OD37 How The PICOTS-ComTeC Framework For Digital Health Interventions Can Be Useful For Health Technology Assessment

Zsombor Zrubka, Annette Champion, Rossella Di Bidino (rossella.dibidino@policlinicogemelli.it), Anke-Peggy Holtorf, Jagadeswara R Earla, Artem Boltyenkov, Masami Tabata-Kelly, Carl Asche and Anita Burrell

Introduction: The diffusion of digital health interventions (DHIs) requires agreement on a minimum information framework to define them. The ISPOR Digital Health (DH) Special Interest Group (SIG) developed the PICOTS-ComTeC framework based upon a systematic review and a Delphi study. It is an enriched version of the traditional PICOTS widely adopted in health technology assessment (HTA). ComTeC stands for communication, technology, and context.
Methods: The PICOTS-ComTeC is based upon a review that included the Shannon–Weaver model of communication, AHRQ Quality Measures, technology, geography, and the World Health Organization classification of DHIs followed by a Delphi panel. The development process adhered to the EQUATOR guidelines. The PICOTS-ComTeC aims to be a flexible and versatile tool tested on different DHIs. The results of the testing are discussed from the HTA perspective considering the tool's additional value, utility for and applicability to HTA. The additional value is strictly linked to the actual need for a dedicated PICOTS for DHIs and its implications for HTA assessments of DHIs.
Results: The PICOTS-ComTeC was tested internally and externally to the ISPOR DH-SIG on four DHIs for breast cancer surgery/management/patient education, one DHI for obesity, and one DHI for patients with heart failure. The testing phase demonstrated the level of detail required to use the tool, hitherto available evidence to cover all domains, and opened up discussion on implications of the PICOTS-ComTeC framework for HTA related activities (i.e., scoping, literature search, comparator selection). It emerged that there is a diffuse lack of homogeneity and details when DHIs are defined in the literature with significant implications for conducting appropriate HTAs.
Conclusions: The diffuse adoption of the PICOTS-ComTeC for patient-facing DHIs will promote a greater level of detail in order to define homogenous DHI groups. The implications for HTA range from the definition of relevant research questions to the selection of the most appropriate comparator so that assessments are geared to fulfill the needs of decision-makers.

OD38 Real-World Analysis Of First-Line Maintenance Treatment For Patients With Nonsquamous Advanced/Metastatic Non-Small-Cell Lung Cancer

Umit Tapan (umit.tapan@bmc.org), Kelly F. Bell, Amine Aziez, Jiaqian Sun, Mandy Du, Ella Xiaoyan Du, Qi Hua, Hongbo Yang and Manasee Shah

Introduction: Pemetrexed and immunotherapies (e.g., pembrolizumab) are approved for first-line maintenance (1LM) treatment of nonsquamous advanced/metastatic non-small-cell lung cancer (NSCLC), but real-world data on their use are limited. The objective of this study was to assess 1LM clinical outcomes, safety, and treatment patterns of immunotherapy versus immunotherapy+pemetrexed among patients with advanced/metastatic NSCLC from the EU4 (France, Germany, Italy, Spain)+UK.
Methods: Data from patients in the US, Canada, and EU4+UK with nonsquamous advanced/metastatic NSCLC without targetable mutations were collected via electronic case report form. Physician-identified patients (≥18 y) in the EU4+UK were eligible for this subgroup analysis if they achieved stable disease or complete or partial response with first-line platinum-based chemotherapy +immunotherapy (January 2019 to March 2021) and received 1LM immunotherapy or immunotherapy+pemetrexed. Patients were followed from index (1LM initiation) until last physician contact or death. Outcomes were overall survival (OS), progression-free survival (PFS), treatment patterns and duration, and adverse events.
Results: Among the selected 367 patients (male, 71.9%; mean±StDev age, 63.4±7.2 y; current/former smokers, 85.8%), 203 (55.3%) received immunotherapies, most commonly pembrolizumab (n=173; 85.2%), and 164 (44.7%) received immunotherapy+pemetrexed. Patients receiving immunotherapy had longer median adjusted OS and PFS compared to those receiving immunotherapy +pemetrexed (OS hazard ratio [HR]: 0.63; 95% confidence interval [CI]: 0.36, 0.90; PFS HR: 0.58; 95% CI: 0.38, 0.79). Patients receiving immunotherapy versus patients receiving immunotherapy+pemetrexed had longer median treatment duration (14.0 vs 10.3 mo; $p<0.001$) and were less likely to experience anemia (19.7% vs 33.5%; $p<0.01$). Results were similar in the overall study population.
Conclusions: In this real-world study, among the selected patients with nonsquamous advanced/metastatic NSCLC who achieved stable disease or complete or partial response with first-line therapy, the addition of pemetrexed to immunotherapy in 1LM did not appear to confer a clinical benefit. Identifying treatments that can improve clinical outcomes for these patients remains an area of unmet need.

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