NAPCRG 52nd Annual Meeting — Abstracts of Completed Research 2024.

Submission Id: 6656

Title

Where Did the Patients Go? Understanding Patient Non-Enrollment in the HOMER Trial on Buprenorphine Treatment for Opioid Use

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

Context: Opioid use disorder (OUD) leads to significant morbidity and overdose death in the United States. The prevalence of OUD has reached epidemic proportions, yet enrolling patients in primary care clinical trials on medication for treatment of OUD (MOUD) can be challenging even under ideal circumstances. Objective: Describe factors that appear to be associated with non-enrollment of patients in a comparative effectiveness trial on MOUD induction. Study Design and Analysis: Multiple-method analysis using descriptive statistics and iterative ground theory techniques to identify salient themes about patient non-enrollment. Setting: Sixty (60) US-based primary care practices from the State Networks of Colorado Ambulatory Practices & Partners and AAFP National Research Network who agreed to participate and enroll patients. Population studied: Clinicians and staff perspectives, plus patient enrollment data. Intervention/Instrument: Monthly field notes maintained by research staff; de-identified patient tracker data provided by participating clinics. Outcome measures: none. Results: Reasons for non-enrollment were a combination of patient and clinic factors. Practices understood enrollment criteria, had methods to identify potentially eligible subjects, and were supported by research staff with enrollment strategies. Six of 15 practices that were unable to enroll patients had started new patients on MOUD and offered the HOMER to eligible patients, but without success. Common explanations for non-enrollment were: overall lower-than-expected volume of patients seeking MOUD; patients initiating MOUD outside primary care; patients unwilling to be randomized (preferred a specific induction method), needed immediate treatment (could not wait for randomization), or simply not interested in participating in a study. In several cases where eligible patients were provided enrollment information in HOMER, patients appeared to not follow-up with the study team and next steps in the enrollment process. Practice factors such as clinician absence/turnover and not accepting new OUD patients may have affected patient enrollment. Conclusion: Despite the

prevalence of OUD in the US, enrollment in a study on MOUD induction proved challenging for some participating primary care practices, likely due to fewer than expected numbers of patients seeking to initiate MOUD in primary care settings and unwillingness from patients and clinicians to be randomized to a study arm.