

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.