Study Protocol

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

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Scientific Background

Cirrhosis, or advanced liver disease, affects approximately four million people in the US. Approximately 100,000 Veterans under the care of the Veterans Health Administration (VA) have cirrhosis due to alcohol, hepatitis C (HCV), fatty liver disease, or other causes, and this number is rapidly increasing. There are lifesaving measures that providers can take to prevent harm from cirrhosis, including providing access to screening for liver cancer. However, less than 30% of Veterans receive guideline-concordant cirrhosis care.

In 2015, the VA's HIV, Hepatitis and Related Conditions Program Office (HHRC) established the national Hepatic Innovation Team (HIT) Learning Collaborative as part of its efforts to improve Veterans' access to new, highly effective HCV treatments. The PI's previous work evaluating the HIT Collaborative program identified specific implementation strategies that were associated with higher rates of HCV treatment using an annual 73-item survey based on the Expert Recommendations for Implementing Change (ERIC) implementation strategy taxonomy.

In 2018, the HIT Collaborative's focus pivoted from HCV elimination towards cirrhosis care. The PI's evaluation team and other investigators aimed to develop a manualized cirrhosis care intervention that would help VA facilities develop and roll-out implementation strategies unique to their needs. The framework for this manualized intervention was based on an implementation strategy bundle called Getting To Outcomes (GTO), a 10-step approach that guides organizations through the process of choosing, implementing, evaluating, and improving an evidence-based practice (EBP) or intervention. While GTO had been applied to many content domains and settings, it had yet to be tested in healthcare settings. In addition, GTO was designed for selection of effective *interventions*, not for the selection of *implementation strategies* to implement a pre-specified intervention.

Thus, "Getting to Implementation" (GTI) was created to support the selection, tailoring, and use of implementation strategies in health care settings. An adaptation of GTO, GTI was developed using the evaluation team's surveys to identify effective strategies associated with improved cirrhosis care, as well as interviews with providers at VA facilities that were performing well on guideline-concordant cirrhosis care metrics.

This study aims to test the effectiveness of GTI to increase cirrhosis EBP uptake in VA facilities that are performing low on cirrhosis care metrics.

Study Objectives

The goal of this study is to assess the effectiveness of GTI's set of prescribed data-driven implementation strategies in increasing liver cancer screening for Veterans with cirrhosis at participating VA facilities. GTI is an 8-step program supported by a facilitation team with clinical and evaluation expertise that provides participating facilities' implementation teams with guidance and training to select and implement effective strategies to best fit their needs in order to improve care.

Study Design & Methods

This interventional study is a hybrid type III, stepped-wedge, cluster-randomized trial. Participating facilities will be randomized to the time that they receive the intervention. All intervention activities will be completed virtually.

Study Procedures

Intervention

Getting to Implementation (GTI) is an 8-step intervention involving biweekly meetings with a 2-person facilitation team. In addition to the participating facility's preliminary step of forming a local implementation team, GTI steps include:

- Step 1 – Identify Gaps and Goals
- Step 2 – Assess Facilitators and Barriers
- Step 3 – Choose Implementation Strategies
- Step 4 – Adapt Strategies and Address Readiness
- Step 5 – Plan Implementation
- Step 6 – Implement and Evaluate
- Step 7 – Improve Implementation
- Step 8 – Sustain Implementation

The intervention is delivered to the participating facility's implementation team over a 6-month active implementation period, followed by a 6-month sustainment period.

Manual

The GTI manual will guide the intervention. It includes step-by-step instructions through the GTI steps, worksheets, and resources. The GTI manual specifies eight "core" strategies found to be empirically associated with better cirrhosis care outcomes. Each of the core implementation strategies includes an accompanying appendix to aid in operationalizing it, and a tracking form to document use and fidelity.

Meetings

GTI facilitators will hold biweekly, 1-hour virtual meetings for a 6-month period to guide the participating facility's implementation team through GTI. This will be followed by 3 additional meetings over the 6-month sustainment period.

Toolkit

The GTI Toolkit includes editable versions of worksheets from the GTI manual. Participating facilities will complete these tools collaboratively with facilitators during meetings.

Data Collection

Facilitators will track GTI implementation and fidelity from several sources. A tracking spreadsheet will be used to record the time spent on each step, how and by whom GTI tools were completed, challenges encountered, and other relevant field notes. Additional sources include contemporaneous notes from biweekly meetings; completed GTI tools; and summative interviews with local implementation teams asking about their experiences with GTI and facilitation, the core strategies, and barriers and facilitators experienced.

Clinical outcomes at the facility- and patient-level will be obtained from the national Advanced Liver Disease Dashboard, which uses data from the VA's Corporate Data Warehouse (CDW) to identify Veterans with cirrhosis and to track interventions such as abdominal imaging (i.e., liver cancer screening).

Study Population

VA Facilities
We will enroll up to 12 VA facilities in the lowest quartile of guideline-concordant cirrhosis care. Implementation will be conducted in three steps over a 2-year period, with four facilities crossing from control to intervention every 6 months until all sites are exposed to the intervention.

Veterans
Veterans with cirrhosis engaged in care at a participating VA facility will be included in analysis. Engagement in care will be defined as having at least one encounter for clinical care in the prior 18 months. Veterans will be assigned to the facility in which they receive their primary care at the time of randomization.