Study Statistical Analysis Plan (SAP)

Official Title: Using Data-Driven Implementation Strategies to Improve the Quality of Cirrhosis Care

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Statistical Analysis Plan

Data were analyzed using intent-to-treat principles, such that Veterans were assigned to their Veterans Health Administration (VA) facilities at the start of the study and all VA facilities were included in analysis (other than those no longer part of the VA Corporate Data Warehouse due to change to the Cerner electronic health record mid-trial). The primary question was whether GTI was associated with improved hepatocellular carcinoma (HCC) surveillance rates at the end of intervention and at 12 months post intervention. This was assessed using generalized linear mixed models with logistic regression. Investigators first modeled the association between Getting to Implementation (GTI) and HCC surveillance without adjustment for individual- or facility/cluster-level covariates. Subsequently, they adjusted for individual- and cluster-level covariates, and then did sensitivity analyses to assess whether removing early pandemic period (January 1, 2020–September 30, 2020) data impacted models. These models all assessed the patient-level binary outcome of receipt of HCC surveillance in the 6-month period. Initially, investigators specified three random effects: the random effect for the repeated measures from individual i in cluster k, the random cluster-by-time interaction, and the within-cluster ICC. However, the cluster-by-time interaction was found to be unneeded because it approximated 0. Note that the assignment of interventions is confounded with time in the stepped-wedge, cluster-randomized trials, so modeling the background secular trend is important to remove the bias in estimating the effect attributed solely to the intervention. Investigators assume that the average secular trend is a distinct value during each period, and they used a nonparametric representation for the time effect (categorical time).