PD146 Can We Properly Evaluate Genetic And Genomic Applications? A Systematic Review Of Health Technology Assessment Reports

Giuseppe Migliara (gmigliara@gmail.com), Antonio Sciurti, Ilaria Mussetto, Maria Roberta De Blasiis, Giuseppe Di Lorenzo, Dr Francesco Pierri, Immacolata Leone, Carolina Marzuillo, Paolo Villari and Valentina Baccolini

Introduction: The last decade has witnessed a steady adoption of personalized medicine. However, the evaluation of genetic and genomic tests is not straightforward. The purpose of this systematic review was to identify health technology assessment (HTA) reports assessing genetic and genomic tests to summarize the methodologies used, the maturity level of the evidence included, and the highlighted research gaps.
Methods: The PubMed, Scopus, and Web of Science databases were searched for HTA reports of genetic or genomic tests. The main national and international HTA report repositories (e.g., the international HTA database) were also searched. HTA reports that were specifically created to assess genetic or genomic technologies and included at least three core evaluation components (analytic validity, clinical validity, clinical utility, economic evaluation, organizational aspects, or ethical, legal, and social implications) were included. This study was supported by the European Commission and the Ministry for Universities and Research under the National Recovery and Resilience Plan (M4C2-I1.3 Project PE_00000019 "HEAL ITALIA").
Results: Overall, 27,331 unique records were retrieved, 55 of which were included in the systematic review. The reports were mainly from Australia (29%), Canada (27%), and the UK (25%); focused on pharmacogenomics (36%) and oncology (35%); and investigated test use for treatment guidance (42%) or diagnosis (29%). The most reported evaluation components were economic evaluation (87%), clinical utility (76%), and clinical validity (67%). On the other hand, personal utility (7%), patients' perspectives (27%), and ethical (15%), legal (11%), and social (24%) implications were poorly represented. Analytical validity, safety, and organizational aspects were included in about half of the reports.
Conclusions: Although these are only preliminary results, the substantial lack of a shared standard in the evaluation of genetic and genomic applications is clear given the heterogeneity of the dimensions addressed among the reports. Theres is a need to strengthen evaluation of the neglected dimensions, which are often of primary importance in defining the value and risks of personalized medicine.

PD147 Overview Of Multiplex Antigen Near-Patient Tests For Acute Respiratory Infections

Tom Lynch (tomaslynch26@gmail.com), Cillian McDowell, Eimear Burke, Carol McLoughlin, Michelle O'Neill, Susan Spillane and Máirín Ryan

Introduction: Multiplex antigen near-patient tests (NPTs) can detect multiple virus-specific antigens during acute infection. This project aimed to provide an overview of evidence on the effectiveness, advantages and disadvantages, and feasibility of multiplex antigen NPTs to identify common respiratory pathogens (including SARS-CoV-2 and one or both of the influenza and respiratory syncytial viruses) in residential and primary care settings.
Methods: A non-systematic literature search was conducted on the 28 July 2023 in the MEDLINE, Embase, Cochrane Library, and ClinicalTrials.gov databases to identify relevant literature. National and international agency websites were searched for guidance or recommendations relating to multiplex antigen NPTs. Relevant citations were screened and extracted by one reviewer and cross-checked by a second reviewer. Health technology assessments, systematic reviews, observational studies, and randomized and non-randomized controlled trials were considered eligible for inclusion in the overview. No formal quality appraisal of included documents was conducted. Due to the variation in study types, study findings were narratively assessed.
Results: Ten documents were identified in total. One complete prospective evaluation and seven incomplete clinical trials were identified. No relevant primary studies were identified for effectiveness outcomes such as time to appropriate treatment with antibiotics or antivirals. An evaluation published by the Haute Autorité de Santé in France reported that there was insufficient performance data regarding multiplex antigen NPTs in clinical practice. In a joint statement on respiratory virus testing, the Public Health Laboratory Network and Communicable Diseases Network in Australia indicated that antigen NPTs were not recommended due to their poor ability to identify influenza A.
Conclusions: Evidence on the effectiveness, advantages, disadvantages, and feasibility of multiplex antigen NPTs to detect common respiratory pathogens in primary and residential care settings is sparse. Studies are required to assess the diagnostic performance (relative to reverse transcription polymerase chain reaction tests) and clinical utility of multiplex antigen NPTs in residential and primary care settings.

https://doi.org/10.1017/S0266462324003805