

OP49 Are Propensity-Score-Based Adjusted Indirect Comparisons Feasible For All European Joint Clinical Assessments Based On Non-Randomized Data?

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Introduction: The EU HTA member state coordination group has finalized methodological guidance on indirect comparisons that states that propensity score (PS) methods should generally be used for indirect comparisons of non-randomized data in joint clinical assessments (JCAs). Half of new oncology approvals by the European Medicines Agency (EMA) between 2020 and 2023 were based on non-randomized data. This study aimed to identify how many of these were able to submit PS-based comparisons.

Methods: Using IQVIA's Market Access Insights (MAI) database of HTAs and regulatory approvals, we characterized evidence packages submitted to EMA and HTA agencies of EU member states according to the use of PS-based comparisons and access to individual patient data (IPD) from comparator studies.

Results: Of the 56 oncology approvals between 2020 and 2023, 30 (54%) were based on non-randomized data, of which 23 (23%) submitted PS-based indirect comparisons to EMA (15 therapies) or to HTA agencies (23 therapies). Electronic health record (EHR) or chart reviews were the most common source of comparative RWE, but agencies only took this evidence into account in fewer than half of HTAs where it was available. Use of PS-based methods also did not lead to more positive HTA outcomes than the alternative unanchored matching-adjusted indirect comparisons (MAICs) to aggregated data.

Conclusions: The prevalence of oncology approvals based on single-arm trials is expected to be a key challenge to the success of JCA. Unanchored comparisons will be required, but IPD was not necessarily shown to reduce uncertainty in HTAs analyzed in this research, and in about half of cases, comparisons to aggregate data were preferred due to applicability and heterogeneity concerns. Thus, the source of comparator data appears more relevant than the comparison method in HTAs, which contrasts with the available EU HTA coordination group guidance that focuses mainly on methodological aspects.

OP50 NICE Listens: Engaging The Public On How Environmental Sustainability Should Be Considered In Health Technology Assessment

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Introduction: Involving the public is essential to building trust in health technology assessment (HTA) organizations. The National Institute for Health and Care Excellence (NICE) runs a deliberative public engagement program, NICE Listens. It was used to explore informed public opinion on how environmental sustainability should be taken into account in HTA.

Methods: Twenty-three general public participants from across England took part in three iterative online workshops (each lasting two or three hours, held three weeks apart in 2022). The workshops included trade-off exercises, role-play, group discussion, and video clips from interviews with sustainable healthcare experts.

Results: Strong support was found for NICE taking action to make healthcare more environmentally sustainable. Support increased as participants learned that sustainable healthcare offers co-benefits, such as reduced burden on the National Health Service through better self-management of conditions. Participants did not want health outcomes to be compromised in pursuit of sustainability. We identified some circumstances where they found it acceptable to consider the environmental impact of interventions in decision-making: when effective treatments already exist; when the condition is not severe; when the alternative is equally cost effective; and when greener options are marginally higher in cost but as clinically effective as the alternative.

Conclusions: The findings demonstrate that environmental sustainability is clearly considered a relevant element of value. They also offer insight into how the environmental impact of health interventions should be considered in HTA. Further research should focus on methods for consistent measurement of the environmental impacts of health interventions and the incorporation of those impacts into decision-making.

OP51 Strategies For Training Laypeople To Participate In Health Technology Assessment: A Scoping Review

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Introduction: This study aimed to map strategies for educating laypeople about health technology assessment (HTA). Although

integrating community is challenging, the engagement of patients/public in the processes of HTA has garnered support and endorsement from international network agencies. Dissemination of information, educational empowerment, and training are vital to give individuals capacity to partake in the intricate web of processes actively.

Methods: This review considered studies addressing educative strategies to train laypeople on HTA, additionally mapping and summarizing relevant methodological papers from any international HTA agency. Four databases were searched for qualitative, quantitative, and mixed methods study designs. The grey literature search included policy and practice documents from HTA and health organization websites. Two reviewers independently completed title and abstract screening before the full-text review and data extraction.

Results: The main contributors to the production of knowledge about educating laypeople in HTA were the United Kingdom (40%), Spain (20%), and Canada (13%). Most studies included were conducted in the context of the United Kingdom (27%), followed by Spain (20%), and international networks context (20%). The main strategies included conference-like events (21%), the production of educational materials (18%), training (11%), and the use of plain language (8%). Furthermore, international HTA and health agencies have offered courses, and online training produced and made available online guidance materials for increasing laypeople's participation in the HTA process.

Conclusions: Despite the global efforts to educate laypeople on HTA, jurisdictional variations underscore the need for a more inclusive approach. Strategies like events, educational material production, training, and clear-language use offer diverse avenues for public engagement. International agencies' commitment to courses, online training, and guidance reflects a collective effort to enhance public involvement.

OP52 How Will European Joint Clinical Assessment Impact National Decision-Making?

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Introduction: In 2025, oncology drugs with new active substances and advanced therapy medicinal products will undergo joint clinical assessment (JCA). The comparative analysis of the clinical evidence as defined in the Regulation (EU) 2021/2282 on health technology assessment (HTAR) will save national/regional submissions of the same evidence. JCA will be available early supporting appraisal and decision-making, which remains within the responsibility of member states (MS).

Methods: Targeted searches on JCA and statements from stakeholders were performed and analyzed. We conducted interviews with current and former national payers, as well as members of HTA agencies, across Germany, France, Italy, and Eastern Europe to explore their perspectives on the anticipated implications of JCA on decision-making processes and reimbursement strategies in Europe. Focus was on reduced/additional effort for authorities and health

technology developers (HTDs), required national amendments, and potential discrepancies between JCA outcome and MS benefit evaluations.

Results: Stakeholders appreciate the standardized methodology and guidance on HTA, which, especially in countries without an established HTA system, could enhance patients' access to new treatments by considering JCA in decision-making. The comprehensive evidence compilation may also save resources in pursuing national/regional submissions. On the other hand, country-based appraisals within the MS could lead to diverse conclusions, and there is uncertainty as to which extent national authorities will adopt JCA and how its integration into decision-making will be handled. Some stakeholders challenge an impact on local patients' access as reimbursement and pricing processes remain within MS responsibility.

Conclusions: JCA is a long-desired achievement and will set the groundwork for timely access of new treatments in the MS. However, presently there are several uncertainties on how JCA will impact decision-making and whether MS appraisal could lead to contradictory value conclusions for a given treatment. Future adjustments to national/regional procedures and refinement of the JCA framework are expected.

OP53 An Actionable And Legible Toolbox For The Appraisal Of Healthcare Innovations Developed Through Nationwide Stakeholder Collaboration

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Introduction: In Québec, Canada, decisions about implementing innovations are taken both centrally for province-wide access and locally by healthcare institutions. There is no systematic evaluation process and various stakeholders are involved, notably within a new nationwide governance structure. There was a wish to increase consistency and clarity with the principles and methods used by various bodies across the innovation lifecycle.

Methods: The starting point was the Institut national d'excellence en santé et services sociaux (INESSS) multidimensional framework, which focuses on the population-level, clinical, economic, organizational, and sociocultural value of drugs, technologies, and interventions. The framework, already under evolution drawing on Responsible Innovation in Health (RIH), evolved through collaborative work between INESSS' methodological and scientific teams, but also and foremost with diverse groups and institutions within the provincial innovation ecosystem (e.g., university-based incubators, regional hospitals). The first steps were to capture current concepts and practices from different stakeholders, as well as their operational needs in terms of assessment tools.