

## PP56 National Immunization Technical Advisory Groups Are Essential For Successful Implementation Of The European Health Technology Assessment Regulation

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**Introduction:** Starting from 2030, vaccines in the European Union (EU) require joint clinical assessments (JCAs), and joint scientific consultations (JSCs) can be requested from 2025. Involvement of national immunization technical advisory groups (NITAGs) is crucial to address vaccine specificities. However, NITAGs are currently not considered in the EU health technology assessment (HTA) framework. This study highlights potential risks for non-applicability of vaccine JCA reports nationally.

**Methods:** This study examined where in the JCA and JSC implementation process NITAGs could play an important role and highlighted the practical challenges of incorporating vaccine JCA reports into already very heterogeneous and complex vaccine access pathways across EU Member States. The EU HTA Regulation process was tested for three countries with different vaccine market access characteristics. This study was conducted using JCA guidance documents, NITAG vaccine assessment guidelines, and communications with the respective decision-making bodies.

**Results:** The EU HTA Regulation framework requires adjustments for vaccine-specific considerations. NITAGs across the EU vary in experience, resources, expertise, and influence on decision-making regarding vaccine assessment and inclusion in the national immunization program. In addition to JCA and JSC, the EU HTA framework also covers horizon scanning, which several NITAGs are currently involved with at national level. However, the EU HTA framework currently lacks explicit requirements for NITAG input in horizon scanning, JSC, and JCA processes. This could lead to unnecessary duplication of work, further complexity of the processes, and lengthening of population time to access to new vaccines.

**Conclusions:** The EU HTA framework of vaccines aims to avoid duplicate efforts and enhance patient access, but current processes that will be introduced may not achieve this optimally. Early and systematic inclusion of NITAGs in the horizon scanning, JSC, and JCA processes is pivotal to mitigate the risk of non-applicability and to successfully realize the objectives of the EU HTA framework.

## PP57 Outcomes Model For Assessing Strategies Improving In Vitro Fertilization Birth Rates

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**Introduction:** Infertility affects one-sixth of women worldwide, with over seven million assisted reproductive cycles performed annually. Oral dydrogesterone is recommended alternatively for luteal phase support in in vitro fertilization (IVF), preventing miscarriages and improving live birth rates. This study aims to develop an outcomes model comparing oral dydrogesterone treatment with the standard of care in the IVF cycle over a 10-year period.

**Methods:** A two-level Markov cohort model in Microsoft Excel includes six health states: IVF, pregnancy, miscarriage, live birth, perinatal death, and maternal death. Miscarriage, live birth, and perinatal death are sub-states of pregnancy. Transition probabilities are based on published rates with medical intervention limited to the first 12 weeks of gestation. A sensitivity analysis of treatment was performed. Data from a published meta-analysis of nine dydrogesterone studies for IVF luteal phase support were used. The baseline cohort is 10,000 Australian females undergoing IVF annually over a 10-year period.

**Results:** Over the 10-year time horizon, compared to standard care, the group treated with dydrogesterone was estimated to increase the number of live births by 3.5 percent (range: 3.4 to 3.7%), reduce the number of miscarriages by 69.4 percent (range: 66.2 to 72.7%), reduce the perinatal death by 10.9 percent (range: 10.4 to 11.4%), reduce the IVF cycles by 11.56 percent (range: 11.0 to 12.11%), and reduce the death of the mothers by 10.9 percent (range: 10.4 to 11.4%).

**Conclusions:** The outcomes model projected that treatment with oral dydrogesterone significantly reduced the number of miscarriages and improved the number of live births compared to the standard of care used for IVF patients in Australia.

## PP58 Enhancing Health Technology Assessment Understanding Through Targeted Educational Programs

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**Introduction:** As health technology assessment (HTA) becomes vital in healthcare decision-making, the demand for specialized education

grows. A new HTA course, tailored to the specific needs of the Republic of Moldova's health system, was launched under a joint project—a collaboration between the World Bank, the Swiss Cooperation Office, Radboud University Medical Center, and the School of Public Health Management. The course targets first- and second-year master's students, and health professionals enrolled in continuing education.

**Methods:** The course aimed to introduce the fundamentals of HTA. Participants included 49 master's students and 26 health professionals. A pre- and post-test model was employed, with participants completing a 10-(multiple) question HTA knowledge assessment at both the start and end of the course.

**Results:** Initial pre-test results showed an average score of 30 percent, reflecting limited prior HTA knowledge. Following course completion, the post-test average escalated to 80 percent. This 50 percent increase in knowledge was consistent across student and professional groups. While a significant 79 percent of participants accurately answered questions about the use of HTA reports from other jurisdictions, identification of stakeholders, and the elements of establishing PICO (population, intervention, comparator, outcome), they found it more challenging to understand the deeper aspects of HTA. Notably, about 72 percent had difficulties with questions related to the main goals of HTA, evaluating the broader impacts of health technologies, and starting the evidence-based deliberative decision-making process.

**Conclusions:** The HTA course successfully covered basic concepts, yet it also highlighted the need for more comprehensive teaching of complex topics. The participants showed varying levels of understanding. This underscores the necessity for an HTA curriculum that equally emphasizes fundamental knowledge and in-depth analysis, preparing future healthcare professionals for complex decision-making in their roles.

## PP59 Do Patient Contributions Matter? A Thematic Document Analysis Of NICE Ultra-Rare Disease Appraisals

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**Introduction:** Patient organizations play a crucial role in health technology assessment (HTA), especially for rare diseases. Despite their important role, the contributions and impact of patient organizations have been overlooked in the literature. This study aims to address this gap by examining the contributions of patient organizations and their nominated experts in National Institute for Health Care and Excellence (NICE) highly specialised technology (HST) appraisals.

**Methods:** We thematically analyzed the scope and frequency of contributions from patient organizations and experts associated with 10 NICE HST appraisals completed between January 2022 and September 2023. First, to allow for a representation of what patient contributions focus on, their written submissions were categorized according to themes following a deductive/inductive approach, employing a tiered system for disease-, technology-, or submission-

specific themes. Second, we compared the themes identified in written submissions with those found in the final NICE recommendations, included in the final evaluation determination (FED), to understand whether and to which extent patients' contributions were considered.

**Results:** From 2013 to 2023, 22 drugs underwent HST assessment, with nearly half appraised during 2022 and 2023. All technologies received positive recommendations. A total of 475 unique patient contributions—from both patient organizations and their nominated experts—were identified in their written submission in support of the 10 HST appraisal assessed, predominantly emphasizing disease-specific themes (53%), such as quality of life. While 42 percent of raised themes aligned with FED content, 52 percent did not. When looking at individual appraisals, the share of themes mentioned in patients' written submission explicitly considered in the FEDs ranged from nine percent to 73 percent, with a median of 50 percent.

**Conclusions:** Despite progress in integrating patient inputs into HTA, this study reveals a discrepancy between patient priorities and explicit consideration in NICE's final recommendations. While NICE consistently adheres to its methodology, certain patient-raised aspects are overlooked. Further research is important to discern the optimal areas and timing for patient contribution, refining NICE's involvement strategies in their decision-making processes.

## PP60 Enhancing Patient Empowerment: European Capacity Building Initiative And Curriculum Development In Health Technology Assessment Training

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**Introduction:** The new Regulation (EU) 2021/2282 on health technology assessment (HTAR) highlights the increasing importance of patient perspectives, emphasizing their crucial role in HTA. The European Capacity Building for Patients (EUCAPA) project aims to empower patients for active involvement in HTA. EUCAPA focuses on equipping patients with capacities through the development of HTA training, including introductory, fast-track, and extended training programs.

**Methods:** Within the EU-funded EU4Health program, the EUCAPA consortium was tasked with capacity building for patients and patient representatives. Training programs were developed using a coproduction approach, integrating patient representatives' perspectives into both curriculum development and the design of training sessions. This innovative approach involved close collaboration between patient representatives and HTA scientists, jointly shaping the