PROTOCOL TITLE: Engaging Patients with Mental Disorders from the ED in Outpatient CARE: A Comparative Effectiveness Workforce Study of Peer Specialists vs. Professional Care Managers (EPIC)

Trial Registration:
ClinicalTrials.gov ID: NCT02989805

PRINCIPAL INVESTIGATOR:

Benjamin Druss, MD, MPH
Professor and Rosalynn Carter Chair in Mental Health
Rollins School of Public Health
404-712-9602 (office phone)
bdruss@emory.edu

VERSION:
August 27, 2019, Updated February 11, 2020

FUNDING SOURCE: Patient-Centered Outcomes Research Institute (PCORI) IHS-1510-32431

Table of Contents

1.0 Study Summary

Study Title	Engaging Patients with Mental Disorders from the ED in Outpatient CARE: A Comparative Effectiveness Workforce Study of Peer Specialists vs. Professional Care Managers (EPIC)
Study Design	Multi-site randomized trial study design across 9 Emergency Departments (EDs) in South Carolina with telepsychiatry programs and 8 matched community mental health centers (CMHC); each CMHC site had one professional care manager and one peer cares specialist manager to deliver Coordination, Access, Referral and Evaluation (CARE) intervention.
Primary Objective	Use quantitative data from the study sample to assess factors, including assignment to a peer versus professional, predicting patient engagement after a mental health emergency visit.
Secondary Objective(s)	Use qualitative interviews with patients and providers to understand stakeholder perspectives on patient engagement after a mental health emergency visit.
Research Intervention(s)/Interactions	The Coordination, Access, Referral and Evaluation (CARE) intervention is a manualized care management program to improve follow up and treatment engagement for patients after admission to psychiatric emergency rooms. CARE will be delivered by a Peer Specialist or Professional Care Manager.
Study Population	Patients admitted to Emergency Department for a primary diagnosis of a mental disorder.
Sample Size	290
Study Duration for Individual Participants	12 months
Study Specific Abbreviations/ Definitions	N/A
Funding Source	Patient-Centered Outcomes Research Institute (PCORI) IHS-1510-32431

2.0 Objectives

The study will examine predictors, including peer versus professional care manager assignment, of treatment engagement after discharge from a mental health emergency visit. The project period will be structured around two aims, one quantitative and one qualitative. Each aim will seek to further the understanding of the patient, provider, and system-level barriers to, and facilitators of, treatment engagement after emergency department (ED) discharge. We will include randomization to peer versus professional care manager as one of the independent variables of interest.

2.1 Aim 1: Use quantitative data from the study sample, including assignment to a peer versus professional care manager, to assess factors predicting patient engagement after a mental health emergency visit.

2.2 Aim 2: Use qualitative interviews with patients and providers to understand stakeholder perspectives on patient engagement after a mental health emergency visit.

3.0 Background

3.1 Emergency departments (EDs)serve a critical role as a safety net for the uninsured and medically disenfranchised.The growth of population-based models of care under the Affordable Care Act are providing an impetus to reduce uncesssary ED use and improve engagement with outpatient care.[1,2] Patients with mental disorders are among the highest users of emergency department services,[3-10] with visits characterized by long lengths of stay, high intensity, and elevated rates of discharge to hospital settings.[11] After discharge, fewer than half of these patients successfully transition to outpatient care, with high rates of readmission.[12,13] Programs that allow patients with mental disorders to successfully transition to outpatient care hold the potential not only to improve quality and outcomes of care for mental disorders, but to free capacity within Emergency Departments to provide care for other urgent needs.[14]

3.2 Despite the potential of care management programs to address transitions of care in people with mental illness, it has been difficult to disseminate these models more broadly.[15] One reason for this challenge in dissemination has been a shortage of mental health professionals who can fill these roles. There are acute shortages of mental health nurses, particularly in community-based, public sector settings.[16] These problems are likely to worsen in coming years as the mental health nursing workforce ages.[16] Similar shortages are seen for mental health social workers.[17] There is now an opportunity to improve care and fill these gaps with a new group of mental health providers, certified peer specialists -- persons with a history of mental illness offering services to other individuals with mental disorders.[18] Beginning in the 1990s, certified peer specialists began to be

employed in providing peer support in community mental health settings.[19] Certified peer specialists help other patients improve outcomes by modeling successful behaviors and coping strategies, and by guiding them to more effectively utilize community resources. Nationwide, there are more than 10,000 peer support specialists,[20] and 32 State Medicaid programs recognize and reimburse mental health services delivered by certified peer specialists, helping ensure the financial sustainability of programs using these providers.[21]

3.3 The existing literature indicates: 1. The potential effectiveness of care management delivered by mental health professionals in improving treatment engagement and reducing inpatient readmissions; and 2. The fact that certified peer specialists appear to be able to deliver an array of mental health services of similar or better quality as mental health professionals. However, there have been no studies comparing certified peer specialists to professionals in interventions to increase treatment engagement and reduce readmissions. This study will be the first to examine the potential benefits and tradeoffs between these two groups of providers.

3.4 The study results will provide insights on the comparative effectiveness of professional and peer care managers in improving linkage to and engagement with outpatient care, as well as the potential mechanisms by which engagement occurs. The results will help patients to address the question “What are the best ways for me to engage with my mental health care?” It will help Emergency Room Providers to address the question “How can I most effectively reduce the likelihood of my patients being readmitted?” For Community Mental Health providers, it can help address the question “How can I help my patients to more effectively engage with care in our facilities?” And for policymakers, “How can we improve transitions of care between Emergency Departments and inpatient services?” “How can certified peer specialists be used most effectively in the evolving mental health workforce?”

4.0 Study Intervention / Design

4.1 The study used a multi-site randomized trial study design across 9 Emergency Departments in South Carolina with telepsychiatry programs and 8 matched community mental health centers (CMHC); each CHMC site had one professional care manager and one peer specialist care manager to deliver the intervention.

4.2 The Coordination, Access, Referral and Evaluation (CARE) intervention is a manualized care management program designed to improve follow up and treatment engagement for patients after admission to psychiatric emergency rooms. It is built on the PCARE intervention, which was designed to improve treatment engagement and treatment outcomes for

patients in outpatient mental health settings.[22,23] The primary enhancement to the PCARE intervention used to develop the CARE intervention was to add an initial treatment linkage call during the Emergency Department stay. Professional and peer care managers delivered the same intervention.

4.3 Care Managers: Licensed nurses/social workers/counselors or certified peer specialists working at the 8 state-funded CMHCs served as care managers. For each emergency department, one professional and one peer care manager was identified at the associated CMHC and dedicated to the project.

- Training for the professional and peer care managers was identical; however, separate sessions were held to prevent contamination. The training program included a description of the overall study design and modules for each of the key domains covered in the intervention. Care managers received the CARE training manual and demonstrated adherence and competency through role-play scenarios.
- Separate quarterly supervision calls were held with peer and professional care managers to reinforce key elements of the intervention.

5.0 Intervention Procedures Involved

5.1 Treatment Linkage: After a "warm handoff" from the research interviewer who screened the participant into the study, the care manager connected with the participant for the Treatment Linkage Call. During the call, the care manager began to establish rapport and collected contact information including telephone and address. The care manager also ascertained the reason for the ED visit and set an initial appointment with the care manager at the CMHC nearest the ED within two weeks.

5.2 Initial Visit: The purpose of the initial visit at the CMHC was to take a history of the participant and began the process of identifying and addressing barriers to engagement in care. The care manager then reviewed the roles of the participant and care manager, emphasizing the importance of the collaborative relationship between them. The care manager and participant jointly examined the reasons for the ED visit, identified attitudinal and logistical barriers to care, and set goals to address those barriers.

5.3 Follow up visits: After the initial visit, the care manager and patient met in-person monthly, with telephone calls in between. The goal of these meetings was to monitor patients' engagement in care and continue to help address attitudinal and logistical barriers to care and discuss progress

on goals. This pattern of visits and calls continued for the first 6 months of treatment with less frequent visits or calls from months 7 to 12.

6.0 Study Timelines

6.1 Project Duration: October 2016 – March 2020

6.2 Enrollment period: April 2017 – May 2019

6.3 Individual subject's participation: 12 months

- Participant enrolled in project and randomized to peer or professional case manager prior to ED discharge.
- Treatment Linkage: Within 72 hours of enrollment, the care manager made initial contact with participant to establish rapport, obtain contact information, ascertain the reason for ED visit, and set initial appointment with care manager at nearest CMHC within two weeks.
- Initial Visit: Within 30 days of enrollment, the care manager and participant met at the CMHC to take a history of the participant and began the process of identifying and addressing barriers to engagement in care. The care manager then reviewed the roles of the participant and care manager, emphasizing the importance of the collaborative relationship between them.
- Follow up visits: After the initial visit, the care manager and patient met in-person monthly, with telephone calls in between. The goal of these meetings was to monitor patients' engagement in care and continue to help address attitudinal and logistical barriers to care.

7.0 Subject Population

7.1 Inclusion Criteria: Broad inclusion criteria were chosen to maximize generalizability of study findings. Inclusion criterion included: 1. Being 18 years of age or older; and 2. Admission to the ED for a primary diagnosis of a mental disorder (ICD-9 Codes 290.xx-302.xx, 306.xx-311.xx); 3. Plan for discharge to participating CMHC; and 4. Lives within the CMHC catchment area.

7.2 Exclusion Criteria: Exclusion criteria comprised of cognitive impairment based on a score of > 3 on a 6-item, validated screener developed for clinical research[24] (which could impede capacity to provide informed consent as well as effective participation in the intervention), not able to speak English, and being admitted to the hospital from the ED.

8.0 Number of Participants

8.1 Target Sample Size: 290 participants

8.2 Actual Enrollment: 326 participants (see Appendix A for Consort Diagram)

9.0 Recruitment Methods

9.1 Study Setting: Nine Emergency Departments in South Carolina and 8 associated community mental health center (CMHC) study sites (see Appendix B for Recruitment Flow Diagram).

- Springs Memorial Hospital ED and Catawba CMHC in Lancaster, SC
- Spartanburg Regional Hospital ED and Spartanburg CMHC in Spartanburg, SC
- Palmetto Health Tuomey ED and Santee-Wateree CMHC in Sumter, SC
- Conway Hospital ED and Waccamaw-Conway CMHC in Conway, SC
- Carolinas Hospital ED and Pee-Dee Florence CMHC in Florence, SC
- Laurens County Memorial Hospital ED and Beckman-Laurens CMHC in Laurens, SC
- McLeod Regional Hospital ED and Pee-Dee Florence CMHC in Florences, SC
- McLeod Medical Center and Tri-County CMHC in Dillon, SC
- Palmetto Health Richland Hospital ED and Columbia area CMHC in Columbia, SC

9.2 Identification and Recruitment: Emergency room telepsychiatrists, Mental Health Liaisons, nurses, and other key ED staff referred patients admitted for a primary diagnosis of a mental disorder for assessment of potential inclusion in the study. A trained research interviewer assessed participants for potential study eligibility, either in person, telephone or via the site's high speed telepsychiatry video connection.

9.3 Screening by research staff involved assessment of all inclusion and exclusion criteria.

- Document date of birth to ensure that patients are 18 years of age or older
- Confirm the primary diagnosis of a mental illness with the person who identified the patient (nurse, liaison, staff, or telepsychiatrist)
- Confirm that the patient lives within the CMHC's catchment area
- Determine that the patient speaks fluent English
- Confirm that the patient will be discharged for care at the participating CMHC

10.0 Consent Process

10.1 Only trained members of the project participated in the informed consent dialogue and/or signing of the informed consent document.

10.2 Trained members of the project assessed for cognitive impairment during the consent process using a 6-item, validated screener and an Informed Consent Quiz (see Appendix C for Informed Consent document and

Informed Consent Quiz). Participants who scored <3 on the cognitive screener or did not score 100% on the Informed Consent Quiz were not eligible to participate in the project. Inability to complete either of these measures could impede capacity to provide informed consent as well as effectively participate in the intervention.

10.3 The procedures of the study and the informed consent document were thoroughly reviewed with the participant in both verbal and written form by a trained study staff member. Only those participants demonstrating adequate comprehension were consented and enrolled in the project.

- Informed consent was obtained in a private room in the ED or in the telepsychiatry room over HIPAA compliant video conferencing. In the latter case, oral consent was obtained via telepsychiatry and ED administrative staff obtained a signed documentation of consent.

11.0 Withdrawal of Participants

11.1 Participants were able to choose to withdraw from the project at any time.

11.2 Participants who chose to withdraw from the project were no longer contacted by the study team or interventionist for project-related activities. Participants had the opportunity to designate preference for continued data collection in the event of withdrawal during the consent process.

12.0 Risks to Participants

12.1 Participants may experience discomfort in answering questions from the study team or interventionist.

12.2 Participants may experience inconvenience when traveling to/from scheduled project visits.

13.0 Potential Benefits to Participants

13.1 Participants may not benefit personally from the project.

13.2 Taking part in the project may help to improve participant's mental health care.

14.0 Qualitative Interviews

14.1 In-depth interviews were conducted over the telephone with 30 patients and 15 care managers to examine the main factors influencing patients' transitions of and engagement in care.

14.2 Patients were invited to participate in the qualitative interviews after they had been in the study for at least 6 months. Additionally, all active care managers were invited to take part in an interview.

14.3 Patients provided informed consent either verbally after the researcher read the consent form to them (a paper copy was provided for their records by mail) or by signing and returning a consent form by mail. Care managers were emailed a consent form, which they signed and returned through secure email or fax.

14.4 The study team developed two semi-structured interview guides—one for patients and one for care managers. The patient interview guides included questions on their reasons for going to the ED, connection to and attendance at the CMHC, barriers and facilitators to attending their appointments, and interactions with mental health providers. The care manager interview guide included questions on their assessment of their patients' barriers and facilitators to transitioning from the ED and engagement in care at the CMHC, as well as questions on interactions with patients.

14.5 Interviews were conducted by phone. All qualitative interviews were digitally recorded, de-identified and assigned a unique identifier, transcribed verbatim, and reviewed for accuracy.

15.0 Data Sources

15.1 South Carolina's Integrated Data Warehouse: The South Carolina Revenue and Fiscal Affairs Office (RFA) has developed over a period of many years a comprehensive health and human services data. The RFA data warehouse pulls client-specific data from an array of health and human services facilities, agencies and organizations and makes possible the integration of data from disparate sources at the client level by means of an internally assigned unique tracking number. State legislation requiring reporting of both private sector and public sector client-level data ensures that the data are comprehensive and complete. The current data warehouse includes information from private sector systems (e.g., hospitals, surgery centers, home health), state agency systems (e.g., Medicaid, mental health, substance abuse, criminal justice), and not-for-profit systems (e.g., free clinics, community health centers). For this study, data were de-identified by use of an encrypted tracking number and were stored on a secure Microsoft SQL Server. All data storage and access procedures are HIPAA compliant. The study team has a long history of collaboration with the South Carolina's RFA in prior projects, with high data quality and completeness of study data.

15.2 The Area Health Resource File was used to identify county-level community predictors of treatment engagement.

16.0 Outcomes and Data Analysis

16.1 Aim 1 Analytic Strategy: First, bivariate models were created to examine differences between each of the patient, provider, and system-level factors and each of the dependent variables. Next, linear regression models were used to examine the association between factors within each of these levels to each of the study outcomes. Finally, hierarchical linear models examined the association between each of the independent and dependent variables simultaneously including all of the patient, provider, and system-level predictors.

16.2 Service Use Outcomes:

- At least one outpatient visit for a mental health problem in the 30 days after ED discharge.
- Proportion of scheduled outpatient visits attended in the 6 months after ED discharge.
- Emergency Department re-admissions in the 6 months after ED discharge.
- All-cause inpatient admissions in the 6 months after ED discharge.

16.3 Effect Size Estimates for 30-day Follow up After ED Discharge:

Size	Type of Model	Effect Size for 30-day follow up after discharge detected with 80% power and $p<0.05$
290	Bivariate	16%
	Multivariate	17.5%

16.4 Aim 2 Analytic Strategy: Transcripts were uploaded into the qualitative software package MaxQDA for data management and analysis. The study team developed an initial codebook using topics from the interview guides and categories of barriers to care from the literature.[25] After the study team jointly coded a group of transcripts by hand to align application of codes, all transcripts were coded by two members of the study team. The lead qualitative researcher reviewed all coding to ensure reliability and updates were made when necessary. Qualitative data were analyzed using thematic analysis, with a focus on comparing themes across the patient and care manager groups.[26] We examined patients' experiences with transitions of care from the ED to outpatient treatment and providers' experiences of supporting care transitions and engagement. We identified main themes related to the barriers and facilitators to patients accessing and engaging in outpatient mental health treatment at the patient, provider, and healthcare systems level.

17.0 Data Safety Monitoring

17.1 A three-member Data Safety Monitoring Board was assembled bi-annually to review study recruitment and potential adverse events.

17.2 Semi-annual reports detailing information about the project description, baseline demographic characteristics, and retention and disposition of study participants were presented to the DSMB and IRB for review.

18.0 Provisions to Protect Privacy and Confidentiality

18.1 All study data was entered at time of screening and enrollment in a Redcap study database. Redcap is a secure, HIPAA compliant, web-based server, can only be accessed by authorized project personnel, and encrypted at rest by a product called GAZZANG.

18.2 Access to and location of Personally Identifiable Information was granted to authorized users on the principle of least privilege.

18.3 Unique identifiers were generated for all study participants; these were the only identifiers used in files for data entry and analysis. Identifying information such as name, address, telephone number was stored in password-protected computer files or locked file cabinets.

18.4 The South Carolina Revenue and Fiscal Affairs Office (RFA) provided a dataset for all service use claims for the participant via secure, encrypted file transfer protocol (FTP). The data was stored on a password-protected, HIPAA-compliant server at Emory University.

18.5 Participant interactions with project staff, including screening and enrollment procedures, and with interventionists, including calls and visits, were held in a private, closed door office, away from clinical care areas.

18.6 Participants were informed that the agreement to participate in the project does not obligate participants to accept any particular treatment and that participants were free to refuse to answer questions and/or withdraw from any part of the project.

19.0 Advisory Board

19.1 The Advisory Board oversaw key study decisions and was involved in the planning for program sustainability and dissemination of results.

19.2 The board included five members from consumer organizations, provider groups, and healthcare systems management.

19.3 The Advisory Board convened for annual conference calls to review materials and make decisions regarding study procedures, implementation, and results.

20.0 Dissemination

20.1 The final analytic data file was de-identified using the "Safe Harbor" method outlined by the U.S. Department of Health and Human Services in order to meet standard §164.514(a) to make the data HIPAA compliant (https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html). Specifically, any identifiers of the individual, relative, employers, or household members of the individual were removed. A full list of the 18 identifiers to be removed under the "Safe Harbor" method can be found at the above link. This HIPAA compliant data file is fully analyzable and will be made available upon request. All analytic code used in the final report will be provided upon request along with codebooks to accompany the de-identified analytic data file.

20.2 The research team will provide results to the Advisory Board to assist in dissemination efforts to their member organizations.

21.0 References

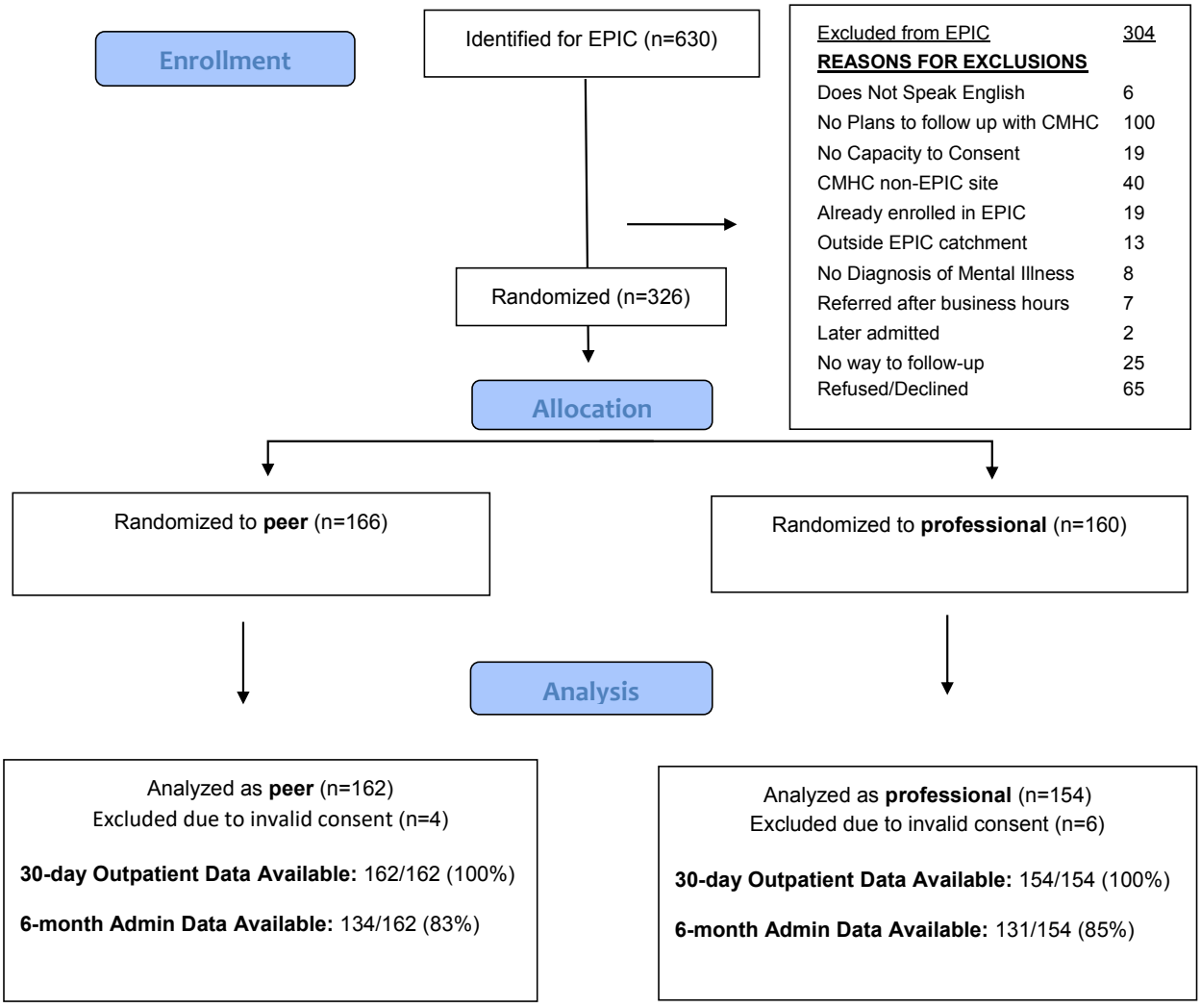
1. Hernandez-Boussard T, Burns CS, Wang NE, Baker LC, Goldstein BA. The Affordable Care Act reduces emergency department use by young adults: evidence from three States. *Health Aff (Millwood)*. 2014;33(9):1648-54. PMCID: 4453768.
2. McClelland M, Asplin B, Epstein SK, Kocher KE, Pilgrim R, Pines J, Rabin EJ, Rathlev NK. The Affordable Care Act and emergency care. *Am J Public Health*. 2014;104(10):e8-10.
3. Knowlton A, Weir BW, Hughes BS, Southerland RJ, Schultz CW, Sarpatwari R, Wissow L, Links J, Fields J, McWilliams J, Gaasch W. Patient demographic and health factors associated with frequent use of emergency medical services in a midsized city. *Academic emergency medicine: official journal of the Society for Academic Emergency Medicine*. 2013;20(11):1101-11. PMCID: 4063348.
4. Doran KM, Raven MC, Rosenheck RA. What drives frequent emergency department use in an integrated health system? National data from the Veterans Health Administration. *Ann Emerg Med*. 2013;62(2):151-9.
5. Clark RE, Samnaliev M, McGovern MP. Treatment for co-occurring mental and substance use disorders in five state Medicaid programs. *Psychiatr Serv*. 2007;58(7):942-8.
6. Hampton LM, Daubresse M, Chang HY, Alexander GC, Budnitz DS. Emergency department visits by adults for psychiatric medication adverse events. *JAMA Psychiatry*. 2014;71(9):1006-14.
7. Harman JS, Scholle SH, Edlund MJ. Emergency department visits for depression in the United States. *Psychiatr Serv*. 2004;55(8):937-9.
8. Albert M, McCaig LF. Emergency Department Visits Related to Schizophrenia Among Adults Aged 18-64: United States, 2009-2011. *NCHS Data Brief*. 2015(215):1-8.
9. Olfson M, Marcus SC, Bridge JA. Emergency department recognition of mental disorders and short-term outcome of deliberate self-harm. *Am J Psychiatry*. 2013;170(12):1442-50.
10. Ting SA, Sullivan AF, Boudreaux ED, Miller I, Camargo CA, Jr. Trends in US emergency department visits for attempted suicide and self-inflicted injury, 1993-2008. *Gen Hosp Psychiatry*. 2012;34(5):557-65. PMCID: 3428496.
11. Case SD, Case BG, Olfson M, Linakis JG, Laska EM. Length of Stay of Pediatric Mental Health Emergency Department Visits in the United States. *J Am Acad Child Adolesc Psychiatry*. 2011;50(11):1110-9.
12. Boudreaux ED, Niro K, Sullivan A, Rosenbaum CD, Allen M, Camargo CA, Jr. Current practices for mental health follow-up after psychiatric emergency department/psychiatric emergency service visits: a national survey of academic emergency departments. *Gen Hosp Psychiatry*. 2011;33(6):631-3.
13. Boudreaux JG, Crapanzano KA, Jones GN, Jeider TA, Dodge VH, Hebert MJ, Kasofsky JM. Using Mental Health Outreach Teams in the Emergency Department to Improve Engagement in Treatment. *Community Ment Health J*. 2016;52(8):1009-1014.
14. Currier GW. Impact of the Patient Protection and Affordable Care Act on Emergency *Psychiatry. J Nerv Ment Dis*. 2015;203(12):901-5.

15. Gaynes BN, Brown C, Lux LJ, Ashok M, Coker-Schwimmer E, Hoffman V, Sheitman B, Viswanathan M. Management Strategies To Reduce Psychiatric Readmissions. Rockville (MD)2015.
16. Hanrahan NP. Analysis of the psychiatric-mental health nurse workforce in the United States. *Journal of psychosocial nursing and mental health services*. 2009;47(5):34-42.
17. Lin V, Lin J, Zhang X. US Social Worker Workforce Report Card: Forecasting Nationwide Shortages." *Soc Work*. 2016;swv047:7-15.
18. Davidson L, Chinman M, Sells D, Rowe M. Peer support among adults with serious mental illness: a report from the field. *Schizophr Bull*. 2006;32(3):443-50. PMCID: 2632237.
19. Sterling E, Von Esenwein SA, Tucker S, Fricks L, Druss BG. Integrating wellness, recovery and self-management for mental health consumers. *Journal of Community Mental Health*. 2010;46(2):130-8.
20. Goldstrom ID, Campbell J, Rogers JA, Lambert DB, Blacklow B, Henderson MJ, Manderscheid RW. National estimates for mental health mutual support groups, self-help organizations, and consumer-operated services. *Adm Policy Ment Health*. 2006;33(1):92-103.
21. Trusts PC. 'Peers' Seen Easing Mental Health Worker Shortage 2013 September 11, 2013.
22. Sirey JA, Bruce ML, Alexopoulos GS, Perlick DA, Raue P, Friedman SJ, Meyers BS. Perceived stigma as a predictor of treatment discontinuation in young and older outpatients with depression. *Am J Psychiatry*. 2001;158(3):479-81.
23. Henderson C, Noblett J, Parke H, Clement S, Caffrey A, et al. Mental health related stigma in health care and mental health care settings. *Lancet Psychiatry*. 2014;1(6):467-482.
24. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care.* 2002;40(9):771-781.
25. Mojtabai R, Olfson M, Sampson NA, Jin R, Druss B, Wang PS, Kessler RC. (2011). Barriers to mental health treatment: results from the National Comorbidity Survey Replication. *Psychological Medicine. 2011; 41*(8):1751–61.
26. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77-101.

22.0 Appendix A

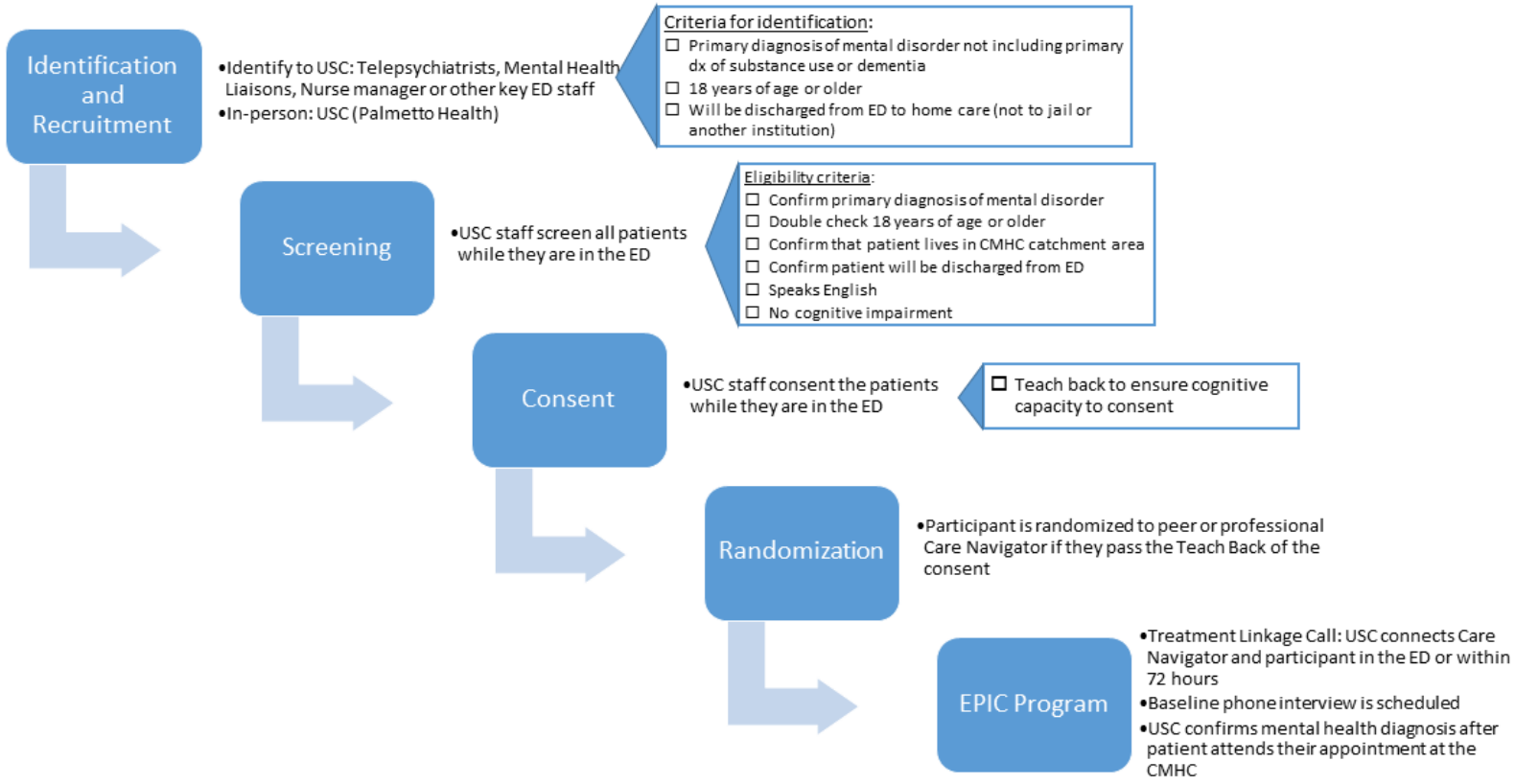
Consort Diagram

EPIC CONSORT Flow Diagram (12/31/2019)



23.0 Appendix B

Recruitment Flow



24.0 Appendix C

Informed Consent Document with Quiz

Name of participant: _____ Age: _____

Title: Engaging Patients in Care (EPIC)

Introduction
You are being asked to take part in a study of a new care navigation program. This opportunity is offered to people who talked to a psychiatrist by video phone call in the Emergency Room, and who were asked to make an appointment at the Community Mental Health Center. This form will tell you everything you need to think about before you decide to take part. **Participation is entirely your choice. If you decide to participate, you can change your mind later on and stop participating.** Joining or not joining the study will not have any effect on your treatment. Before making your decision, carefully read this form, or have it read to you. Ask questions about anything that is not clear. You will be given a copy of this form.

Study Overview
This study provides 'care navigation'. Care navigation is a service that helps guide patients with their health care. If you decide to take part in this study, care navigation will be provided to you at the Community Mental Health Center, and will be **in addition** to your regular care and treatment. A care navigator can be a professional case manager, like a social worker, a nurse, or a psychologist. A care navigator can also be someone who is not a professional, called a "peer support specialist". A peer support specialist is someone who has a mental health problem and has gotten treatment. Peer support specialists have recovered from their mental illness and now help other patients to succeed with their care and recovery. In this study, we will compare patients who have a professional care navigator with patients who have a peer support specialist. Care Navigation will take place at the Community Mental Health Center that is closest to the Emergency Department you visited. We plan to have 1000 people take part in the study over the next 4 years.

Study Procedures: What will happen if you agree to be part of this study?
Screening:
If you decide to take part you will sign this form giving your permission. We will ask you some questions to make sure the study is right for you. We will also ask for your contact information. Then you will be randomly assigned (like tossing a coin) to have care navigation with either a peer support specialist or with a professional case manager at the Community Mental Health Center. We will put you in touch with the care navigator by phone while you are still in the ER. After briefly introducing himself or herself, the care navigator will schedule an appointment to meet with you in person. This first meeting will take place at the Community Mental Health Center, on the day of your first appointment, A few days before your first appointment, your care navigator will call or text you with an appointment reminder.

Clinic Visits:
First visit : At the first visit to the clinic, your care navigator will talk with you for about 30 minutes and ask you about your mental health history and your symptoms, the reasons for your recent emergency room visit, and any difficulties you have getting the care you need.

Months 1-6: During the first 6 months, you will meet in person with your care navigator once a month. These monthly in-person meetings will take about 20 minutes each time. In between these monthly visits, your care navigator will speak with you by phone. These visits and phone calls are designed to help you participate in treatment, manage your mental health better, and overcome problems or issues that may affect attending your mental health appointments. You will be compensated for your effort with a $20 gift card for each of the 6 in-person visit.

Months 7-12: During months 7-12 there are no planned, in-person meetings with your care navigator but he/she will call you monthly during months 7-12 to check on you.

Study Interviews:
There will be 3 study interviews. The first interview will be done by phone either a few days after you have left the Emergency Room, or by phone at your first visit to the Mental Health Clinic. The other two interviews will be done by phone with a study staff member from Emory University. These interviews will take about 30-45 minutes and you will be asked questions about your mental health care, your mental health medications, substance use history, and any problems you have with getting mental health care. You will be compensated for your time and effort with a $50 gift card for **each** interview you complete.

Risks and Discomforts
We do not think there are any significant risks or discomforts related to this study, but there may be possible risks that we don't yet know about. Some participants could get tired during the interviews. If you get tired, you can take a break at any time. You do not have to answer questions you do not want to answer. There is a minor risk of a loss of confidentiality. All of the information that you give us is private and we will do everything we can to protect your information, in ways that we talk about later in this form.

Benefits
Taking part in this program may or may not benefit you personally, but we may learn new things that will help other patients in the future. Taking part in the program may help to improve your mental health care and could possibly reduce problems and issues that might prevent you from getting the care you need. The results of the study of the care navigation program will be used to decide whether this sort of program is helpful for patients.
Costs
There will be no additional costs for participating in the project. Your insurance will be billed for services you get at the mental health center.

Compensation
Interviews: You will get a $50 gift card for completing the 3 study interviews.

Monthly in-person visits: For each in-person visit with your care navigator, you will get a $20 gift card to cover study-related expenses, like travel and phone minutes. You will only get a gift card for visits you have completed. You will get up to $270 if you complete all the study visits and all the research interviews.

Alternatives

At this time there is no alternative to the care navigation we will provide. However, you do not have to take part in this study to be treated at the mental health center or to get linked to a case manager to help you access the appropriate care you need.

New Information

You will be told about anything new that might change your decision to be in the study.

Confidentiality and Privacy

Your privacy is important to us. Health information that identifies you is called "protected health information" or "PHI." To protect your PHI, we will follow all federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA).

Emory University and the University of South Carolina (USC) will keep your participation and any records we create private as required by law. To protect your privacy you will be assigned a unique I.D. number that will be used in our records instead of your name. The only file linking your I.D. number to your name and address will be stored in a secure computer file on a secure network. Only study staff will have access to the secure computer file with your name and unique I.D. number. Study information will be collected and stored in a secure online research storage system, called RedCap on encrypted servers at Emory University. RedCap is a secure online system for collecting and storing information from research studies. RedCap is password-protected and meets the highest levels of security. Only study staff that needs your information for study purposes will have access to RedCap. Any paper study information, other than this form and the contact sheet, will contain only your I.D. number and not your name. Paper study information will be transmitted using secure fax machines. All paper documents will be stored in locked file cabinets, in locked offices at the Community Mental Health Center, or at USC. No information that could identify you will be included in any publications that may come from the study results. Any private or identifying information will be destroyed at the earliest opportunity after the study is complete.

Protected Health Information (PHI) That Will Be Used/Disclosed

In this study, some of your personal information (name, social security number, date of birth, hospital number, etc.) will be used to help us get records that relate to your health and well-being. These records may include information about you such as hospital and doctor visits, mental health services, drug and alcohol services or healthcare visits paid for by Medicaid or Medicare. Our use of this information will not affect your benefits in any way, and the study staff can't use your information until you allow them. Taking part in the study means that you allow the researchers to use your information for the study.

People Who Will Use/Disclose Your PHI
Your PHI may be used or shared with others outside Emory, USC and the South Carolina Department of Mental Health for reasons directly related to how we conduct the study. Once this information leaves our agencies, we cannot guarantee that it will be protected.

Your PHI will be shared with the South Carolina Revenue and Fiscal Affairs Office (RFA) to obtain data for the study.

Your PHI may be shared with the following groups to make sure the research is done correctly and safely:
The study sponsor, PCORI (Patient Centered Outcomes Research Institute)
Institutional Review Boards of Emory University, USC and the South Carolina Department of Mental Health
Government agencies that regulate the research (e.g. the Office of Human Research Protection)

Authorization to Use PHI Is Required to Participate
By signing this form, you give us permission to use and share your PHI in the ways we discussed above. You do not have to sign this form. If you choose not to sign this form you will not be able to participate in the study and will still receive usual care. If you do decide to participate in the study and you do sign this form, your PHI will be used until this research study ends.

If I Sign this Authorization, Can I Change My Mind?
You can change your mind about participating in the study at any time. If you no longer want to be part of the study, we may still use information you have already provided, but we will not collect any new information about you. If you want to withdraw from the study, please contact Suzanne Hardeman, NP at 803-434-1100.

Voluntary Participation and Withdrawal from the Study
You have the right to leave the study at any time without any penalty. You may refuse to do any procedures you do not feel comfortable with or refuse to answer any questions that you do not want to answer.

Who to call if you have questions
If you have any questions about this study please contact Laura Reparaz, (803)-434-6089, or Anna Gordon, (803)-434-1100, during normal business hours.

For questions or concerns about your mental health care, please call your Community Mental Health Center.

If you have questions about the way the study is conducted, please contact Dr. Ligia Latiff-Bolet at the SC Department of Mental Health Institutional Review Board at (803)-898-8619.

Consent Review Questions:

The goal of this study is to see how well care navigation works to help people improve their mental health.	True	False
Being a part of this project does not affect my care and I will still receive treatment at the mental health center.	True	False
Study staff believes there are no significant risks to being in the study.	True	False
Everyone in the study has care navigation from the same person.	True	False
Over the study I will complete 3 interviews, one at the beginning, one at the end of 6 months and one at the end of 12 months.	True	False
I will not receive any payment for participating in the program.	True	False
I can change my mind about being in the study whenever I want.	True	False

Consent & Authorization

I have read this consent form (or had it read to me), and the research study has been explained to me. All of my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____

Printed name of Participant

_____ _____

Signature of Participant Date Time

_____

Printed name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time