The Use Of Real-World Evidence To Support National Institute For Health And Care Excellence Medical Technology Submissions

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Abbreviations

EAC: External assessment centre, **MTEP**: Medical Technologies Evaluation Programme, **MTAC**: Medical technologies advisory committee, **MTG:** Medical technology guidance, **NHS**: National Health Service, **NICE:** National Institute for Health and Care Excellence, **RCT**: randomized controlled trial, **RWE**: real-world evidence, **UK**: United Kingdom.

Objective

- To examine how clinical RWE supports decisions made by NICE MTEP.

Background

- MTEP selects and evaluates new or innovative medical devices and diagnostics to assist the NHS in the uptake of efficient and cost-effective medical technologies (**Figure 1**).
- Although RCTs provide high level clinical evidence, few medical-device RCTs are available, oftentimes due to underfunding or challenges associated with trial design.
- Meta-analyses provide a framework for combining treatment effects and are a higher level of evidence than individual studies.
- Although meta-analyses of RCTs only are most valuable, combinations of RWE and RCTs, or RWE only can offer robust evidence.

Methods

- All MTEP guidance documents published online prior to October 2020 were reviewed.
- The 'case for adoption' recommendation, types of clinical evidence, and clinical critiques for MTEP submissions were extracted and categorized.
- RWE was defined as studies with neither blinding nor prospective selection/control of patient characteristics.

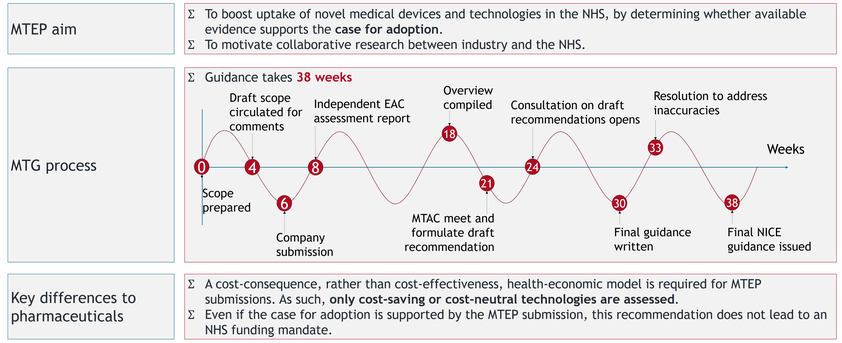

Figure 1 Information box: NICE MTEP - EAC: external assessment centre; MTAC: medical technologies advisory committee; MTEP: Medical Technologies Evaluation Programme; MTG: medical technologies guidance; NHS: National Health Service; NICE: National Institute for Health and Care Excellence.

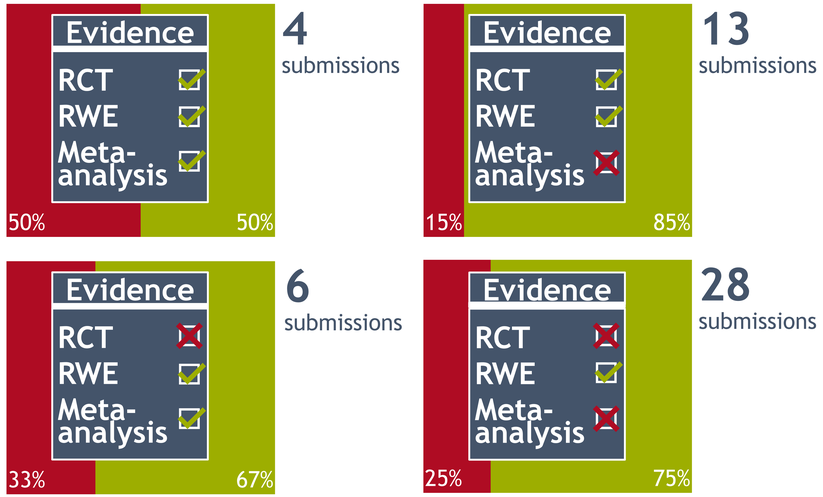

Figure 2 Evidence level and acceptance decision for 45 MTEP submissions - RCT: Randomized controlled trial; RWE: Real world evidence

Accepted submissions

Rejected submissions

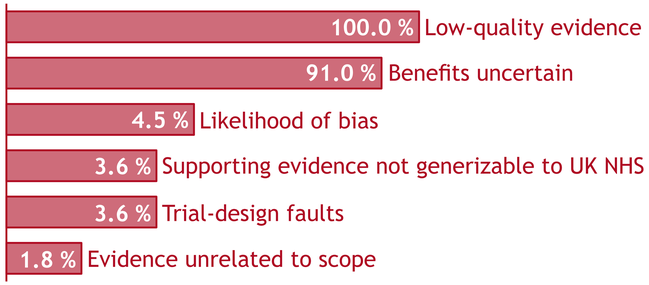

Figure 3 Common critiques among rejected submissions - There were 11 rejected submissions during the investigated time frame. Some submissions were critiqued on multiple issues. This list does not contain all critiques voiced.

Results

- 34 of 45 (76%) MTEP submissions received a positive MTEP recommendation.
- 17 of 45 (38%) submissions utilized RCT evidence as their primary evidence source (of which 13 received positive recommendations), while 10 of 45 (22%) submissions conducted a meta-analysis (of which 6 received positive recommendations).
- A summary of the levels of evidence utilized in MTEP submissions is provided in **Figure 2**.
- All 11 MTEP submissions not receiving a positive recommendation were criticized by the EAC for low-quality clinical evidence. Other key critiques are summarized in **Figure 3.**

Discussion

- There is a greater need for more and higher-level evidence in the field of medical-technology evaluations.
- While high-level evidence such as RCTs and meta-analyses are desired, they do not guarantee a recommendation alone.
- RWE alone can be sufficient for a technology to be recommended by MTEP.
- Evidence is most likely to be accepted when it is generalizable to the UK NHS and fits the scope of the submission; obviously, a clear indication of benefit is required.
- The NICE 5-year strategy (2021-2026) supports the use of RWE in MedTech. NICE also encourage early engagement with manufacturers to align on evidence generation plans and ensure that all evidence can be communicated well

Conclusion

- RWE supports MTEP submissions to a large extent and can enrich the available evidence base for assessing medical technologies.
- Further guidance on the use of RWE in health technology evaluation for medical devices is desirable.

Disclosure
SG, SJS, AHH, MB, and RTT are employees of Coreva Scientific. RS is the owner of Coreva Scientific.