Protocol #: HIIN-BH

TITLE: AN EVALUATION OF EMERGENCY DEPARTMENT TO ADMISSION CONVERSION AMONG PATIENTS WITH A TELEPSYCHIATRIC CONSULT WHO ARE FOLLOWED BY A BEHAVIORAL HEALTH – VIRTUAL PATIENT NAVIGATION TEAM

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The study will be conducted in compliance with the protocol, ICH-GCP and any applicable regulatory requirements.

Protocol Approved By:

PRINCIPAL INVESTIGATOR:

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Wayne Sparks, MD

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Date

EXECUTIVE SPONSORS:

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Print Name

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Signature

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Print Name

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Signature

PROTOCOL SUMMARY	
Study Title	***HIIN – BH:*** *An evaluation of Emergency Department to admission conversion among patients with a telepsychiatric consult who are followed by a behavioral health - virtual patient navigation team*
Study Design	A randomized, quality improvement evaluation
Study Objectives	The primary objective is to evaluate the effect of a behavioral health virtual navigation team compared to usual care among patients with a telepsychiatric consult, on Emergency Department to inpatient conversion. Secondary objectives of the evaluation include: Compare the following between the intervention group and the usual care group: o 45-day post discharge utilization (ED, inpatient, and observation encounters) o 90-day post discharge utilization (ED, inpatient, and observation encounters) o CHS Quality, Comfort, and Care defined 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter. o The patient-centric defined 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility. Additional analyses will be to explore: a. As a sub-analysis, qualitative outcomes will be collected and measured with patients, providers, and leaders. These outcomes will be collected and evaluated, per a sub-study protocol addendum. b. Historical health records may be pulled to explore baseline rates of risk factors among prior behavioral health patients at CHS.
Inclusion/ Exclusion Criteria	Inclusion: • 18 years of age or older • ED visit • Completed telepsychiatric consult at the ED visit • Telepsychiatric consult occurs Monday through Friday during the Navigator's potential hours of operation
Study Procedures	Patients who present to the ED at one of the two participating CHS EDs with a telepsychiatric consult performed will be treated and followed per the proposed CHS behavioral health patient navigation pathway (BH-VPN) or usual care. As part of the current care process, Patients are identified by the ED physician in the ED as needing psychiatric evaluation and a referral is made to the telepsychiatric consult, the care of these patients will follow the allocated BH-VPN pathway or

	usual care. Regardless of participation in the BH-VPN pathway or usual care, the ED providers decide based on available information the ultimate disposition for patients --discharge from the ED or admit to the hospital. Patients who complete a telepsychiatric consult in the ED Monday through Friday during the hours of operation can be enrolled to either the control or intervention arm based on a randomization scheme that randomly allocates days that navigators are available. On days where the navigator is available, all patients who meet eligibility criteria will be considered exposed to the interventions; whereas, on days the navigator is not available all patients will be considered exposed to Usual care. Patients who are in the intervention arm will be offered navigation services for 45 days following ED discharge. The BH-VPN pathway is defined by several key components: • Introduction of the navigation process to the patient, while in the ED • Evaluation of the patient and their needs. • Follow-up evaluation within 72 hours by phone, and weekly contact with the BH-VPN until 45 days post ED discharge • Confirm that a follow-up visit is scheduled and if the patient made it to the appointment. • Placement into an appropriate case management program, if needed
Statistical Analysis	Analyses will include all patients identified as having completed telepsychiatric consult and meeting the additional inclusion and exclusion criteria. Comparisons of the intervention and usual care groups will be made using univariate analyses such as the t-test and chi-square test. The primary outcome, ED to inpatient conversion, will be compared between the two groups of patients using logistic regression. Results will be presented with odds ratios and 95% confidence intervals.

LIST OF ABBREVIATIONS

AMI	Any Mental Illness
BH-VPN	Behavioral Health Virtual Patient Navigation
CHS	Carolinas Healthcare System
CORE	Center for Outcomes Research and Evaluation
C-SSRS	Columbia – Suicide Severity Rating Scale
DHHS	Department of Health and Human Services
EHR	Electronic Health Record
ED	Emergency Department
EDW	Enterprise Data Warehouse
FY	Fiscal Year
HIIN	Hospital Improvement Innovation Network
NC	North Carolina
OCTR	Office of Clinical and Translational Research
PHI	Private Health Information
QCC	Quality, Comfort, and Care
SOP	Standard Operating Procedures

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OBJECTIVES

1.1. Hypothesis

Patients who have had a telepsychiatric consultation in the ED and also receive behavioral health care navigation will have a lower ED to inpatient conversion than patients who receive usual care.

1.2. Primary Objective

The primary objective is to evaluate the effectiveness of the use of a behavioral health – virtual patient navigation team compared to usual care, on the current ED encounter to inpatient conversion rate among patients with a completed telepsychiatric consult.

1.3. Secondary Objectives

The secondary objectives are to examine the behavioral health – virtual patient navigation team's effect on additional patient outcomes, such as the

i. CHS Quality, Comfort, and Care 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter. This measure applies to patients that have a hospital admission subsequent the ED encounter.
ii. The patient-centric 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility. This measure applies to patients that have a hospital admission subsequent the ED encounter.
iii. 45-day post ED discharge utilization (ED, inpatient, observation encounters)
iv. 90-day post ED discharge utilization (ED, inpatient, observation encounters)

2. BACKGROUND

Hospital admissions are common amongst those with mental illness. Significant morbidity exists for patients who are being admitted to a psychiatric hospital from the Emergency Department (ED). Additionally, admission to a hospital setting may have adverse effects on patients psychologically, degrade relationships with therapists, and disrupt continuity of care. Based on verbal reports from psychiatrists providing virtual consults at Carolinas HealthCare System (CHS), providers often decide to admit to a psychiatric hospital because of limited availability of outpatient behavioral health resources.

The number of patients seeking psychiatric services continues to grow at the national, state, and system level. In 2015, there were an estimated 43.4 million adults aged 18 or older in the United States with AMI (Any Mental Illness) within the past year. This number represented 17.9% of all U.S. adults [1]. In North Carolina, every 2.5 minutes a person in behavioral health crisis visits an ED [2]. For Carolinas Healthcare System's Metro EDs, Behavioral Health visits increased from 8,449 in 2011 to 14,293 in 2016 (internal report). In North Carolina's FY12, 19,020 persons seeking help in an ED for a primary mental health, developmental disability, or suicide attempt issue accounted for 26,009 visits, a repeat visit rate of 27%. Thirteen percent of those re-admissions occurred within 30 days. (DHHS data analysis of NC Medicaid

Claims)[3]. Based on a Premier Quality Advisor Report that includes readmissions for 26 Carolinas Healthcare System hospitals, patients who have a primary behavioral health diagnosis demonstrated a 7% readmission rate in 2015.

As the number of behavioral health patients presenting to the acute care EDs for psychiatric care continues to increase, we find there is a significant need to find interventions that will avoid unnecessary admissions or readmissions of these patients. Through verbal reports, ED psychiatrists at CHS must make the decision to admit a patient because there is no one to facilitate an outpatient appointment, ensure medications are filled, or provide follow-up so the patient can be discharged. Hospital readmission within 30 days of discharge usually represents a negative clinical outcome for patients with mental disorders and may be due to factors such as poor access to adequate community-based aftercare and challenges in psychiatric medicine and self-care[4]. Some of these challenges could be addressed by patient navigation, which has been shown to be effective. The largest suicide intervention trial in the U.S has shown a 30 percent reduction in suicide attempts over a 1 year follow-up as compared to standard care in the ED. This intervention utilized safety planning periodic check-ins via a phone call[5].

Carolinas Healthcare System's began utilizing telepsychiatry in 1997. The success of the virtual model led to the development of the robust program that exists today. The CHS virtual model currently offers 21 Metro EDs 24-7 access to licensed clinicians and psychiatrists who are able to provide psychiatric evaluations and dispositions. A 2007 study showed psychiatric consultation and short-term follow up provided by telepsychiatry can produce clinical outcomes that are equivalent to those achievable when patients are seen face to face[6].

The Hospital Improvement Innovation Network (HIIN) is a nationwide effort to reduce preventable hospital acquired conditions and hospital readmissions. Part of the HIIN effort surrounding behavioral health patients, includes identifying packages or key components most effective at preventing psychiatric admission and exploring ways to efficiently apply effective strategies. As a complement to the telepsychiatry program, a partnership has been formed with HIIN to develop a patient navigator program to provide short-term follow up to patients who are evaluated by telepsychiatry and potentially eligible for discharge home. The patient navigator will connect with the patient virtually prior to discharge from the ED and assist the patient in obtaining services and overcoming any barriers for 45 days post ED discharge.

By providing this wrap-around service to complement Carolinas HealthCare System's telepsychiatry program, we expect to decrease the number of patients admitted for inpatient psychiatric treatment and increase the number of discharges from the ED by providing another layer of service to our providers and patients. Additionally, we aim to decrease hospital inpatient admissions and increase after-care compliance with medications and appointments through short-term follow up. In one study regarding inpatient psychiatric care, it was found that patients who did not comply with at least one outpatient appointment after discharge were two times more likely to be readmitted than those who kept at least one appointment after discharge[7].

3. RATIONALE

To enhance the care of patients with a telepsychiatric consult, Carolinas HealthCare System (CHS) has designed a Behavioral Health Virtual Patient Navigation pathway (BH-VPN). The BH-VPN will monitor patients and assist with navigation through a weekly phone call after their index ED encounter for up to 45 days post ED discharge. The BH-VPN aims to improve patient outcomes through standardized approaches that leverage analytics and technology, while bridging care coordination. When a patient is presents to a participating CHS ED sites, those with a telepsychiatric consult completed on a randomized intervention day, during the hours of operation, are provided the option of participating in the BH-VPN. A patient can choose not to receive care by the navigator post discharge.

The BH-VPN pathway includes the following key components: introduction to the patient follow-up process prior to ED discharge, follow-up evaluation within 72 hours by phone and weekly contact, confirmation that a follow-up visit is scheduled, where applicable confirm in-network follow-up appointments are completed with a CHS provider, and placement into an appropriate case management program, if needed. There may be cases where patients are eligible to enroll in full case management programs based on their insurance and certain criteria. For example, if a patient has Medicaid through Cardinal Innovations, a managed care organization providing local behavioral health care, and meets certain criteria, and would no longer require navigation services. A patient's contact with the BH-VPN ends after 45 days following ED discharge, or if there is a failure to contact, becomes enrolled with a case-management program, declines services, or the patient dies. The navigator will ensure the patient is enrolled in a case management program through contact with staff before ending contact with the patient.

This research project is a pragmatic, randomized quality improvement evaluation which seeks to evaluate the effects of standardizing the use of a BH-VPN among patients with a telepsychiatric consult. The outcomes evaluation of this quality improvement intervention has been designed to integrate into the routine care and minimize frontline staff burden by deploying an evaluation in a real-world setting.

4. SUBJECT AND SITE SELECTION

4.1. Accrual

As part of current care, patients are identified by an ED physician in the ED as needing psychiatric evaluation, and a referral is made to the telepsychiatric provider for a virtual consult. Patients are eligible to be included in analysis for the project if they meet the inclusion\exclusion criteria and the telepsychiatric consultation occurs during potential BH – VPN hours. We will accrue patient data for evaluation during a period starting in June 2017. Based on data from 2016, we estimate 500 patients will complete a telepsychiatric consult in a 6-month period during potential BH-VPN hours of operation. Patients will not be accrued on days where the navigators could not potentially be available, such as nights, weekends, and holidays.

Once a patient is in the intervention arm, the patient remains in the intervention arm until 45 days, or if there is a failure to contact (4 phone calls in 12 days), if the patient becomes enrolled with a case management program, declines services, or if the patient dies. After 45 days, a patient is eligible to be re-enrolled in either arm of the study.

A patient remains in the control arm for 45 days unless the patient returns to the ED on a day where patients are being randomized to the intervention arm.

4.2. Participating Sites

Patients will be exposed to the intervention or usual care at two participating ED's in Carolinas HealthCare System. The following Carolinas Healthcare System ED sites will be participating in this project.

- Carolinas HealthCare System Pineville
- Carolinas HealthCare System Union

4.3. Inclusion\Exclusion Criteria

4.3.1. Inclusion Criteria

Eligible patients must meet each of the following criteria:

- Present to an ED at participating sites
- Completed a telepsychiatric consult as captured in the electronic medical record
- Telepsychiatric consult completed Monday through Friday during the Navigator's potential hours of operation
- ≥ 18 years of age at time of ED admission

4.3.2. Exclusion Criteria

No exclusion criteria.

4.4. Evaluable Population

Patients included in the evaluable population for this project, will have their data inform the final outcomes assessment. All patients who meet the inclusion criteria and have a completed telepsychiatric consult will be assessed. Evaluation will be by intent to treat. All patients in the both arms will be assessed for the primary outcome. Patients admitted directly from the ED or have neurocognitive disabilities from the intervention arm will not receive services from the BH-VPN. Patients in either arm have the following potential disposition: (admission to the hospital for medical reasons, admission to a behavioral health facility by voluntary or involuntary commitment, discharge from the ED, or death).

5. OVERALL DESIGN

5.1. Outcome Variables

5.1.1. Primary Outcome Variable

The primary outcome variable is ED to inpatient or observation conversion. This is a patient that presents to either of the two CHS ED sites and then within 5 days of their ED discharge are admitted for any reason to a CHS facility as an inpatient or observation patient. In the electronic medical record, 2 hospital encounters are shown, the ED encounter and the inpatient\observation hospital encounter. Based on data from 2016 at CHS, most patients discharged from the ED who convert to an admission do so within 2 days of their ED discharge. Five days were chosen to maximize the conversions attributed to the ED encounter.

5.1.2. Secondary Outcome Variable(s)

Secondary outcome variables of the evaluation include:

Examining the BH-VPN's effect on additional patient outcomes as compared to usual care, such as

a. CHS QCC defined 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter. This measure applies to patients that have a hospital admission subsequent the ED encounter.
b. The patient-centric defined 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility. This measure applies to patients that have a hospital admission subsequent the ED encounter.
c. 45-day post ED discharge utilization. Utilization is defined as an inpatient, observation, or ED encounter at a CHS facility.
d. 90-day post ED discharge utilization. Utilization is defined as an inpatient, observation, or ED encounter at a CHS facility.

5.1.3. Additional assessments

As a sub-analysis, qualitative outcomes will be collected and measured with patients, providers, and leaders. These outcomes will be collected and evaluated, per a forthcoming sub-study protocol addendum. Patient details will be identified and pulled from the EMR retrospectively after their completion of the study. Historical health records may be pulled to explore baseline rates of risk factors among prior behavioral health patients at CHS.

5.1.4. Adverse Events

Safety/Serious Adverse Events that will be specifically monitored/evaluated include suicide ideation and death. Suicide ideation is tracked among the intervention population at each touch

point. Death rates can be compared between the usual care and intervention populations once a month using data in the Enterprise Data Warehouse. Death is noted based on notification to CHS by a friend or family member or from identification of death from the social security death index which occurs through monthly updates.

5.2. Randomization and Allocation

Randomization for the purposes of this project, will be based on days the Navigators are available to treat patients who've completed their telepsychiatric consult per the BH-VPN or usual care. Patients may be in the ED for multiple days. Their enrollment status depends on the day and time of their initial telepsychiatric consultation. Navigation will only be available for those patients whose consult occurs during intervention day/times. As part of the research design and rollout of this project, randomization will occur at the day level with the days being identified as intervention or usual care days for the duration of the study. We expect an average of 3.7 patients seen daily for both hospitals combined. Patients will accrue in both arms of the study Monday through Friday during the hours of operation. Patients will not be accrued on days where the navigators are not available such as weekends, nights, and holidays.

5.3. Behavioral Health Virtual Patient Navigation (BH-VPN)

The BH-VPN outlines the flow of patients from initial contract to their follow-up calls (see Appendix 1). In the existing ED workflow patients are identified by an ED physician in the ED as in a behavioral health crisis and needing psychiatric evaluation. A referral is made to the telepsychiatric provider for a virtual consult performed on a tablet in the ED. Once the consultation is completed, the patient is placed either in usual care (the control) or BH-VPN (the intervention arm of the study). The placement is dependent upon the day and hours of the week, as to whether navigation is available. After virtual consultation is performed via tablet, the telepsychiatrist will recommend to the ED provider that the patient either be admitted or discharged from the ED, ultimately that decision lies with ED provider. If the patient is in the intervention arm does not have neurocognitive disabilities such as Alzheimer's and discharge is recommended, the patient will be approached by the virtual navigator. The patient has the option not to be followed by the navigator. The navigator will complete the initial virtual behavioral health assessment. The initial health assessment contains information such as preferred communication method, primary care provider, psychiatry provider, collateral resources, recent ED and hospital utilization, substance use disorder, medication barriers, appointment barriers, community resources, and crisis planning.

The follow-up assessments, which will occur during navigation phone calls every at least weekly includes information such as a suicide ideation safety screening, an appointment reminder, appointment barrier evaluations, medication obtainment follow-up, substance use disorder follow-up, supportive listening, psychoeducation, community resource follow-up, and additional crisis planning.

The Columbia-Suicide Severity Rating Scale (C-SSRS) helps identify whether someone is at risk for suicide, and the severity and immediacy of the risk. It also identifies level of support the person needs. The screening tool is administered during each phone contact to measure suicide ideation. If a patient is deemed actively suicidal then the navigator will recommend transfer to mobile crisis, calling 911 for a well-check, or 911 to go to the ED as per current standard of care.

5.4. Follow-up

Patients being treated on the BH-VPN will receive a follow-up phone call within 24 to 72 hours from discharge, and then weekly for up to 45 days. A follow-up assessment is completed upon each phone call.

5.5. Patient Completion of Participation

Patients who are treated per the protocol on the control or intervention arm will complete their participation after 45 days or if one of the following occurs:

- Unable to connect: calls attempted over 12 days (intervention arm only)
- Death
- Enrolled in another Care Management program (intervention arm only)
- Declined services
- 45 days post-discharge completed

A patient's utilization may be tracked post 45 days after completion.

5.6. Continuation of the Intervention

Participating ED sites may continue treating patients with the BH-VPN after the study period has ended.

6. DATA COLLECTION AND REPORTING

Patient demographics, comorbid conditions, and utilization will be obtained from the electronic medical record and billing systems. Data from the initial assessment and follow-up contacts will be stored in HealtheCare, a care management platform in Cerner. Data will be retrieved by an application specialist on the research team. Data may be retrieved retrospective to a patient's completion of the intervention or usual care arm of the study. A monthly executive summary will be produced, showing patient volume, percent patients with suicidal ideation, and utilization.

6.1. Sample size analysis and statistical analysis

We are conducting the study for about 6 months leading to approximately 6 months*4 weeks*5 days=120 days with 60 days allocated to intervention and 60 allocated to treatment as usual. This study is designed to detect a 15% absolute reduction in the inpatient admission within 5 days of index ED presentation with the usual care group assumed to have a 50% inpatient admission rate (internal report). We will have 85% power to detect this reduction with a total sample size of 414 (α=0.05) using a Chi-square test for independence. We will not need to adjust for attrition as the primary outcome of inpatient admission <5 days is obtainable from electronic health records for all individuals. To account for the possible correlation among patients seen in the ED on the same day, we have inflated the sample size by 10% assuming the average number of patients per ED per day is 2 and the intra-class correlation coefficient=0.1 (Design effect=1+(2-1)ICC). Therefore, our target sample size is N=456.

6.2. Statistical analysis

All analyses will follow intention to treat such that patients will be analyzed based on the allocated intervention on the day of their ED visit (BH-VPN or treatment as usual). We will compare the two groups on age, sex, suicide ideation, and neurocognitive disorders to assess for balance, which is inferred with randomization.

The primary outcome, inpatient admission $\leq$ 5 days, will be compared between the two groups of patients using a chi-square test. We will explore differences by site by conducting stratified analysis by hospital. We will attempt to adjust for the correlation among patients seen on the same day using a generalized linear mixed model with a log link and random effect for day, nested within hospital. If convergence problems arise due to small sample sizes, we will collapse by week rather than day. We will also control for hospital as a fixed effect in the model. Results for group comparisons will be presented with odds ratios and 95% confidence intervals.

Secondary outcomes are 45-day post discharge utilization (yes/no), 90-day post discharge utilization (yes/no), QCC defined 30-day readmission (yes/no), and patient centric 30-day readmission (yes/no). Each of the secondary outcomes are dichotomous and will be compared using the same approach as the primary outcome. All tests will be two sided and the data will be analyzed using SAS Enterprise Guide version 6.1. For all outcomes, we assume if there are no visits in the CHS electronic medical record that the value for having a visit is null; therefore, there will be no missing data for the primary or secondary outcome measures.

6.3. Data Collection Dates

The implementation of the BH-VPN will begin in June among patients with a completed telepsychiatric consult.

7. PROJECT TIMELINE

Project Timeline	2017								2018			
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Initial IRB Submission												
Site/Teammate Training (SIV)												
Prepare Methods manuscript												
Registration with Clinical Trials.gov												
First Patient on Study												
Last Patient on Study												
Study Duration												
Final Data Analysis												
Internal white paper												
Manuscript Prep and Submission												
Conference Presentation/Posters												

8. INTERVENTION PLAN

8.1. Navigator Assessments

The initial assessment within 72 hours will capture the following components:

- Communication method
- Insurance
- Primary care provider
- Outpatient Psychiatry provider
- Collateral resource
- Recent visit summary
- Substance abuse
- Medication barriers
- Appointment Barriers
- Transportation needs
- Access to medications
- Community Resources
- Columbia-Suicide Rating Scale to assess for suicide ideation

8.2. Follow-up Assessments

The weekly follow-up contact assessments are comprised of the following components:

- Columbia-Suicide Rating Scale to assess for suicide ideation
- Appointment reminder\follow-up
- Medication access barriers
- Substance use disorder follow-up
- Supportive listening
- Psychoeducation
- Utilization of community resources
- Crisis planning and adherence to the plan by the patient

9. STUDY GOVERNANCE

This quality improvement trial will be conducted at Carolinas HealthCare System. It will be run jointly by the Center for Outcomes Research and Evaluation (CORE) and the Behavioral Health Department. Wayne Sparks, MD, (ED Psychiatry) will serve as the Principal Investigator with oversight from the Executive Committee (EC). Jason Roberge, PhD, MPH will serve as co-principal investigator on behalf of CORE. The EC will consist of leaders across the System involved in the trial, quality improvement, and implementation (Table 1). The EC will have the overall responsibility of trial oversight and direction. The EC will support dissemination of project findings and next steps. The EC will receive monthly progress reports and will meet periodically for status updates from the team and to set direction. When appropriate, ad hoc committee meetings will be scheduled to discuss pressing concerns.

Table 1. Executive Committee	
Wayne Sparks	Behavioral Health
Manuel Castro	Behavioral Health
John Santopietro	Behavioral Health
Scott Furney	CHS Executive Leadership/Internal Medicine
Mary N. Hall	CHS Executive Leadership
James Hunter	CHS Executive Leadership
Scott Rissmiller	CHS Executive Leadership

9.1. Protocol and Pathway Training

Background, protocol and process steps will be presented to psychiatrists and nurse practitioners who will be providing virtual psychiatric consultations. The role of virtual patient navigator and randomization scheme will be presented so expectations are clear that this is not available every day/time or weekends. This will be presented at the Department of Psychiatry meeting, which includes Emergency and Telepsychiatry Departments. Attendees may also include providers, who at some point may see patients who have been through this pathway, but will not be directly involved in providing evaluations. Education will be provided to the emergency department staff involved in this project, so that they are aware of the process and the role of the virtual patient navigator.

10. SAFETY RISKS AND REPORTING

The data collection and intervention for this project presents no more than minimal risk to patients. However, patients who present to the ED with a behavioral health crisis are considered a high-risk population. The implementation of the BH-VPN and its components complement ongoing patient care through virtual patient navigation within CHS. The addition of an evaluation design that aligns with existing patient care where there are limited resources thus confers minimal additional risk to patients. Resource constraints do not allow for the virtual patient navigation to be offered on all days allowing for a natural experimental design.

Implementation of new innovative techniques in the usual care process potentially introduces an increased possibility for care elements that are less effective, as effective, or more effective in providing quality of care. To address additional risk, or increased time without direct visual and in-person medical supervision we will collect the following potential adverse events: deaths, and reported events of suicidal ideation. These events will be weighed against average expected rates in this population by independent providers and experts in behavioral health and research, who will serve on a data and safety monitoring board.

Other potential risks of participation in this project include, the risk of health information disclosure. There is always the risk of disclosure of a patient's private health information (PHI) or medical information. However, the processes identified in this protocol to enable the execution of this project, do not increase inherent risk of disclosure. Carolinas HealthCare System utilizes several hard and soft safety controls in the protection of patient information and medical records. Security controls include, but are not limited to, multiple system firewalls, access restrictions to patient records and information, locked offices and buildings housing research and patient data, and multiple layers of username and password protected computer and system access. The project team will ensure that appropriate handling of patient PHI follows standard CHS procedure. In the event of PHI disclosure, the appropriate internal departments will be informed and processed per legislation and privacy regulations.

10.1. Data and Safety Monitoring Board (DSMB)

Per the NIH, A DSMB is an independent advisory body of experts appointed to assess, at regular intervals, the progress of a trial, review accumulating data, evaluate safety event reports, and determine critical efficacy endpoints in a manner that contributes to the safety of subjects and the continued validity and scientific merit of the trial. Due to the project's high risk population, this protocol will be monitored according to the protocol-specific data and safety monitoring plan, and will abide by standard operating procedures set forth by both the Carolinas Healthcare System Office of Clinical and Translational Research and CORE. It is the responsibility of the Principal Investigator to monitor the safety data for this study. The Principal Investigator, Statistician, and other team members will meet as needed to review enrollment and retention, safety data for all subjects, study progress, and validity/integrity of the data. Documentation of these meetings will be kept with study records. The Principal Investigator will submit data to the project-specific Data and Safety Monitoring Board according to the overarching Data and Safety Monitoring Plan.

10.2. Data Quality Assurance

This study will be organized, performed, and reported in compliance with the study protocol, standard operating procedures (SOPs) of the CORE and CHS OCTR, and other applicable regulations and guidelines (e.g. GCP).

10.3. Safety Reporting to the IRB

All events occurring during the conduct of a protocol and meeting the definition of a reportable safety event per the Chesapeake IRB guidelines, will be reported to the IRB within 10 working days of the Investigator learning of the event, per their requirements.

Major protocol deviations that result in a threat to subject safety or the integrity of the study will be reported to the IRB per their requirements.

10.4. Safety Monitoring by the Sponsor

The conduct of this project will abide by standard operating procedures set forth by both CHS OCTR and CORE. It is the responsibility of the Principal Investigator to monitor the safety data for this study. The Principal Investigator, Statistician, and other team members will meet as needed to review enrollment and retention, safety data for all subjects, study progress, and validity/integrity of the data. Documentation of these meetings will be kept with study records.

11. RESEARCH COMPLETION

The Principal Investigator has the right to close the project at any site any time.

For any of the above closures, the following applies:

- Closures should occur only after consultation between involved parties.
- All affected institutions must be informed as applicable, according to local law.
- In case of a partial study or site closure, patients still participating in the COPD clinical pathway, or those who are considered in follow-up, must be taken care of in an ethical manner.

The study will be considered complete when one or more of the following conditions is met:

- The enrollment period has ended, and the data collection period is complete.
- All subjects have dropped out or discontinued from the study after the enrollment period is completed, but prior to data collection cutoff as described in section 8.3.
- The IRB, DSMB, or Principal Investigator discontinues the study.
- The Principal Investigator defines an administrative or clinical cut-off date.
- The DSMB deems the study inefficacious or unsafe.

Upon study completion, a final report will be presented to the Executive Committee and all key stakeholders. The final report will detail all findings including primary, secondary and exploratory outcomes. The team will also prepare a manuscript for publication focused on outcomes and feasibility of implementation of the transition clinic.

12. ETHICAL AND LEGAL ISSUES

12.1. Ethical and Legal Conduct of the Study

The procedures set out in this protocol, pertaining to the conduct, evaluation, and documentation of this study, are designed to ensure that the Investigators abide by Good Clinical Practice (GCP) guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study will also be carried out in keeping with the applicable local laws and regulation(s).

Documented approval from appropriate agencies (e.g. IRB) will be obtained before the start of the study, per GCP, local laws, regulations, and organizations.

Strict adherence to all specifications laid down in this protocol is required for all aspects of study conduct; the Investigators may not modify or alter the procedures described in this protocol.

Modifications to the study protocol will not be implemented without consulting the Principal Investigator and the IRB, as applicable. The Principal Investigator must assure that all study personnel, including co-investigators and other study staff members, adhere to the study protocol and all applicable regulations and guidelines regarding research both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and properly documented.

12.2. Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

12.3. Disclosure of Data

The Principal Investigator, his associates and co-workers, and the appropriate regulatory agencies may use the information and data included in this protocol as necessary for the conduct of the study. Information contained in this study, and data and results from the study are confidential and may not be disclosed without the written permission of the Principal Investigator.

13. RETENTION OF RECORDS

Essential documentation including all IRB correspondence, will be retained for at least 2 years after the investigation is completed. Documentation will be readily available upon request.

14. PUBLICATION POLICY

The Principal Investigator or designee must send any draft manuscript, abstract, or conference presentation to members of the project Executive Committee for feedback and transparency, prior to submission of the final version. The Principal Investigator will be responsible for all relevant aspects regarding data reporting and publication.

The Principal Investigator or designee will ensure that the information and results regarding the study will be made publicly available on the internet at www.clinicaltrials.gov.

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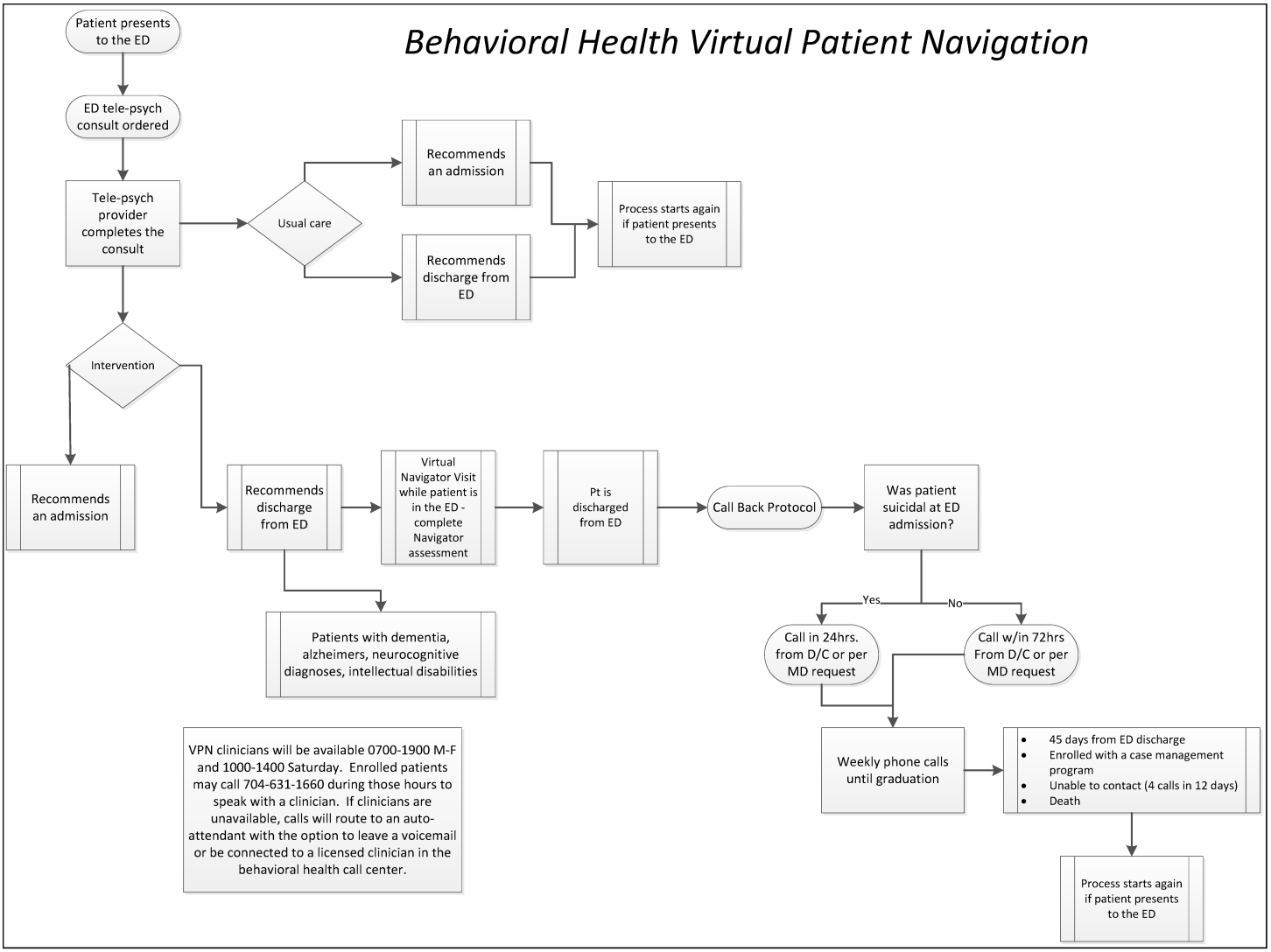
APPENDICES

APPENDIX 1: Patient Navigation

This diagram shows the contact points among patients receiving care by the BH-VPN.



APPENDIX 2: Suicide Ideation steps

This diagram shows the procedure if a patient is identified with suicidal ideation from the CSSRS screening tool. This tool is administered during each phone contact.