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Objectives

- To perform an audit of clinical literature reviews submitted as part of the NICE Medical Technologies Evaluation Programme.
- To identify the methodological and reporting approaches most likely to be criticised, and explore the impact of such criticism.

Background

- As part of the National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme (MTEP) assessment, manufacturers conduct a systematic literature review (SLR), which is appraised by an independent External Assessment Centre (EAC).
- SLRs are intended to find all relevant evidence describing clinical efficacy of the assessed technology; therefore, high-quality and robust SLRs may facilitate decision-making.
- Our work builds upon a previous audit of SLRs that have been submitted to NICE as part of the technology appraisal process.¹

Methods

- EAC reports and Medical Technologies Guidance (MTG) documents of all published MTEP submissions that presented a clinical literature review, and for which both documents were publicly available as of March 2018, were reviewed.
- The methodology of the clinical SLR, studies identified, types of EAC feedback, and the recommendation received were extracted by a single reviewer.
- EAC feedback criteria were pre-defined into 4 major categories ('search strategy', 'record selection', 'data extraction' and 'PRISMA flow diagram') using 22 specific questions based on relevant reporting standards and quality appraisals.

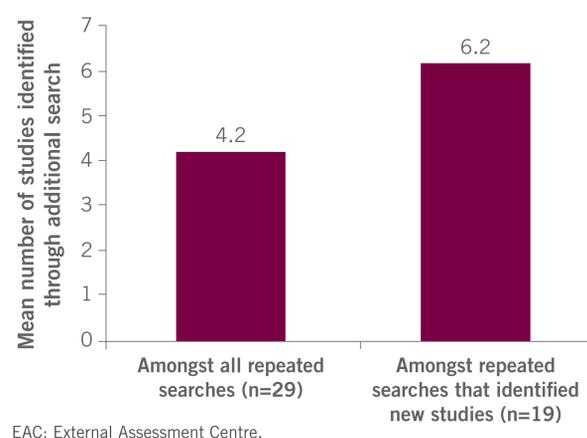
Results

- Of the 37 MTEP submissions available, 33 presented a clinical SLR (32 SLRs and 1 ongoing literature review process) and were eligible for analysis.
- Amongst the 33 appraisals, the highest level of evidence identified was randomised controlled trials (RCTs) in 58%, controlled studies in 9%, and non-controlled studies in 33% of the submitted reviews.

EAC Criticism of Literature Reviews

- All reviews received at least one criticism from the EAC; the mean number of criticisms per review was 9.7.
- The category that was most commonly criticised was 'search strategy'; however, the most common criticism at the individual component-level was disagreement with the inclusion or exclusion of studies, which occurred in 74% of reviews (Figure 1).

Figure 2 | Studies identified in the EAC's additional literature searches



Additional Analyses Undertaken by the EAC

- The EAC performed its own literature search for 88% of appraisals, identifying additional literature in two-thirds of these cases (Figure 2).
- In total, 24% of MTEP submissions included a meta-analysis. The EAC performed their own meta-analysis for 15% of submissions that did not.

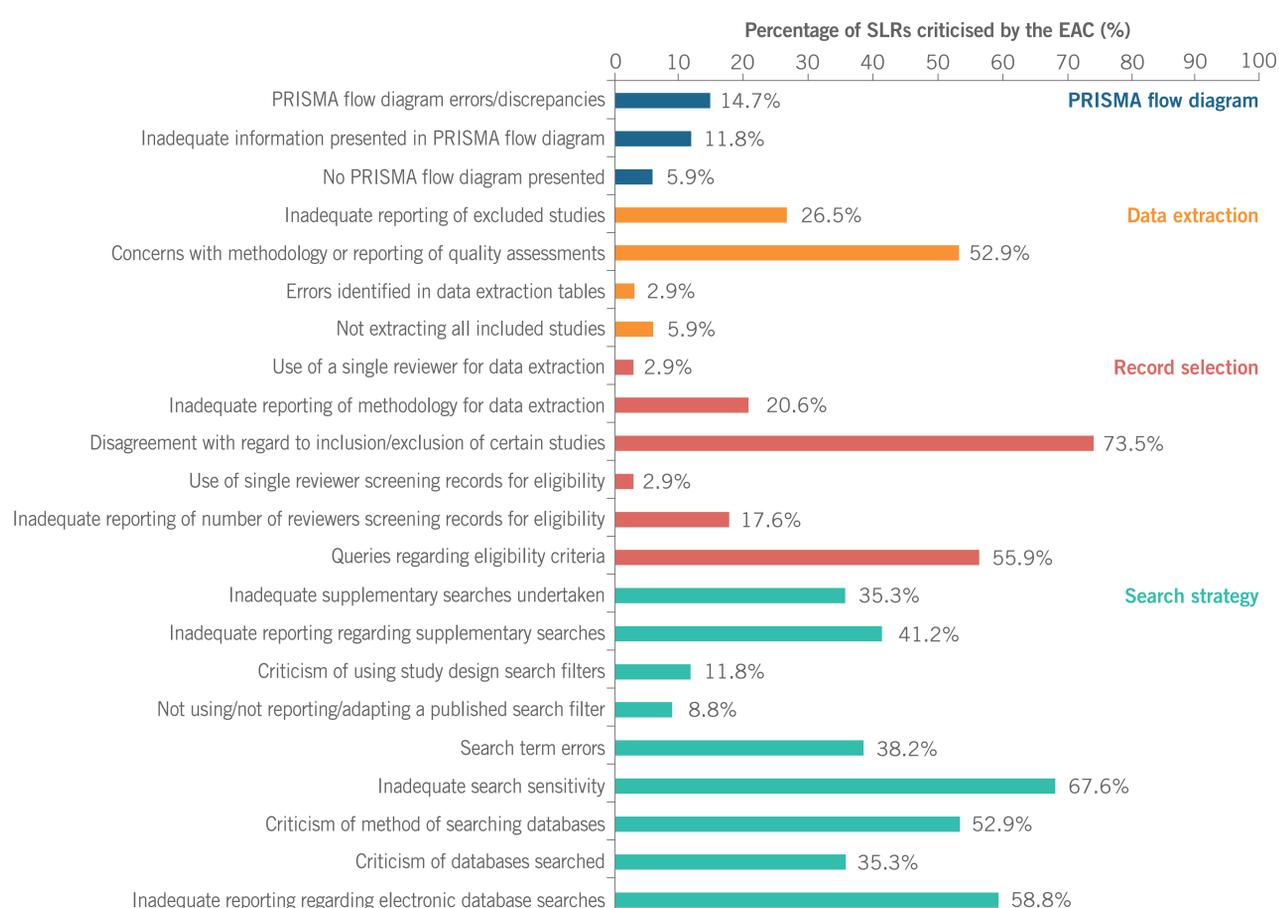
Impact of EAC Feedback

- Overall, reviews supporting submissions that were not recommended received the same amount of criticism as those which were ($p=0.93$) (Figure 3).
- When comparing assessments with a positive recommendation against those without, there was a very similar proportion of assessments for which the EAC conducted its own SLR (81% vs 83%, respectively), and EAC reviews that found additional studies (65% vs 67%, respectively).

Figure 3 | Impact of the EAC's criticism on recommendation



Figure 1 | Summary of EAC criticisms of SLRs



EAC: External Assessment Centre; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SLR: systematic literature review.

Key Recommendations to Manufacturers

- Construct error-free and adequately sensitive search strategies, and perform searches in appropriate databases.
- Develop suitable eligibility criteria to ensure all relevant publications are included, and ensure all studies are strictly reviewed according to such criteria.
- Perform quality assessments of included studies using established and validated criteria.
- Report full details of:
 - Searches and supplementary searches conducted, including search filters, dates and the number of results returned
 - The approach used for record screening and data extraction

Conclusions

- Literature reviews supporting MTEP submissions typically fail to meet the methodological and reporting standards required for high-quality SLRs. Comparison with previous research suggests that MTEP clinical literature reviews receive more criticism than SLRs supporting single technology appraisal submissions.¹
- Given the clear guidance in the NICE MTEP submission template to be systematic and transparent in evidence presentation, a surprisingly wide variety in SLR quality supporting MTEP submissions was observed.
- It is unlikely that the quality of SLRs directly impacts decision-making. However, our results identify areas where manufacturer SLRs can be strengthened and more clearly reported, which may help to streamline the MTEP appraisal process.

References

- Leonard, SA. *et al.* Value in Health. 2017;20:A697-8.

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