

studies. Findings resulting from the systematic review were contextualized with information collected from administrative databases, clinical program documentation, and experiential data obtained from rehabilitation professionals. Recommendations were elaborated based on the aggregated data sources and informal deliberations by a committee involving researchers and clinicians.

Results. Out of 5014 selected references, 14 studies examining 13 interventions which targeted social integration of the management of PAS were included. Interventions with the strongest evidence base are user-centered (i.e., support individual choices and personal autonomy), individualized (i.e., considered individual needs and characteristics), and educational (i.e., support the acquisition of strategies and abilities). The evidence base was considered “emerging” for interventions which are systemic in nature (i.e., relate to familial, social, cultural, educational or professional environments), interdisciplinary (i.e., involve clinicians with distinct training, competences and expertise), and ecological (i.e., which involve interventions in the client’s living settings). While additional research is necessary to better support their efficacy, these interventions exhibited promising effects on various outcomes.

Conclusions. The analysis and synthesis of three streams of information resulted in five clinical practice recommendations relating to integration to school and productive activities, psychological adaptation, integration in living settings and independence, social life and sense of belonging, and finally, use of PAS. Recommendations should help support clinicians in rehabilitation settings.

PP05 Effect Modifiers In Indirect Treatment Comparisons: Guidance Is Needed To Ensure An Unbiased Identification In Decision-Making

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Introduction. Unadjusted effect modifiers (EM) in indirect treatment comparisons (ITC) can produce biased and uncertain results in health technology assessments (HTA). Even though research on advanced ITC methods to adjust for EMs has attracted much attention, less emphasis has been placed on how these EMs are identified and assessed in the first place. This is surprising given the evidence-based approach underpinning all analyses supporting HTAs. To address this gap, our aim was to identify what HTA guidance exists on the selection process for EMs, and how the selection of EMs has been justified in the context of published ITCs.

Methods. A pragmatic review of HTA guidance documents was conducted in 2021 to describe current requirements for the selection of EMs for ITCs. A supplementary Embase and Medline search was conducted to identify primary research on ITCs published between 2015-2021 presenting information on how EMs were selected to inform these analyses.

Results. Our review found that guidance on this topic focusses on developing and testing different methodologies to adjust for EMs.

No detailed guidance was identified in any of the reviewed HTAs, although the National Institute for Health and Care Excellence (NICE) briefly mentioned that companies should identify EMs through a topical review or expert discussions. Similar findings were also revealed through the database search; few published ITCs included information on the EM selection process which was either based on evidence highlighted in the literature or findings from prior trial subgroup analyses. No reference to a systematic identification of EMs was found.

Conclusions. To fill the guidance gap identified in our review an extension of current ITC guidelines (including those from HTA bodies) is needed, including (i) indication on how EMs should be identified through systematic reviews, (ii) a quantitative assessment of the EM distribution and (iii) formal expert elicitation prior to the selection of ITC methods. Without these additional steps, ITC results may be biased, potentially negatively impacting decision-making and ultimately patient care.

PP06 Clinical Effectiveness Of Fluticasone Furoate Nasal Spray For Perennial Allergic Rhinitis In Children: A Systematic Review And Meta-Analysis

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Introduction. Although previous studies suggest that fluticasone furoate nasal spray (FFNS) is superior to placebo in reducing symptoms in adolescents and adults with allergic rhinitis (AR), there is still uncertainty about its clinical effectiveness in the pediatric population. The aim of this study was to assess the clinical effectiveness of FFNS, compared with placebo, in reducing nasal symptoms in children with perennial AR.

Methods. A systematic review was conducted of studies identified from the MEDLINE and Embase databases that were published up to January 2021. The population of interest was patients aged 2 to 12 years with perennial AR. Included studies were limited to randomized controlled trials (RCTs) comparing FFNS (110 µg once daily) with placebo. The outcomes of interest included the reflective Total Nasal Symptom Score (rTNSS) and safety. Meta-analyses were performed using RevMan 5.4. The Cohen’s guideline was used to assess the minimum clinically important difference for rTNSS; that is, if the pooled standardized mean difference (SMD) and the lower limit of the 95 percent confidence interval (CI) exceed -0.5, the treatment effect was considered clinically significant.

Results. Three RCTs (959 pediatric patients) were included. One study evaluated the short-term use of FFNS, one evaluated the long-term use of FFNS, and the third evaluated both the short- and long-term use of FFNS. FFNS produced a statistically significant reduction in rTNSS (SMD -0.35, 95% CI -0.63, -0.08; $p < 0.001$) relative to placebo in the long-term treatment studies, but not in the short-term studies. However, since the mean reduction did not reach the minimum clinically important difference (SMD -0.5), these results

were not considered clinically relevant. The safety outcomes for FFNS were similar to placebo.

Conclusions. The currently available evidence suggests that FFNS does not produce a meaningful clinical effect on nasal symptoms in children with perennial AR, compared with placebo. In the past decade, however, some guidelines have unequivocally endorsed this treatment.

PP07 Improving The Use Of Real-World Evidence In The Development Of NICE Guidance

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Introduction. The National Institute for Health and Care Excellence (NICE) is determined to make better use of health and social care data in the development of its guidance. Real-world data (RWD) has the potential to significantly improve our understanding of the value of new and existing health and social care interventions. RWD is already widely used to characterize populations, interventions, and outcomes and to populate economic models, but its use in estimating the effects of interventions remains limited, especially for medicines. Key barriers to its greater use in this context include limited transparency around studies, sometimes a lack of confidence in their integrity, and methodological concerns around how studies have addressed major sources of potential bias.

Methods. This abstract focuses on the real-world evidence (RWE) framework developed by NICE to support its ambitions. The framework was developed in an iterative way based on: reviews of best practice approaches to the conduct and assessment of real-world evidence studies; case studies; and workshops with key external stakeholders. The initial version of this living framework focuses on de novo RWE studies using individual patient data.

Results. The RWE framework consists of an overarching research governance framework which describes expectations around the planning, conduct, and reporting of RWE studies across uses of real-world data. Uses are categorized by risk according to their importance to decision-making, the impact of decisions on patient and system outcomes, and their complexity as proxied by risk of bias. Studies of the effects of interventions on patient health and system outcomes are considered the highest risk. The research governance framework is supported by a tool to aid assessment of data suitability for its intended application, and detailed guidance on the conduct and reporting of comparative effect studies using RWD, following the target trial approach.

Conclusions. The RWE Framework underpins NICE's ambitions to make better use of RWD in its guidance and is intended to improve the quality and utility of RWE studies submitted to NICE enabling more consistent and appropriate evaluation.

PP08 Evaluation Of Nutritional Status In Diabetic And Non-Diabetic Chronic Kidney Disease Patients Using A Web Tool

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Introduction. Poor nutritional status, a complex consequence of numerous interrelated factors, is poorly characterized in patients with chronic kidney disease (CKD) before they commence dialysis. This study aimed to characterize the risk factors and prevalence of malnutrition among patients with CKD, with or without diabetes mellitus, before they underwent dialysis at a tertiary care public teaching hospital.

Methods. This longitudinal observational study utilized a Pt-Global web tool© to assess the nutritional status of patients based on their Subjective Global Assessment score as follows: a score of two to three indicates that patient and family education is required; scores of four to eight mean that intervention is required as indicated by symptoms; and a score of nine or more indicates a critical need for intervention. Glomerular filtration rate calculated using the Chronic Kidney Disease Epidemiology Collaboration equation was used as the measure of kidney function. Multinomial regression analyses were used to ascertain the predictors of poor nutritional status.

Results. A total of 450 patients (265 men and 185 women) who had CKD, with or without diabetes, and were not on dialysis were recruited during the period of study. The average age of the patients was 53.9 years (standard deviation 14.2). 'Severe' malnutrition was present in 152 (33.8%) patients, while 140 (31.1%) were 'mildly or moderately' malnourished, and 158 (35.1%) were 'well-nourished'. Patients with CKD and diabetes were more severely malnourished: 68 were rated as mild or moderate (15.1%) and 91 were rated as severe (20.2%). The prevalence of malnutrition increased with the decline of residual renal function. Fatigue, loss of appetite, pain anywhere in the body, constipation, dry mouth, feeling full quickly, and physical and functional inactivity were the most common risk factors for poor nutritional status.

Conclusions. This study presents real-world evidence of poor nutritional status in patients with CKD and confirms that it is more common in individuals who are diabetic and have poor kidney function and hypoalbuminemia. Emphasis on nutrition in patients with CKD is important for improving their health.