



PICO Consolidation within the EU Joint Clinical Assessment: Stakeholder Perspectives on Sustainable Implementation under the HTA Regulation

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Summary

Regulation (EU) 2021/2282 introduced the Joint Clinical Assessment (JCA) as a central component of the new European Health Technology Assessment (HTA) framework. A key step within the JCA process is the consolidation of Population, Intervention, Comparator and Outcomes (PICO) proposals submitted by Member States (MSs) into a common assessment scope. However, differences in standards of care, healthcare systems and evidentiary expectations across Europe create important challenges for the implementation of PICO consolidation. This study investigated how PICO consolidation can be implemented in a sustainable and practical manner while balancing the needs of MSs, health technology developers (HTDs) and other stakeholders. A two-round, mixed-methods, modified Delphi study was conducted involving representatives from MS HTA bodies, industry, patient organisations and methodological experts. Round 1 explored challenges and potential solutions, while Round 2 assessed areas of agreement and prioritisation. The findings were further contextualised through discussion with representatives of the European Commission. The results indicate that the main challenges of PICO consolidation extend beyond methodological questions. Governance and decision-right uncertainty emerged as the strongest area of consensus, while comparator heterogeneity, workload pressures and long-term scalability risks were identified as key operational priorities. Stakeholders also highlighted challenges related to evidence generation, uncertainty management and national adaptation of JCA outputs, alongside potential approaches including clearer governance structures, stronger prioritisation mechanisms, improved coordination, lifecycle evidence strategies and structured national contextualisation. Overall, the study suggests that PICO consolidation should be understood not as a purely methodological exercise, but as an interconnected implementation challenge involving governance, prioritisation, evidence generation, transferability and stakeholder coordination. Sustainable implementation may therefore depend less on achieving complete harmonisation and more on developing transparent and operationally workable mechanisms capable of managing heterogeneity across MSs. By providing an early multi-stakeholder assessment of PICO consolidation under the HTAR framework, the dissertation contributes to the emerging evidence base on JCA implementation and identifies priorities for future methodological, organisational and implementation efforts.