OD14 Harmonization Of HTA For Digital Health Technologies: The EU-Funded European Digital Health Technology Assessment Project

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Introduction: The European Digital Health Technology Assessment (EDiHTA), an EU-funded project, aims to deliver the first European digital HTA framework co-created by all relevant stakeholders, validated and ready to use. It responds to the need to harmonize tools, methods, guidelines, and frameworks that are already adopted or under development. All types of digital health technologies (DHTs) and Technology Readiness Levels (TRLs) are covered.
Methods: The EDiHTA project adopts a multistakeholder, multidomain, and modular approach to reach a consensus on a common HTA framework for DHTs (e.g., mApp, telemedicine, artificial intelligence). The currently available HTA frameworks refer to different DHTs (e.g., MAST, DiGA, MAS-AI), include different HTA domains, respond to the needs of different stakeholders, and are applicable in specific local and national contexts. In the majority of cases, they are applicable only in advance TRL. In a few cases, they are already adopted in regulatory/HTA processes. The lack of coordination and harmonization has significant implications for all stakeholders, manufacturers and patients included.
Results: The EDiHTA project adopts a holistic approach involving all relevant stakeholders for consensus building at national and European levels. Cross-border collaboration among stakeholders will be reinforced by the definition of a common taxonomy based on consensus building, and the development and validation of common methods and the HTA framework. Evidence requirements will be defined and made more transparent to increase support for health technology manufacturers. In addition, the harmonization effort, together with the development of a digital platform for the HTA framework, will allow faster and safer access to DHTs by patients/citizens.
Conclusions: The goal of the EDiHTA project is to provide the first European digital HTA framework for DHTs that will be adopted by all relevant stakeholders along the lifecycle of digital technologies to promote sustainable health systems. A consortium comprising 15 partners from eight countries, including all relevant stakeholders, works to reach these goals within the next four years.

OD15 Multiparametric Magnetic Resonance Imaging In Biopsy-Naive Patients: A Real-World Evidence For Decision-Making In Prostate Cancer Pathway

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Introduction: Use of multiparametric magnetic resonance imaging (mpMRI) in the prostate cancer (PCa) diagnostic pathway could reduce prostate biopsy (Bx) in Bx-naive patients. The objective was to assess the feasibility of implementing a new PCa diagnostic pathway with the addition of mpMRI in a real care environment.
Methods: Following an HTA report published in 2019 by our team, a committee involving stakeholders (e.g., urologists, radiologists, hospital managers) was created to review the PCa diagnostic pathway including mpMRI in Bx-naive patients and both systematic and targeted 3DTRUS-MRI fusion Bx when Bx was recommended. Data in the new PCa diagnostic pathway were collected between September 2021 and June 2022. The comparison group is a cohort of 629 men who underwent an initial systematic transrectal ultrasound Bx in 2017 when prostate mpMRI was not available. Clinically significant PCa (csPCa) was defined as Grade Group ≥2.
Results: In 2021 and 2022, 1,336 Bx-naive patients were referred to a urologist. Recommendations were: 703 (53%) for follow-up in six to 12 months, 254 (19%) directly to systematic Bx, and 379 (28%) to mpMRI. Overall, csPCa was diagnosed in 246/427 (58%) patients referred to mpMRI or Bx in the 2021 to 2022 cohort compared to 274/629 (44%) patients in the 2017 cohort ($p<0.05$). The new diagnostic pathway prevented 33 percent of patients from having Bx. Shorter delays between initial consultation with urologists and transmission of Bx results were observed for patients referred directly for prostate Bx compared to mpMRI before Bx (mean: 2.8 vs 9.1 months).
Conclusions: Experimentation in a real care setting has highlighted the added value of the early involvement of urologists in the diagnostic pathway of prostate cancer for the triage of patients. Integration of mpMRI was associated with a lower number of patients referred for prostate Bx and a higher csPCa detection rate.

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