

**TITLE: A VIRTUAL NAVIGATION INTERVENTION TO REDUCE
BEHAVIORAL HEALTH ADMISSIONS FROM RURAL EMERGENCY
DEPARTMENTS (VIBRANT)**

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ADMISSIONS FROM RURAL EMERGENCY DEPARTMENTS (VIBRANT)**

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

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PROTOCOL SUMMARY	
Study Title	A Virtual Navigation Intervention to Reduce Behavioral Health Admissions from Rural Emergency Departments (VIBRANT)
Study Design	A randomized trial evaluating a quality improvement initiative
Study Objectives	<p>Primary objective:</p> <ul style="list-style-type: none"> • Compare the effectiveness of having the Behavioral Health – Virtual Patient Navigation (BH-VPN) program available compared to usual care, on admission rates among patients in the ED with a telepsychiatric consult <p>Secondary objectives:</p> <ul style="list-style-type: none"> • Compare demographics and Charlson comorbidity score between the two arms of the study • Compare the patient-centric 45-day utilization rate after the ED visit (ED, IP, OBS, encounter) between the 2 arms of the study • Compare the frequency of patients with an encounter with a self-harm diagnosis within 45 days of the ED visit between the 2 arms of the study • Compare the frequency of patients who return to the ED and have a telepsychiatric consult within 45 days of their initial ED visit between the 2 arms of the study <p>Reporting for the Duke Foundation:</p> <ul style="list-style-type: none"> • Count/frequency of patients in the intervention and usual care arms presenting to an ED that have a telepsychiatric consult during the intervention • Count/frequency of patients with an admission after telepsychiatric consult in the intervention arm • Count/frequency of patients active in the BH-VPN • Count/frequency of patients active in the BH-VPN program that had an encounter with a self-harm code within 45 days of their ED visit • Count/frequency of patients active in the BH-VPN program that have an acute care visit (ED, IP, OBS) within 45 days of their ED visit • Count/frequency of patients active in the BH-VPN program that return to an Atrium Health emergency department with a telepsychiatric consult within 45 days of their ED visit • Count/frequency of patients active in the BH-VPN program that improve their PHQ-9 score, among patients with an initial score >10

	<ul style="list-style-type: none"> • Count/frequency of active in the BH-VPN program that report suicide ideation on their initial PHQ-9 (Q2>0), that no longer report suicide ideation on their last PHQ-9 (Q2=0) • Count/frequency of patients active in the BH-VPN program with successful case closure (complete the program or have a successful referral in care)
<p>Inclusion/ Exclusion Criteria</p>	<p>Inclusion:</p> <ul style="list-style-type: none"> • Present to an ED at participating sites • Complete a telepsychiatric consult as captured in the electronic medical record • Complete a telepsychiatric consult during the navigator’s hours of operation • ≥ 18 years of age at time of ED encounter <p>Exclusion:</p> <ul style="list-style-type: none"> • No exclusions
<p>Study Procedures</p>	<p>Patients are identified by a clinician in the ED as needing psychiatric evaluation and a referral is made to a tele-psych provider for a virtual consult. Patients who complete a telepsychiatric consult in the ED can be enrolled to either the control or intervention arm based on a randomization scheme that randomly allocates days that navigators are available. Psychiatrists are reminded through daily communication as to whether the BH-VPN program is available and the ED locations. The psychiatrist will make a recommendation to admit or discharge the patient. For patients that have a discharge recommendation on days that BH-VPN is available, patients will be offered the BH-VPN program. Enrolled patients are followed for up to 45 days. Each patient will receive the following core components:</p> <ol style="list-style-type: none"> 1. Introduction to the patient follow-up process prior to discharge 2. Follow-up evaluation within 72 hours by phone and weekly contact 3. Confirm that an in-person follow-up visit with an appropriate provider or clinician is scheduled. Where applicable, confirm in-network follow-up appointments are completed. 4. Ongoing assessment: substance use disorder, medication barriers, and appointment barriers 5. Assist with community resources, crisis planning, and supportive listening 6. Placement into an appropriate case management program, if needed. <p>On days where the navigator is available, all patients who meet eligibility criteria will be considered exposed to the intervention; whereas, on days the navigator is not available all patients will be considered exposed to usual care.</p>

Statistical Analysis	Analyses will include all patients identified as having completed telepsychiatric consult and meeting the inclusion criteria. Baseline comparisons of the intervention and usual care groups will be made using univariate analyses. The primary outcome, hospital admission, and secondary outcomes will be compared between the two groups of patients using generalized linear mixed-effects model with a logit link function. Results will be presented with odds ratios and 95% confidence intervals.
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LIST OF ABBREVIATIONS

BH-VPN	Behavioral Health - Virtual Patient Navigation
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
NC	North Carolina
OCTR	Office of Clinical and Translational Research
PHI	Private Health Information
SOP	Standard Operating Procedures

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OBJECTIVES

1.1. Hypothesis

Index admission rates will be lower among patients who complete a tele-psych consult at an ED on days where the Behavioral Health - Virtual Patient Navigation (BH-VPN) program is available compared to patients who complete a tele-psych consult at an ED on days where the BH-VPN program is not available.

1.2. Primary Objective

Compare the effectiveness of having the VBHI program available compared to usual care, on modifying the admission rate from the ED.

1.3. Secondary Objectives

The secondary objectives are to compare the behavioral health – virtual patient navigation team’s effect on additional patient outcomes

- I. Compare the patient-centric 45-day utilization rate after the ED visit (ED, IP, OBS, encounter)
- II. Compare the frequency of patients with an encounter with a self-harm diagnosis within 45 days of the ED visit
- III. Compare the frequency of patients who return to the ED and have a telepsychiatric consult within 45 days of their initial ED visit

1.4. Reporting for the Duke Foundation

- Count/frequency of patients presenting to an ED that have a telepsychiatric consult during the intervention
- Count/frequency of patients with an admission after telepsychiatric consult in the intervention arm
- Count/frequency of patients enrolled in the BH-VPN program
- Count/frequency of patients enrolled in the BH-VPN program that had an encounter with a self-harm code within 45 days of their ED visit
- Count/frequency of patients enrolled in the BH-VPN program that have an acute care visit (ED, IP, OBS) within 45 days of their ED visit
- Count/frequency of patients enrolled in the BH-VPN program that return to an Atrium Health emergency department with a telepsychiatric consult within 45 days of their ED visit
- Count/frequency of patients enrolled in the BH-VPN program that improve their PHQ-9 score, among patients with an initial score >10
- Count/frequency of patients enrolled in the BH-VPN program that report suicide ideation on their initial PHQ-9 (Q2>0), that no longer report suicide ideation on their last PHQ-9 (Q2=0)

- Count/frequency of patients enrolled in the BH-VPN program with successful case closure (complete the 45-day follow-up period or have a successful referral in care)

2. BACKGROUND

The primary arena for emergency psychiatric care is in emergency departments (ED), largely because of the impact of deinstitutionalization and other social forces on the mentally ill community.^{1,2} Lack of community-based care for mental illness has contributed to increasing inpatient behavioral health admissions and long stays in the emergency department.³ The high volume of psychiatric patients seen and waiting in hospital EDs may prevent other medical patients from obtaining timely care.⁴ The average delay for admission to a NC state hospital for psychiatric care in 2012 was 3 days and rose to 3.5 days in 2013.⁵ Other contributors to the problem of patients with psychiatric conditions crowding EDs include diminishing access to mental health care in the community, shrinking mental health resources, and increasing fragmentation of resources.⁶

Mental health care in rural regions is a national priority.⁷ In 2016, 18.7% of residents of rural counties have some diagnosed form of mental illness. In addition, 3.9%, or approximately 1.3 million residents of rural counties experienced serious thoughts of suicide.⁸ The Tennessee Hospital Authority estimates a cost of \$9,472 for an inpatient admission with a behavioral health diagnosis.⁹ EDs servicing rural areas often do not have the staff to support patients presenting with a behavioral health crisis. In North Carolina, 70 of its 100 counties have no child and adolescent psychiatrists, 28 have no practicing psychiatrists and 18 counties have only one psychiatrist.¹⁰

Visits to EDs for behavioral health crises are common; in North Carolina, a person in behavioral health crisis presents to an ED every 2.5 minutes.¹¹ Due to the lack of coordinated resources and high recidivism, many patients are admitted to a psychiatric facility perhaps unnecessarily, rather than receiving the care coordination that could prevent an admission.⁶ Virtual care offers an efficient means for patient evaluation, treatment recommendations, and follow-up care due to the remoteness of rural EDs and lower volume of patients needing services. Integrating patient navigation into emergency mental health care delivery may address many of the barriers to patient success post-discharge. Patient navigation has a growing evidence base for improving patient outcomes.¹² The use of virtual care has been shown to improve access and engagement of patients with their care teams. Post-discharge follow-up has also been shown to effectively reduce suicide attempts, with one study that evaluated periodic phone check-in after ED discharge showing a 30% reduction in suicide attempts.¹³

The proposed study builds upon evidence of virtual patient navigation effectiveness among prior research. The novelty of this study is in its design, as prior studies have used cohort designs for causal inference to inform care delivery for patients with mental illness. This randomized trial will provide greater precision and rurality to assess evidence of whether the addition of virtual patient navigation to telepsychiatric consults decreases initial hospitalization, readmissions, and repeated use of the ED among patients presenting to rural EDs with a behavioral health crisis.

3. RATIONALE

To enhance the care of patients with a telepsychiatric consult, Atrium Health has designed a Behavioral Health Virtual Patient Navigation (BH-VPN) program. Navigators 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 presents to a participating Atrium Health ED, 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 program. A patient can choose not to receive care by a navigator post discharge.

The BH-VPN program 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 an Atrium Health 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 other criteria. For example, if a patient has Medicaid through Cardinal Innovations, a managed care organization providing local behavioral health care, and meets specific criteria, would no longer require navigation services. A patient's contact with the BH-VPN program 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. For those patients enrolled in a case management program, then navigator will ensure the patient is in contact with case management program staff before ending contact with the patient.

This research project is a pragmatic, randomized evaluation of a quality improvement initiative which seeks to evaluate the effects of standardizing the use of a BH-VPN program among patients with a telepsychiatric consult. The outcomes evaluation of this intervention has been designed to integrate with 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 a provider 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 criteria and the telepsychiatric consultation occurs during potential BH-VPN program hours. We will accrue patient data for evaluation during a period starting in October 2019. Based on prior data, we estimate about 1,100 patients will complete a telepsychiatric consult in a 14-month period. Patients will not be accrued on days/times when the navigators would be not available (e.g. 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.

4.2. Eligibility Criteria

4.2.1. Inclusion Criteria

Eligible patients must meet each of the following criteria:

- Present to an ED at participating sites
- Complete a telepsychiatric consult as captured in the electronic medical record
- Complete a telepsychiatric consult during the navigator's hours of operation (Monday-Friday 7AM to 11PM and Saturday 7AM to 7PM)
- ≥ 18 years of age at time of ED admission

4.2.2. Exclusion Criteria

- Patients currently enrolled in the BH-VPN program upon their index ED encounter

4.3. Evaluable Population

Patients included in the evaluable population for this project, will contribute data to the final outcomes assessment. All patients who meet the inclusion criteria will be assessed for the primary outcome (intent to treat). Patients will have one of the following ED discharge dispositions: (admission to the hospital for medical reasons, admission to a behavioral health facility by voluntary or involuntary commitment, discharge from the ED, or death). A patient will contribute to the analysis once, using their initial enrollment to either arm of the study.

5. OVERALL DESIGN

5.1. Outcome Variables

5.1.1. Primary Outcome Variable

The primary outcome variable is ED to hospital admission. This is a patient that presents to an Atrium Health ED and then is admitted for any reason. A patient's disposition is tracked in the electronic medical record. The disposition is simply indicated as admitted or not admitted.

5.1.2. Rates and Variable Descriptions

- a. Demographic characteristics (age, race, gender)
- b. Charlson comorbidity index score

- c. Patient-centric defined 45-day utilization rate. This is a utilization rate among patients with an ED, inpatient, or observation encounter to any Atrium Health facility (≤ 45 days after the ED admit date)
- d. Frequency of self-harm diagnoses within 45 days of the index ED encounter at any Atrium Health location facility (≤ 45 days after the ED admit date)
- e. Frequency of patients who return to the ED and have a telepsychiatric consult (≤ 45 days after the ED admit date)

5.1.3. Reporting for the Duke Foundation

- Count/frequency of patients presenting to an ED that have a telepsychiatric consult during the intervention
- Count/frequency of patients with an admission after telepsychiatric consult in the intervention arm
- Count/frequency of patients enrolled in the BH-VPN program
- Count/frequency of patients enrolled in the BH-VPN program that have an encounter with a self-harm code within 45 days of their ED visit
- Count/frequency of patients enrolled in the BH-VPN program that have an acute care visit (ED, IP, OBS) within 45 days of their ED visit
- Count/frequency of patients enrolled in the BH-VPN program that return to an Atrium Health emergency department with a telepsychiatric consult within 45 days of their ED visit

PHQ-9 are taken about every 2 weeks during a patient's enrollment. The post PHQ-9 score will be the score closest to the 45-day follow-up period.

- Count/frequency of patients enrolled in the BH-VPN program that improve their PHQ-9 score, among patients with an initial score >10
- Count/frequency of patients enrolled in the BH-VPN program that report suicide ideation on their initial PHQ-9 ($Q9>0$), that no longer report suicide ideation on their last PHQ-9 ($Q9=0$)
- Count/frequency of patients enrolled in the BH-VPN program with successful case closure (complete the 45-day follow-up period or have a successful referral in care)

5.2. Randomization and Allocation

Randomization will be based on days the navigators are available to treat patients who've completed their telepsychiatric consult. 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. Patients will accrue in both arms of the study during the navigators' days and hours of operation. Patients will not be accrued on days where the navigators are not potentially available such as weekends, nights, and holidays.

Block randomization will be used to assign days the intervention is offered. In each 7-day period (Monday through Saturday) there will be three days the program is offered and three days where the program is not offered. The program is not available to patients in the ED on Sundays. The hours of availability are 7AM to 11PM Monday through Friday and 7AM to 7PM on Saturdays.

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

The BH-VPN outlines the flow of patients from initial contact to their follow-up calls (see Appendix 1). In the existing ED workflow, patients are identified by a clinician in the ED as needing psychiatric evaluation and a referral is made to a tele-psych provider for a virtual consult. Patients who complete a telepsychiatric consult in the ED can be enrolled to either the control or intervention arm based on a randomization scheme that randomly allocates days that navigators are available. Psychiatrists are reminded through daily communication as to whether the BH-VPN program is available and the ED locations. The psychiatrist will make a recommendation to admit or discharge the patient. The ED physician will make the final decision on whether to admit or discharge the patient from the ED. Patients that have a discharge recommendation on days the program is available, will be offered the BH-VPN program. Enrolled patients are followed for up to 45 days.

If a discharge recommendation is made, a patient will be approached again by the navigator virtually for enrollment into the BH-VPN program. The patient has the option not to be followed by the navigator. Before discharge, the navigator will complete an initial virtual behavioral health assessment. The initial health assessment contains information such as preferred communication method, primary care provider, psychiatry provider, PHQ-9 screening, 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 at least weekly, may include information such as a suicide ideation safety screening, an appointment reminder, appointment barrier evaluations, medication obtainment follow-up, substance use disorder follow-up, PHQ-9 screening, supportive listening, psychoeducation, community resource follow-up, and additional crisis planning. Phone calls are weekly as standard care but may be more often depending on the individual needs of the patient. Appointments are dependent on a patient's specific needs and may be with a therapist or psychiatrist as well as other providers in the community such as primary care or referral to a community provider.

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, call 911 for a well-check, or call 911 to send the patient to the ED as per current standard of care.

5.4. Follow-up

Patients being treated in the BH-VPN program 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 Graduation from the BH-VPN Program

For the intervention arm, successful completion is defined as

- Enrolled for 45 days post ED admit date
- Enrolled in another Care Management program

For the intervention arm, failure to complete is defined as

- Unable to connect: 4 calls attempted over 12 days
- Death
- Declined services initially or after enrollment

5.6. Continuation of the Intervention

Participating ED sites may continue utilizing the BH-VPN program 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 bi-monthly report will be produced for the intervention arm. The report will be by ED site and overall.

- Count of patients meeting the inclusion criteria
- Count of patients with a HealtheCare account
- Count of patients enrolled in the BH-VPN program
- Patient list with their enrollment status in HealtheCare

A monthly report will be produced for the intervention arm. The report will be by ED site and overall. Report to be generated following the end of the previous month.

- Count of patients meeting the inclusion criteria
- Count of patients with a HealtheCare account
- Count of patients enrolled in the BH-VPN program

- Patient list with their enrollment status in HealtheCare

An Annual report will be prepared for the Duke Foundation measures.

6.1. Sample size analysis and statistical analysis

Given the preliminary data from our previous study, we will power the proposed study to detect at least an 8% absolute difference between hospital admission in the VIBRANT intervention and usual care groups. The usual care group is assumed to have a 60% inpatient admission rate based on prior data. There is 85% power to detect this reduction with a total sample size of 1,030 ($\alpha=0.05$) using a Chi-square test for independence. To account for the possible correlation among patients seen in the ED on the same day, we inflated the sample size by 10% assuming the average number of patients per ED per day is 2 with a 0.1 intra-class correlation coefficient (design effect = $1 + (2-1)*ICC$).¹⁴ Thus, the target sample size is $n=1,133$. The power was calculated using PASS 15 Power Analysis and Sample Size Software (2017). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.

6.2. Statistical analysis

Prior to analysis, descriptive statistics will be calculated to screen all variables for accuracy and to examine distributions.

All analyses will follow the intention-to-treat (“ITT”) principle, such that patients will be analyzed based on their assignment to the BH-VPN program or usual care. Balance in baseline characteristics between the groups will be assessed using Student’s t-test for normally distributed data, the Wilcoxon rank sum test for ordinal data or interval data that are not normally distributed, and the chi-square test for categorical data. Normality will be assessed using the Shapiro Wilk test and Q-Q plots.

The primary outcome, hospital admission (yes/no), is a binary dependent variable and will be compared between the BH-VPN and usual care groups using a generalized linear mixed-effects model with a logit link function. To adjust for correlation among patients seen on the same day and in the same ED, the model will include a random effect term for day nested within ED. The primary predictor in the model is an indicator for assignment to the BH-VPN program versus usual care. Additional baseline covariates will be included in the model if they are either strongly correlated with the dependent variable or show baseline imbalance between the two groups.

A similar approach will be used for the secondary outcomes to assess the patient-centric 45-day utilization rate, encounters with a self-harm diagnosis rate, and ED readmission rate. The models assessing these measures will be generalized linear mixed-effects models with a logit link, where utilization, diagnosis, or readmission, (yes/no) is the binary dependent variable. Independent variables in the models will be as described above for the primary analysis.

In addition, per-protocol analyses of the primary and secondary outcomes will be performed to evaluate the effect of BH-VPN program participation, in contrast to the ITT analysis evaluating the effectiveness of randomization to the program. The per-protocol analyses will include only subjects who received and adhered to the treatment (BH-VPN program or usual care).

Other binary outcome variables (e.g., frequency of patients active in the BH-VPN program) will be analyzed using descriptive statistics, unadjusted odds ratios, and 95% confidence intervals.

All tests will be two sided and the data will be analyzed using SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NC, USA).

6.3. Data Collection Dates

The implementation of the BH-VPN will begin in October 2019 among patients with a completed telepsychiatric consult.

7. INTERVENTION PLAN

7.1. Navigator Assessments

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

- Communication method
- PHQ-9
- 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

7.2. Follow-up Assessments

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

- Columbia-Suicide Rating Scale to assess for suicide ideation
- PHQ-9
- 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

8. STUDY GOVERNANCE

This randomized trial will be conducted at Atrium Health. It will be run jointly by the Center for Outcomes Research and Evaluation (CORE) and the Behavioral Health Service Line. Wayne Sparks, MD, (Psychiatry) will serve as the clinical 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 provide trial oversight and direction. The EC will support dissemination of project findings and next steps. The EC will receive progress reports from the team. When appropriate, ad hoc committee meetings will be scheduled to discuss pressing concerns.

James Rachal	Atrium Health Executive Leadership – Psychiatry
Wayne Sparks	Atrium Health Executive Leadership – Psychiatry
Martha Whitecotton	Atrium Health Executive Leadership – Behavioral Health
Sue Deluca	Atrium Health Executive Leadership – Behavioral Health
Michael Gibbs	Atrium Health Executive Leadership – Emergency Medicine
Andrew McWilliams	Atrium Health Executive Leadership – CORE Medical Director

8.1. 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.

9. SAFETY RISKS AND REPORTING

The data collection and intervention for this project presents no more than minimal risk to patients. The implementation of the BH-VPN program and its components complement ongoing patient care through virtual patient navigation within Atrium Health. The BH-VPN program is currently offered at 10 urban EDs within Atrium Health. This study is evaluating the BH-VPN program among additional rural EDs that will offer the program to their patients. The addition of an evaluation design that aligns with existing patient care where there are limited resources thus confers minimal additional risk to patients.

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. Atrium Health 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 Atrium Health procedure. In the event of PHI disclosure, the appropriate internal departments will be informed and processed per legislation and privacy regulations.

9.1. Data Quality Assurance

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

9.2. Data Monitoring by the Sponsor

The conduct of this project will abide by standard operating procedures set forth by both Atrium Health and CORE. The Principal Investigators, statistician, and other team members will meet as needed to review enrollment and retention, study progress, and validity/integrity of the data. Documentation of these meetings will be kept with study records.

10. RESEARCH COMPLETION

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

For any closure, the following applies:

- Closures should occur only after consultation between involved parties.
- In case of a partial study or site closure, patients still participating in the BH-VPN program, 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.
- The IRB or Principal Investigator discontinues the study.
- The Principal Investigator defines an administrative or clinical cut-off date.

Upon study completion, a final report will be presented to the Executive Committee and all key stakeholders. The final report will detail 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 BH-VPN program.

11. ETHICAL AND LEGAL ISSUES

11.1. 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.

Modifications to the study protocol will not be implemented without consulting the Principal Investigator and IRB approval, 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 required data will be collected and properly documented.

11.2. 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.

11.3. 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.

12. RETENTION OF RECORDS

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

13. 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.

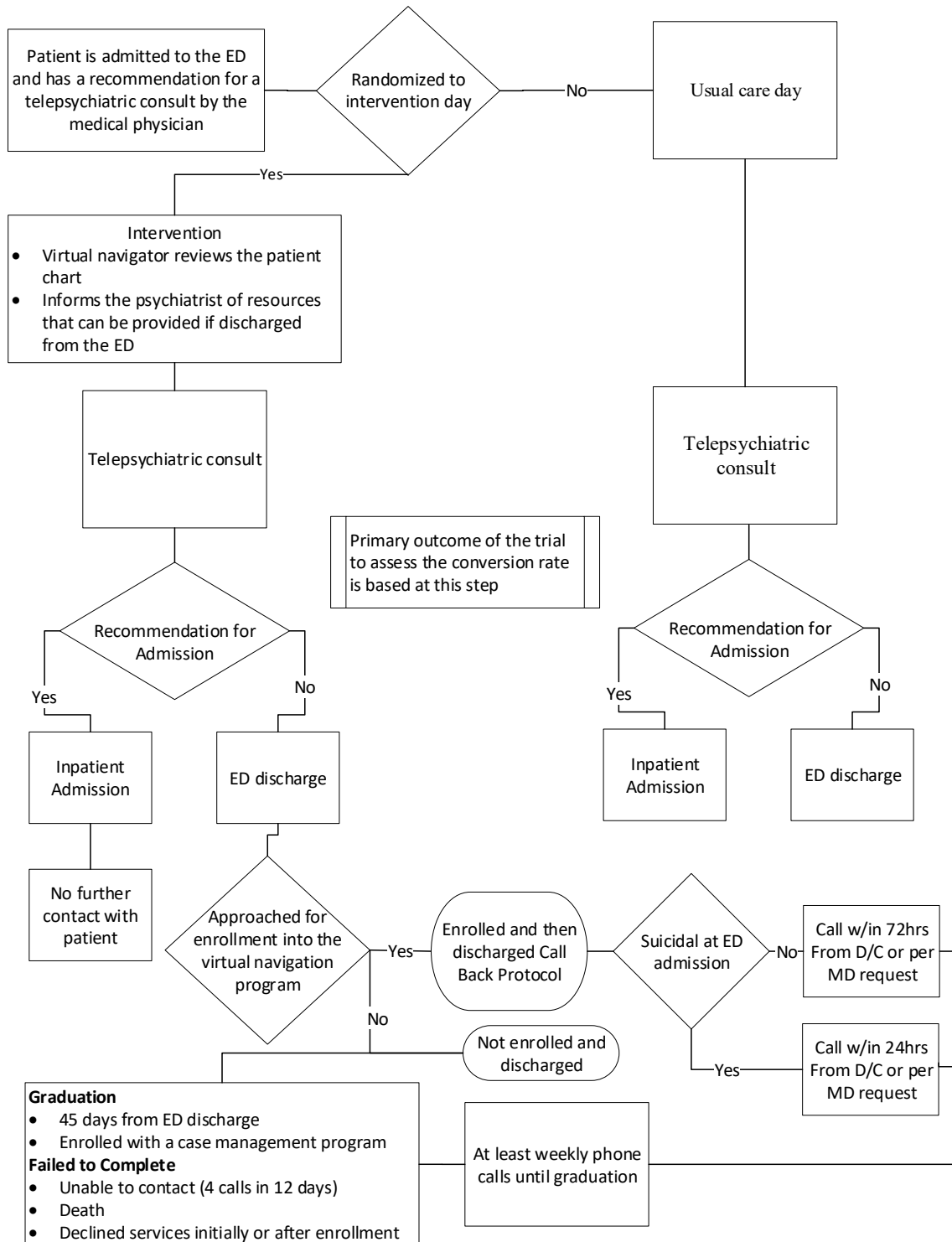
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APPENDICES

APPENDIX 1: Patient Navigation

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



APPENDIX 2: Suicide Ideation steps

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

