Comparison of Systematic Literature Review Requirements Among Health Technology Assessment Agencies in the UK and Ireland

HTA193

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Background and objectives

- Systematic literature reviews (SLRs) are often required for health technology assessment (HTA) submissions to provide a comprehensive analysis of the existing evidence for a specific intervention and its comparator(s).
- The objective of this study was to compare the SLR requirements for reimbursement submissions across the United Kingdom (UK) and Ireland.

Methods

- Reimbursement submission guidelines from the following HTA agencies were identified on their respective websites, and were reviewed and compared:
  - National Institute for Health and Care Excellence (NICE) – England[1]
  - All Wales Medicines Strategy Group (AWMSG) – Wales[2]
  - Scottish Medicines Consortium (SMC) – Scotland[3]
  - National Centre for Pharmacoeconomics (NCPE) – Ireland[4]
- Additionally, HTA agencies were contacted directly via contact details on their websites, in order to clarify any ambiguous guidance, and to enquire about their position on SLRs being undertaken within a specific time period prior to submission.

Results

- An overview of the SLR requirements of the four HTA agencies investigated is presented in Table 1. Additional detail on the specific guidance given by each HTA agency is presented in Table 2.
- Although AWMSG provided some guidance on SLR requirements on their website, when contacted directly a representative stated that the AWMSG HTA process is fully aligned with that of NICE.

Clinical systematic literature reviews

- All four HTA agencies require an SLR of clinical data. Key SLR requirements include reporting search strategies, inclusion and exclusion criteria, PRISMA diagrams, and lists of included and excluded studies. Two reviewers were required for NICE, AWMSG, and NCPE, whereas this criterion was not specified by SMC.
- All four HTA agencies expect a critical appraisal of included studies, although no agency requires the use of specific quality assessment tools.
- When contacted directly, three HTA agencies, NICE, AWMSG, and NCPE, specified that they require the date of search for an SLR to be less than 6 months prior to the date of submission. Whilst SMC do not require this, they state that an SLR conducted within 6 months of submission is desirable, to capture all relevant and up-to-date data.

Economic systematic literature reviews

- An SLR of economic models, including critical appraisal, is mandated by NICE alone. If no relevant economic evaluations are identified, NICE requires this to be stated and rationalised.
- NICE and SMC are the only HTA agencies assessed that explicitly require an SLR of healthcare resource use (HCRU) and cost data. Although NCPE does not specifically require an SLR for this purpose, it specifies that the method used to generate resource use and cost data in the economic evaluation should be identified using a systematic method.
- NICE allows the search strategy for a HCRU and cost SLR to be extended to capture other countries if the systematic search yields limited data for England alone.
- NICE, AWMSG, and NCPE require an SLR for utility data. Additionally, SMC require a utility SLR when utility values used for economic models have been sourced from the published literature.

Discussion & conclusions

- SLR requirements among HTA agencies vary within the UK and Ireland. Although all the agencies require a clinical SLR with a critical appraisal of included studies, the requirement for economic SLRs varies, with NICE and AWMSG being the only agencies to mandate an economic model SLR.
- In general, the SLR requirements were well reported; however, one key issue identified is the lack of clear reporting regarding economic SLRs. In addition, timeframes between SLR searches and submissions were not reported within relevant submission guideline documents. When HTA agencies were contacted directly, they provided additional relevant information that was not publicly available, for example, that the typical timeframe between an SLR search and a HTA submission should be less than 6 months.
- Given there are some variations between UK and Irish HTA agencies, the SLR requirements for each must be considered when preparing for a specific HTA process.

Table 1: Overview of SLR requirements of NICE, SMC, AWMSG, and NCPE

Submission requirement	NICE (England)	SMC (Scotland)	AWMSG (Wales)	NCPE (Ireland)
Clinical SLR required?	✓	✓	✓	✓
Economic evaluation SLR required?	✓	✗	✓	✗†
HCRU and cost SLR required?	✓	✓	✓	✗‡
HSUV SLR required?	✓	✓	✓	✓

†While NCPE do not require a SLR for HCRU & cost data, it is required that costs are identified using a systematic method. ‡SLRs are required for HRQOL data (not limited to utility data only).
Abbreviations: AWMSG, All Wales Therapeutics and Toxicology Centre; HCRU, healthcare resource use; HSUV, health state utility value; NICE, National Institute for Health and Care excellence; NCPE, National Centre for Pharmacoeconomics; SLR, systematic literature review; SMC, Scottish Medicines Consortium.

Table 2: Additional details on SLR requirements of NICE, SMC, AWMSG, and NCPE

Submission requirement	NICE (England)	SMC (Scotland)	AWMSG (Wales)	NCPE (Ireland)
Search strategy & data sources	• Perform SLRs according to a pre-defined protocol • Clearly state and rationalise if no relevant economic evaluations are found	• Present full electronic search strategies for all databases, including any limits applied (include origin/name of filters used) and the number of results retrieved • List all information sources, including platform used, databases searched and years of coverage, date search was conducted, details of any personal communications • Report eligibility criteria, preferably using the PICOS framework (including date limits, language limits, publication or study type limits, human/animal limits applied)	• Fully aligns with NICE SLR requirements	• Perform SLRs according to a pre-defined protocol • Include a description of the search strategy, inclusion and exclusion criteria applied and restrictions used in locating studies (for example, language, population, and year)
Study selection & data collection	• Two reviewers required to screen studies • Procedure for resolving disagreements between reviewers should be clearly reported as outlined in the PRISMA • Record excluded studies and provide a rationale for why studies were excluded • HCRU & cost: If the systematic search yields limited data for England, the search strategy may be extended to capture data from other countries	• PRISMA diagram indicating the flow of studies through the SLR should be provided • List of studies included or excluded (with reason for exclusion) should be provided • Details of studies should be taken from complete published reports or publications produced by regulatory authorities. If a published report of the study is not available, details should be taken from clinical study reports • Abstracts and posters may be provided to demonstrate that information is in the public domain but are not appropriate sources for descriptions of the study methodology or primary outcomes of studies. However, if adequately detailed, they may be references for some relevant additional data	• Fully aligns with NICE SLR requirements	• Two or more reviewers should be involved in the selection process • The mechanisms used to resolve disagreement should be clearly outlined • A log of ineligible studies should be maintained including a rationale for their individual exclusion in relation to the study question
Assessment of bias	• Critical appraisal of included studies required • Tools should be used to try and assess unpublished or partly published studies	• Provide a quality assessment of studies included, indicating which tool has been used to assess for bias • The risk of bias for each domain assessed by the specific tool should be tabulated and reported and an overall assessment of the risk of bias stated	• Fully aligns with NICE SLR requirements	• Individual studies selected based on the inclusion criteria should be critically assessed for their validity and relevance to the study question
Time period from date of search to date of submission†	• The date of search of the SLR should be less than 6 months prior to the date of submission	• SMC does not state that an SLR should be undertaken within a specific period prior to submission; however, an SLR conducted within 6 months of submission is desirable	• Fully aligns with NICE SLR requirements	• SLRs for comparative clinical effectiveness and HRQoL evidence should be updated within 6 months of submission

†Timeframe requirements were not publicly available and were obtained by directly contacting HTA agencies via email.
Abbreviations: AWMSG, All Wales Medicines Strategy Group; HCRU, healthcare resource use; HRQoL, health-related quality of life; NICE, National Institute for Health and Care Excellence; NCPE, National Centre for Pharmacoeconomics; PICOS, population, intervention, comparator(s), outcome(s), study design; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SLR, systematic literature review; SMC, Scottish Medicines Consortium.

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