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A qualitative study of manufacturers' submissions to the UK NICE single technology appraisal process

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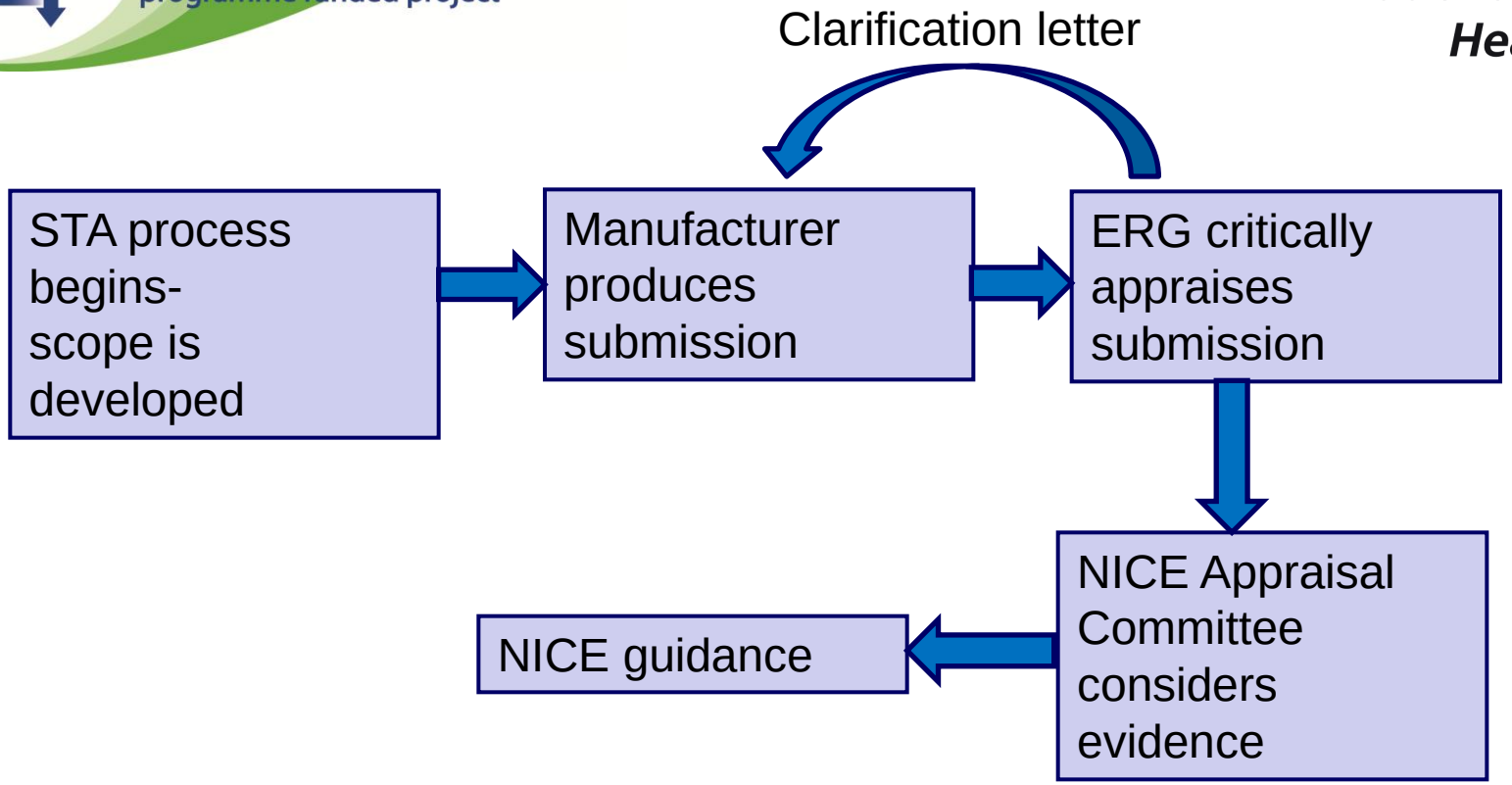
Outline

- Background
- Methods
- Results
- Recommendations

NICE STA process

- Introduced in 2005
- Single technology for a single condition
- Manufacturer produces a submission outlining the clinical and cost effectiveness of the technology
- Evidence Review Groups (ERGs) critically appraise the submission and produce a report
- A clarification letter is sent to the manufacturer by NICE with questions from the ERG
- ERG report and submission are used by the NICE Appraisal Committee to make recommendations on the use of technologies


Clarification letter
STA process begins- scope is developed
Manufacturer produces submission
ERG critically appraises submission
NICE Appraisal Committee considers evidence
NICE guidance

NICE STAs

- Manufacturer has approximately 9 weeks to produce a submission
- ERG has 8 weeks to produce a report
- Responsibility of the manufacturer to present the case for the technology
- The ERG does not produce a new review or new model

Research team

University of Sheffield

- Eva Kaltenthaler
- Chris Carroll
- Patrick Fitzgerald
- Diana Papaioannou
- Ron Akehurst

University of Liverpool

- Rumona Dickson
- Angela Boland

Critical appraisal research

- Short report commissioned by NIHR Evaluation, Trials and Studies Coordinating Centre

Aims were to:

- identify current approaches used by the ERG groups to critically appraise manufacturers' submissions
- Identify recurring themes in clarification letters
- Map the NICE STA process for the first 95 STAs
- Develop a new ERG report template
- Make recommendations

Methods: ERG reports

- Thematic analysis of first 30 completed ERG reports using a framework approach
- Data on the strengths and weaknesses of each manufacturer submission were extracted and coded
- Themes emerging from data:
  - process
  - reporting
  - satisfying objectives
  - reliability and validity of findings
  - content

Methods: clarification letters

- Thematic analysis of 21 clarification letters associated with the 30 ERG reports
- Set of open codes to categorise data
- Data categorised into:
  - clinical and economic issues
  - indirect comparisons
  - licensing
  - systematic review methods
  - report quality

Results of thematic analysis of ERG reports

- Common issues and concerns were identified
- Many positive comments on the quality of the submissions
- 90% (27/30) identified inadequate reporting of processes
- 67% (20/30) identified criticisms of data being used, especially in models
- 57% (17/30) identified issues with the conduct of the systematic review

Results of thematic analysis of clarification letters

- 400 points of clarification were analysed
- Majority of points related to the economic data analysis
- Issues included:
  - clarification of data sources and choices
  - queries about modelling decisions
  - requests for additional analyses
  - queries regarding internal inconsistencies between the clinical and economic sections of the submission

Development of recommendations

- Workshop to discuss key findings
- 50 participants from all 10 ERG groups NETSCC and NICE
- Set of recommendations for manufacturers ERG teams and NICE
- Many positive aspects in submissions

Recommendations

1. Submissions should be comprehensive, clearly written, appropriately copy edited and internally consistent.
2. Definitions for all key terms and abbreviations should be provided.
3. There should be transparency in the reporting of methods and analyses.
4. Where applicable, reviews should adhere to internationally accepted standards for conducting and reporting reviews.

Recommendations

5. Where there is a single clinical study the study report and protocol should be an addendum to the submission.
6. There should be clear reporting of methods and results used for indirect comparisons.
7. The submission should provide relevant and sufficiently detailed data related to clinical progression, outcomes and adverse events.
8. There should be clear and concise rationale for the synthesis of clinical data.
9. Clear rationale should be provided for the types of analyses chosen for use in the submission.

Recommendations

10. There should be clear and concise rationale for the development of economic models and the assumptions used to develop models need to be provided.
11. A systematic review of utility values should be included where appropriate in the submission.
12. Reviewing of model parameter values should be comprehensive and transparent. How comprehensive depends on how critical the parameter is.

Limitations

- Only the first 30 completed STAs were included in this analysis
- Changes to the STA process: manufacturer's template, clarification process
- We looked at ERGs interpretation of the manufacturers' submissions
- ERGs have different interpretations

Conclusions

Manufacturers' submissions can never contain all necessary data but these recommendations may help to improve the quality of submissions to the NICE STA process.

References

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