relevant studies had been missed.
- The database of information established for this audit should provide a rich data source for further investigative research aimed at providing manufacturers with informative insights related to appropriate practice in SLRs for health technology assessments.

References

References to individual STAs and ERG reports are available on request. Acknowledgements

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