PP36 Real-world Effectiveness Of Umeclidinium And Umeclidinium/Vilanterol For Chronic Obstructive Pulmonary Disease: A Singapore Database Study

Shannon Ng (shannon_ng@moh.gov.sg), Benjamin Ong and Kwong Ng

Introduction: Long-acting muscarinic antagonist (LAMA) monotherapy and LAMA in combination with a long-acting beta2 agonist are preferred over inhaled corticosteroid/long-acting beta2-agonist (ICS/LABA) therapy for Global Initiative for Chronic Obstructive Lung Disease (COPD) Group B and C patients. This study assesses impact of the subsidy decision of umeclidinium (umec) and umeclidinium/vilanterol (umec/vil) on Singapore's healthcare system.
Methods: A retrospective cohort study was conducted using national health record databases. Maintenance-naive COPD patients, with no concurrent asthma, initiated on umec, umec/vil, or ICS/LABA from 2016 to 2020, were included. Patient demographics, comorbidities, and clinical characteristics were balanced using propensity score matching. Primary outcomes measured were the rate of severe or moderate COPD exacerbation and pneumonia hospitalization within one-year follow-up. Effect size was estimated using incidence rate ratio (IRR) with 95% confidence intervals (CIs) from Poisson regression. Markov model extrapolated the number of exacerbations and pneumonia hospitalizations avoided arising from the initiation of umec or umec/vil over ICS/LABA.
Results: Patients initiated on umec (n=1,019) were less likely to experience severe (IRR 0.649; 95% CI: 0.438, 0.961) and moderate exacerbations (IRR 0.713; 95% CI: 0.569, 0.892) than ICS/LABA. Similarly, umec/vil-treated patients (n=1,206) had lower rates of severe (IRR 0.713; 95% CI: 0.517, 0.985) and moderate exacerbation (IRR 0.778; 95% CI: 0.642, 0.942). Both therapies were safer than ICS/LABA, with fewer pneumonia hospitalizations for umec (IRR 0.719; 95% CI: 0.532, 0.973) and umec/vil (IRR 0.781; 95% CI: 0.623, 0.980). Coupled with reduced drug cost from value-based pricing, subsidy potentially resulted in SGD53 million (USD39 million) cost savings over 10 years.
Conclusions: As the largest real-world study conducted among COPD patients in Singapore, our findings contribute to the limited real-world evidence in the region. Compared to ICS/LABA, umec or umec/vil were associated with better COPD control and reduced rates of pneumonia hospitalization. This confirms the importance of appropriate prescribing of COPD therapies and validates the subsidy decision.

PP37 Guidance On Using Hospital-Based Real-World Evidence In Health Technology Assessments For Oncology

Zainab Al-khayat (z.alkhayat@nki.nl), Nora Franzen, Valesca P Retèl and Wim H van Harten

Introduction: Real-world evidence (RWE) is increasingly used in healthcare research to address evidence gaps, reduce uncertainty about medical technology benefits, and provide real-world insights. Efforts to integrate RWE in regulatory and health technology assessment (HTA) processes are growing. However, variations among countries pose challenges. The objective is to analyze and compare various (inter)national RWE guidelines, focusing on real-world hospital data utilization.
Methods: We conducted a review to identify RWE guidance published from 2016 to 2023, with a focus on the EU5 nations (UK, France, Germany, Italy, and Spain) and the ONCOVALUE consortium affiliates (Finland, the Netherlands, Denmark, Italy, and Portugal). To ensure a comprehensive overview, we also investigated Canada, the European Medicines Agency (EMA), ISPOR, and the European Society for Medical Oncology (ESMO). We conducted in-depth interviews with HTA experts of all included countries, focusing on real-world hospital data within the European HTA context. The interviews underwent thematic analysis related to the utilization of RWE in HTA.
Results: We identified nine guidance reports: six focused on HTA-RWE (Medicinrådet/Denmark, NICE/UK, AQuAS/Spain, HAS/-France, IQWiG/Germany, CADTH/Canada), one from EMA, and two international (ISPOR, ESMO). Only NICE, IQWiG, and CADTH offered recommendations covering hospital data, emphasizing the data curation process. HAS addressed considerations in choosing secondary data sources, while IQWiG established robust criteria for registries to ensure data quality. Regarding patient-reported outcomes data, only HAS and NICE provided recommendations in their guidance. The HTA experts acknowledged the value of hospital data but expressed caution due to its unstructured nature, noting that the use of hospital-based RWE is more accepted in descriptive studies.
Conclusions: Guidances prioritize the clinical domain, emphasizing transparency, fitness for purpose, reproducibility, robustness, bias minimization, and generalizability. Notably, there's a lack of comprehensive source-specific guidance for real-world data sources, including registries, hospitals, claims, and wearables. Enhanced guidance on the total data generation process, (data mapping, data federation), cost data, quality of life, and cross-border data usage would strengthen hospital-based RWE assessments.

https://doi.org/10.1017/S0266462324002095