Study Title: Testing the Effectiveness of a Graphic Novel Health Education Curriculum for Patients with Addiction

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Data Analysis Plan

Data Management and Analysis- All interview and self-report measures will be completed via a web-based data entry program that has been used at TRI and the University of Pennsylvania for the past 5 years. Direct data entry reduces errors that can occur when transferring information from paper forms into electronic files. See our Data Management Plan for data integrity procedures. Prior to performing analyses, standard data screening/cleaning procedures will be applied: re-screening the data for data-entry errors, assessing the extent and pattern of missing data, and checking that appropriate assumptions of normality are met, employing remedial measures when necessary. We will check to confirm that the groups do not differ at baseline on relevant background variables using analyses of variance (ANOVA) for continuous variables and log-linear models for discrete or ordinal responses. The randomization process should minimize the need for the inclusion of covariates to reduce bias in the treatment comparisons. However, relevant covariates will be considered for inclusion in the analyses to improve the precision of estimation of the effects [1].

Exploratory Hypothesis 1: Patients in the TK Condition will participate in shared decision making conversations with their counselors at higher rates than patients randomized to ***TAU.*** Number of sessions in which patients indicate that their counselors conducted a shared-decision making conversation at the 6-week and 3-month follow-up will be examined. Average number of sessions per patient will be compared at the 6-weeks and 3-month follow-up point. We will calculate effect sizes between conditions using Cohen's d. Quality of shared decision making conversations will be calculated using a subscale of the fidelity checklist. Differences in patient perceived quality will be averaged, and effect sizes will be calculated using Cohen's d.

Exploratory Hypothesis 2: Patients in the TK will report greater satisfaction and acceptability with their individual sessions than patients randomized to TAU. Scores on the Patient Satisfaction measure will be averaged and compared between conditions for the assessment at the three-month follow-up point. We will calculate overall Satisfaction rating and Satisfaction with the Referred Services Subscale score. We will calculate effect sizes using Cohen's d.

Exploratory Hypothesis 3: Patients in the TK condition will demonstrate increased alcohol and drug abstinence (UA verified) and fewer days of self-reported alcohol and drug use during treatment and at follow-up than TAU patients. We will compare rates of urinalysis-confirmed abstinence in the two groups at weeks 6 and 12.. The model will include terms for group, time, and their interaction, and baseline urine result along with any other necessary variables will be included as covariates. We will also compare days of self-reported alcohol and drug use based on the TLFB completed at the 6- and 12--week assessments. We will examine mean differences in abstinence rates and days of use, and estimate effect sizes using Cohen's d.

Exploratory Hypothesis 4: Patients assigned to the TK condition will demonstrate improved ASI Alcohol Severity Scores relative to patients assigned to TAU. We will calculate the ASI Alcohol Severity Score for patients in each condition, and examine change scores from baseline to 3-months. We will examine size of effect between condition change scores using Cohen's d.

Exploratory Hypothesis 5: Patients assigned to the TK condition will demonstrate higher rates of engagement in substance abuse treatment than patients assigned to TAU. Patients in the two groups will be compared on the number of treatment sessions attended in the past 90 days at the 3-month assessment. We will estimate size of effect differences on retention using Cohen's d.

Exploratory Hypothesis 6: Patients assigned to the TK condition will demonstrate higher rates of Vivitrol initiation than patients assigned to TAU. A logistic regression model will be used to compare patients in the two groups on initiation rates at the 3-month assessment. Patients will be considered MAT initiated if they receive a Vivitrol injection during the relevant time period, or if they attended an evaluation for Vivitrol and were deemed inappropriate for Vivitrol and referred to an alternative MAT.

Missing Data: As recommended by Lavori [2], we will analyze the data under an intent-to-treat principle in which all patients initially randomized will be included. We will characterize the group of patients who drop out before the end of the study using logistic regression models to relate dropout to these characteristics. These characteristics will be drawn from the data gathered during the study. These analyses will allow us to determine whether the drop out process is completely at random. We cannot test whether the process is missing at random (i.e. drop-out independent of values of

missed responses, conditional on covariates and observed responses), but we will attempt to obtain information on the reason for drop out. The mixed effects models will accommodate some missing data and drop out. We will examine simple pattern mixture models [3] to assess whether the longitudinal missing data are ignorable.

References

1. Hauck WW, Anderson S, Marcus SM. Should we adjust for covariates in nonlinear regression analyses of randomized trials? *Controlled Clinical Trials.* 1998;19(3):249-256.
2. Diggle PJ, Heagerty PJ, Laing KY, Zeger SL. *Analysis of longitudinal data (2nd Ed.).* Oxford, England: Oxford University Press; 2002.
3. Scott CK, Dennis ML, Foss MA. Utilizing Recovery Management Checkups to shorten the cycle of relapse, treatment reentry, and recovery. *Drug Alcohol Depend.* 2005;78(3):325-338.