



Challenges facing the health technology assessment (HTA) submissions of second-line treatments for advanced oncology

Bhadti S; Redhead G; Tatman S; Lang SH
Mtech Access, Bicester, United Kingdom

ISPOR Poster Acceptance Code: HTA94
Abstract ID: 131507

Aims & Methods

- To determine the clinical evidence base, analyses, and criticisms of advanced oncology HTA submissions
- The NICE website was searched for HTA submissions assessed in the previous 12 months (to 18th April 2023) in advanced or metastatic oncology receiving second-line treatments
- The following data were extracted by one reviewer and checked by a second:
 - Study design characteristics of the included trials
 - Statistical analyses
 - Thematic analysis of criticisms raised by the EAG/committee
- The identified submissions were matched to those from Canada (CADTH) and Germany (G-BA/IQWiG), to assess similarities and differences

Summary of submissions to NICE

- 21 of 96 (22%) NICE submissions were identified for advanced oncology
- Of the 21 submissions: 15 were accepted; five were terminated; one was rejected
- 16 submissions were appraised (shown in the figure 1)
- Reasons for rejection of TA850:
 - Lack of direct comparative evidence
 - The approach to identifying RWE (for comparator arm) may not have been robust
 - Indirect comparisons were associated with uncertainty and limited use of covariates
- Trials ranged in size, from 26 to 700 participants

Additional evidence provided by RWE

- Nine of 16 submissions included RWE
- 22% (2 of 9) identified RWE data by systematic review
- RWE provided comparative data (n=7)
- RWE validated clinical trial efficacy and safety data (n=3)

Additional evidence provided by expert opinion

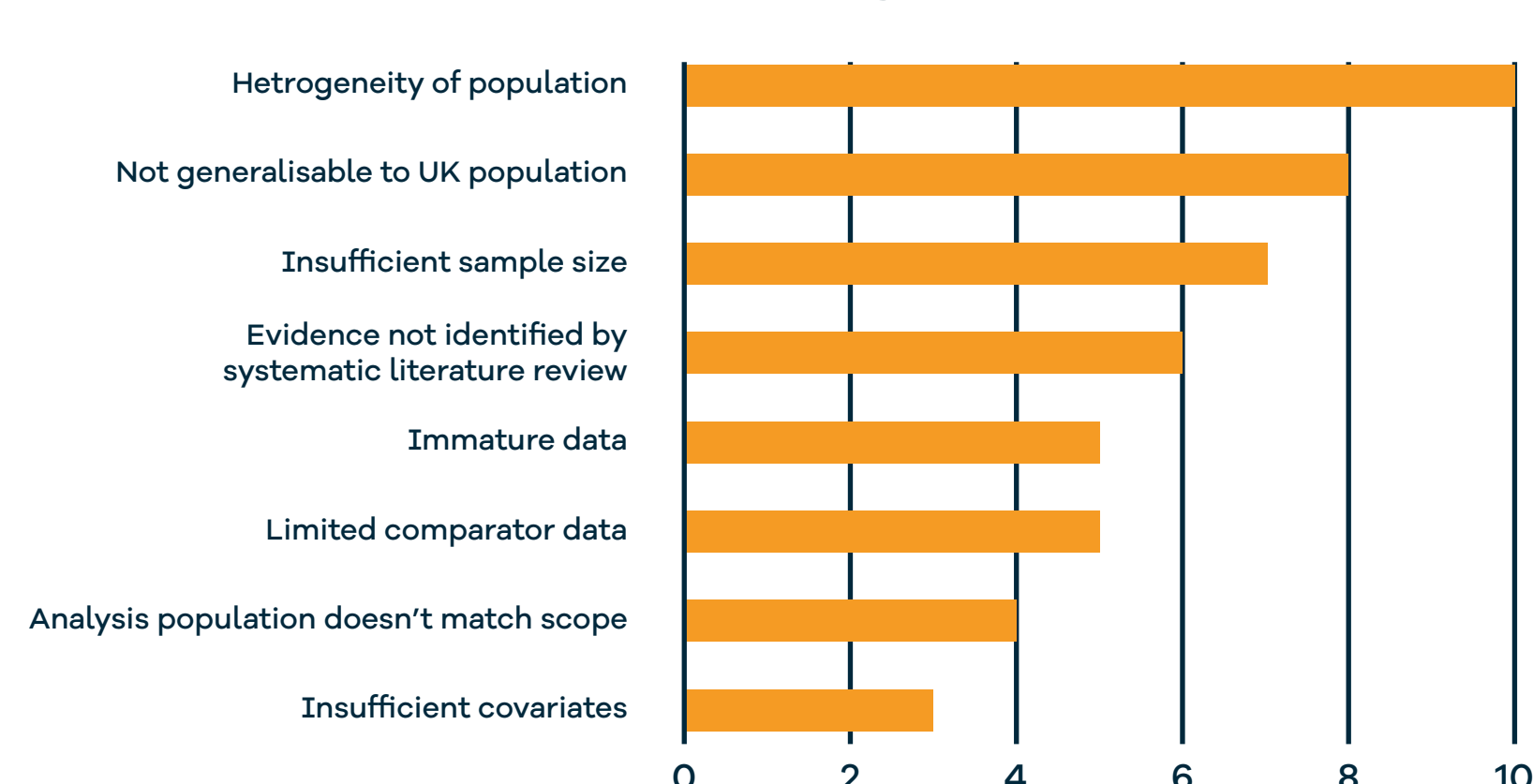
- Eight submissions included expert opinion to:
- Validate prognostic variables/effect modifiers (n=6)
 - Identify the proportions of patients receiving subsequent therapy (n=1)
 - Select the most appropriate comparator (n=1)
 - Select proxy populations (n=1)

Figure 2: Types of statistical analyses identified in the submissions (n=16)



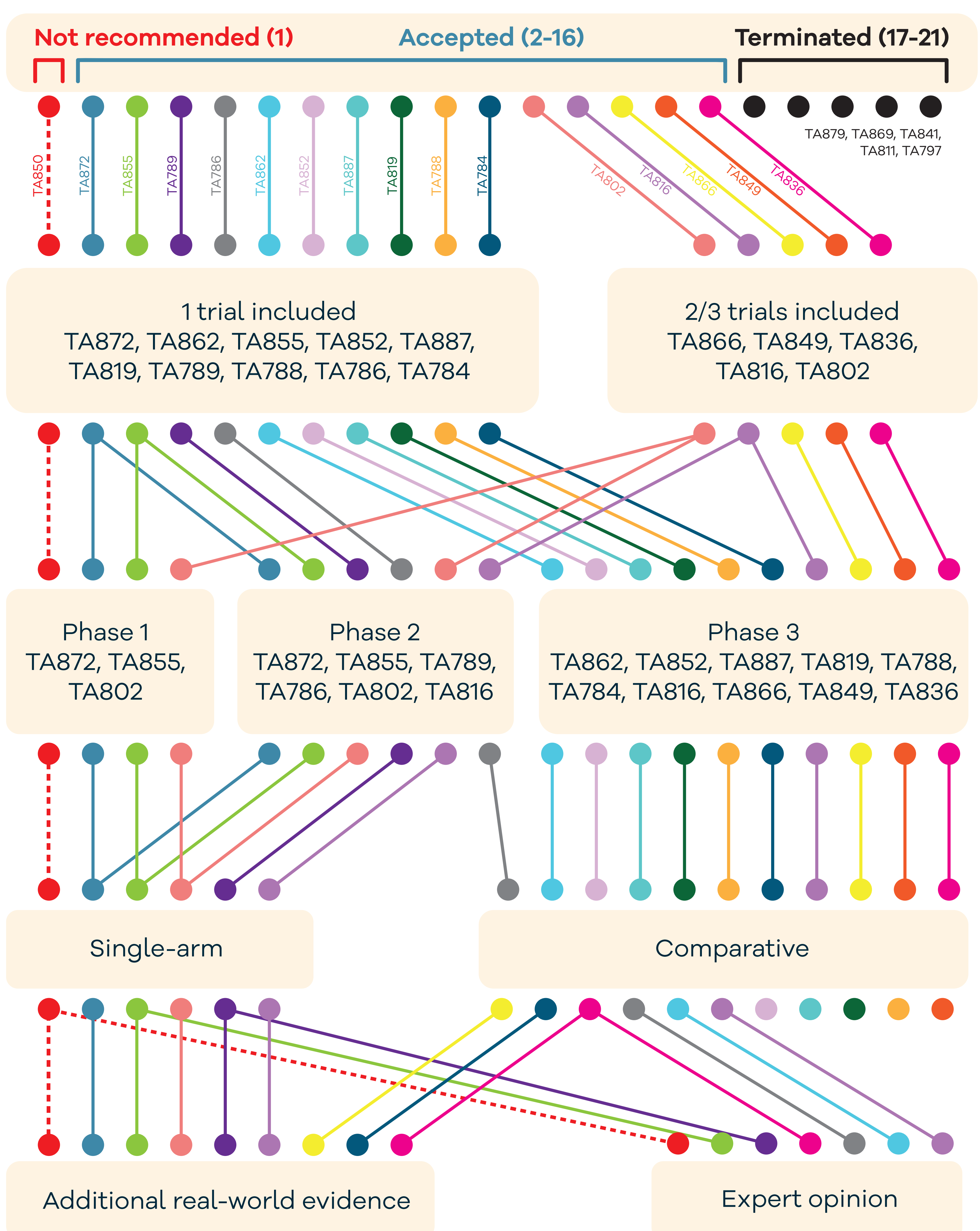
Abbreviations: ITC, indirect treatment comparison; MAIC, matching-adjusted indirect comparison; NMA, network meta-analysis; RCT, randomised controlled trial. The most frequently reported analysis was an ITC (n=10), followed by MAIC (n=9).

Figure 3: Thematic analysis of the criticisms raised by the External assessment group/committee (n=16)



- The most frequently reported criticisms:
 - Heterogeneity of trial populations
 - Not generalisable to UK population
 - Insufficient sample size
 - Evidence not identified by SLR

Figure 1: Study characteristics of the NICE submissions



Comparison to IQWiG submissions

- 15/16 NICE appraisals were matched to IQWiG:
- The appraisal rejected by NICE was also rejected by IQWiG
 - 5/14 submissions approved by NICE were not approved/showed no benefit by IQWiG
 - 3/15 did not include the same trial evidence
 - 3/8 NICE appraisals that included RWE also considered RWE for IQWiG
 - The evidence review contained a greater discussion around HRQoL and safety

Comparison to CADTH submissions

- 15/16 NICE appraisals were matched to CADTH:
- The appraisal rejected by NICE was also rejected by CADTH
 - 3/14 submissions approved by NICE were not reimbursed by CADTH
 - 1/15 did not include the same trial evidence
 - 4/8 NICE appraisals that included RWE also considered RWE for CADTH
 - The evidence review contained a greater discussion around HRQoL and safety. Criticisms were broadly similar to NICE

Conclusion

- A large proportion of HTA submissions to NICE are in second-line treatments for advanced oncology
- Evidence for advanced oncology indications is limited and often immature
- To address the lack of evidence, submissions to NICE are frequently supplemented by RWE and expert opinion. Approximately half of similar submissions to CADTH or IQWiG are supplemented by RWE
- Reasons for rejection or criticism are frequently concerned with the lack of comparable evidence and the inclusion of RWE that is not identified via systematic review
- Early evidence generation strategies should include systematic review for RWE and prognostics factors to supplement clinical evidence



ISPOR Europe 2023, 12-15 November 2023, Copenhagen, Denmark

Acknowledgements

The authors would like to thank Janine Ross, Sarah Batson and Laura Mathers for their contribution to identifying the evidence for the poster.

(Stand No. C3-053)

References

- NICE (TA850) Available from: <https://www.nice.org.uk/guidance/ta850> [accessed July 2023]
- NICE (TA872) Available from: <https://www.nice.org.uk/guidance/ta872> [accessed July 2023]
- NICE (TA855) Available from: <https://www.nice.org.uk/guidance/ta855> [accessed July 2023]
- NICE (TA789) Available from: <https://www.nice.org.uk/guidance/ta789> [accessed July 2023]
- NICE (TA786) Available from: <https://www.nice.org.uk/guidance/ta786> [accessed July 2023]
- NICE (TA862) Available from: <https://www.nice.org.uk/guidance/ta862> [accessed July 2023]
- NICE (TA852) Available from: <https://www.nice.org.uk/guidance/ta852> [accessed July 2023]
- NICE (TA887) Available from: <https://www.nice.org.uk/guidance/ta887> [accessed July 2023]
- NICE (TA819) Available from: <https://www.nice.org.uk/guidance/ta819> [accessed July 2023]
- NICE (TA788) Available from: <https://www.nice.org.uk/guidance/ta788> [accessed July 2023]
- NICE (TA784) Available from: <https://www.nice.org.uk/guidance/ta784> [accessed July 2023]
- NICE (TA802) Available from: <https://www.nice.org.uk/guidance/ta802> [accessed July 2023]
- NICE (TA816) Available from: <https://www.nice.org.uk/guidance/ta816> [accessed July 2023]
- NICE (TA866) Available from: <https://www.nice.org.uk/guidance/ta866> [accessed July 2023]
- NICE (TA849) Available from: <https://www.nice.org.uk/guidance/ta849> [accessed July 2023]
- NICE (TA836) Available from: <https://www.nice.org.uk/guidance/ta836> [accessed July 2023]
- NICE (TA879) Available from: <https://www.nice.org.uk/guidance/ta879> [accessed July 2023]
- NICE (TA869) Available from: <https://www.nice.org.uk/guidance/ta869> [accessed July 2023]
- NICE (TA841) Available from: <https://www.nice.org.uk/guidance/ta841> [accessed July 2023]
- NICE (TA811) Available from: <https://www.nice.org.uk/guidance/ta811> [accessed July 2023]
- NICE (TA797) Available from: <https://www.nice.org.uk/guidance/ta797> [accessed July 2023]

Abbreviations

CADTH: Canadian Agency for Drugs and Technologies in Health, EAG: External assessment group, G-BA: Federal Joint Committee, HTA: Health Technology Assessment, ITC: Indirect treatment comparison, IQWiG: Institute for Quality and Efficiency in Health Care, MAIC: Matching-adjusted indirect comparison, NHS: National Health Service, NICE: National Institute for Health and Care Excellence, NMA: Network meta-analysis, PFS: Progression-free survival, RWE: Real-world evidence, SLR: systematic literature review