HTA298

Similarities and Differences Between the NICE and EU JCA Clinical SLR Requirements

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Background and objectives

- The main objectives of the European Union Joint Clinical Assessment (EU JCA) and National Institute for Health and Care Excellence (NICE) health technology assessment (HTA) processes differ, and the clinical systematic literature review (SLR) requirements may reflect the differences in purpose of each process (Figure 1).
- A clinical SLR is crucial for evaluating efficacy and safety evidence for submissions to the EU JCA and NICE.[1,2]
- This study aims to compare the requirements and highlight the key similarities and differences between the clinical SLR approaches of the EU JCA and NICE.

Methods

- Published guidance documents from the EU JCA and NICE were reviewed.[2-5]
- Clinical SLR requirements were extracted and compared across the following domains:
  - Searches and the population, intervention, comparator, outcome, study design (PICOS) framework
  - Study screening
  - Handsearching practices
  - Data extraction and quality assessment
  - Submission dossier.

Results

An overview of the clinical SLR requirements for the EU JCA and NICE Health Technology Appraisal (HTA) submissions is presented in Table 1.

Similarities

- The SLR requirements of the EU JCA and NICE are broadly aligned; both approaches encompass key stages such as literature searching, screening, handsearching, data extraction and quality assessment.
- Transparent reporting is essential in both processes, specifically regarding search strings, the flow of studies through the SLR, and the rationale for inclusion or exclusion of publications.

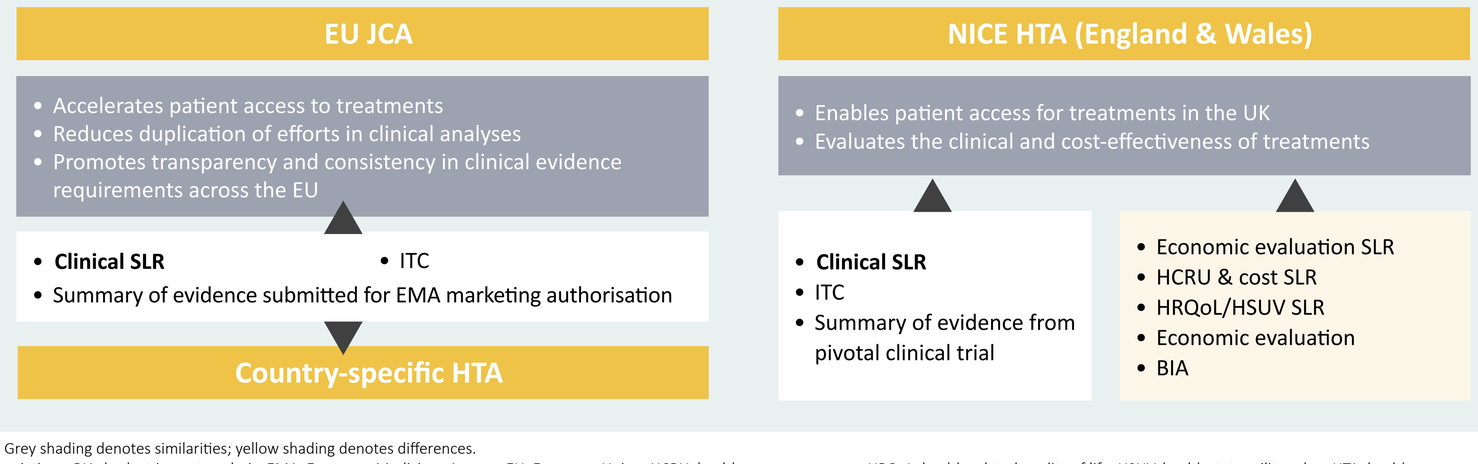
Differences

- Several key differences relating to all SLR stages exist between the EU JCA and NICE approaches.
- The EU JCA mandates searches of MEDLINE and CENTRAL, whereas NICE also requires inclusion of Embase and the Cochrane Database of Systematic Reviews (CDSR).
- Acceptable timelines for the most recent database searches differ between the two processes – the EU JCA prefers a shorter window of 3 months while NICE recommends searches conducted within 6 months prior to submission.[1]
- EU JCA recommends excluding studies reported only as abstracts or posters due to insufficient methodological detail, whereas NICE requires their inclusion in SLRs.
- The EU JCA requires the use of the Risk of Bias 1 (RoB1) tool for randomised trials, noting that although the Risk of Bias 2 (RoB2) tool offers a more detailed bias assessment, it is more time-consuming and RoB1 is already well established. In contrast, NICE allows more flexibility in quality assessment tools but prefers RoB2 for randomised trials.
- Quality assessment of non-comparative studies (e.g. single arm trials, cross-sectional studies, and case studies/reports) is not required by the EU JCA, but appropriate tools should be applied in clinical SLRs for NICE submissions.
- For dossier development, results are to be presented separately according to the PICOS criteria for EU JCA. For NICE, results are to be structured based on a single PICOS framework.

Discussion and conclusions

- Though the EU JCA serves the EU, while NICE focusses on England and Wales only, there are similarities in SLR requirements.
- Robust methods and a requirement for transparent reporting in both approaches ensure high quality SLRs designed to meet agency specific needs.
- The identified differences likely reflect the need for a pragmatic approach to capturing relevant informative evidence within the strict JCA timelines, while encouraging consistent reporting across assessments to facilitate interpretation and the comparison of findings.
- Understanding the similarities and differences between the EU JCA and NICE requirements can help to optimise EU JCA outputs when preparing country-specific HTA submissions, including those for NICE.

Figure 1: Primary objectives and components of EU JCA and NICE HTA submissions



Key: Grey shading denotes similarities; yellow shading denotes differences.
Abbreviations: BIA, budget impact analysis; EMA, European Medicines Agency; EU, European Union; HCRU, healthcare resource use; HRQoL, health-related quality of life; HSUV, health state utility value; HTA, health technology assessment; ITC, indirect treatment comparison; JCA, joint clinical assessment; NICE, National Institute for Health and Care Excellence; SLR, systematic literature review; UK, United Kingdom.

Table 1: Similarities and differences between the clinical SLR approaches of the EU JCA and NICE

SLR stage	EU JCA	NICE
Searches and PICOS framework	Search MEDLINE and CENTRAL; Embase and other databases optional	Search Embase, MEDLINE, CENTRAL, and CDSR
	Searches conducted within 3 months prior to submission	Searches conducted within 6 months prior to submission
	PICOS covers all 27 EU MS	PICOS aligned with UK only
Study screening	Exclude conference abstracts/posters	Include conference abstracts/posters
	Number of reviewers not specified‡	Screening by two reviewers; third reviewer resolves conflicts
	Do not search conference proceedings	Search conference proceedings
Hand searching practices	Clinical trial registries: CTIS, EU-CTR, EMA clinical data platform	Clinical trial registries: clinicaltrials.gov, cancer.gov, EORTC.org, UK clinical trials gateway, WHO International Clinical Trials Registry Platform
	HTA agencies: European Economic Area, Australia, Canada, UK, and USA	HTA agencies: UK, Canada, Australia, and Scotland
	Include subject-specific and patient registries	No requirement to search-subject specific registries
	No specification for other grey literature sources or SLR reference lists	Search other grey literature sources (EuroQoL, google scholar, INAHTA, NIHR) and SLR reference lists
Data extraction and quality assessment	Number of reviewers not specified‡	Data extraction and quality assessment should be performed by one reviewer, checked by a second reviewer, and conflicts should be resolved by a third reviewer
	Use RoB1 for RCTs	Prefer RoB2 for RCTs†
	Use ROBINS-I for non-randomised controlled trials, cohort studies, case-control studies	ROBINS-I for non-randomised studies†
	No quality assessment required for single arm trials, cross-sectional studies, case series/case reports	Quality assessment required but flexibility allowed†
Submission dossier	List databases searched, search dates, and justify search filters	List databases searched, search dates, and justify search filters
	Include list of included studies	Include list of included studies
	Include table of excluded studies from full-text screening, with reasons	Include table of excluded studies from full-text screening, with reasons
	Include PRISMA diagram	Include PRISMA diagram
	Include study selection scenario diagrams	No requirement for study selection scenario diagrams
	Studies identified by handsearching	Studies identified by handsearching
	List studies identified and excluded by handsearching with reasons	List studies identified by handsearching, but no exclusion list required
	List handsearching sources and search dates	List handsearching sources and search dates
	Present results separated by PICOS criteria	Present results for a single PICOS criterion only

†Although NICE prefer these tools, NICE allow flexibility in the choice of tool for quality assessment; ‡Assumed two reviewers with third for conflict resolution.
Key: Grey shading denotes similarities; yellow shading denotes differences.
Abbreviations: CDSR, Cochrane Database of Systematic Reviews; CENTRAL, Cochrane Controlled Register of Trials; CTIS, Clinical Trial Information System; EMA, European Medicines Agency; EORTC, European Organisation for Research and Treatment of Cancer; EU, European Union; EU-CTR, European Union Clinical Trials Registry; EuroQoL, European quality of life; HTA, health technology assessment; INAHTA, The International Network of Agencies for Health Technology Assessment; JCA, Joint Clinical Assessment; MS, member states; NICE, National Institute for Health and Care Excellence; NIHR, National Institute for Health Research; PICOS, population, intervention, comparator, outcome(s), study design; PRISMA, Preferred Reporting Items in Systematic Reviews and Meta-Analyses; RCT, randomised controlled trial; RoB1, Cochrane Risk of Bias 1; RoB2, Cochrane Risk of Bias 2; ROBINS-I, Risk Of Bias In Non-randomised Studies of Interventions; SLR, systematic literature review; UK, United Kingdom; USA, United States of America; WHO, World Health Organization.

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