Evaluation of a Pharmacist-Led Meds-to-Beds Program in Patients with Psychiatric Disorders

1. BACKGROUND AND RATIONALE

Nearly half of patients hospitalized with a psychiatric disorder have an unplanned readmission within 30 days of hospital discharge.[1] Unplanned hospital readmissions correlate to both *inferior patient outcomes and increased institutional financial burden*.[1] The need for further care implies inadequate control of a psychiatric condition, subsequently leading to increased medical costs. *Patients suffering from a psychiatric disorder are particularly vulnerable* because of their susceptibility to several predisposing factors, including previous history of psychiatric hospitalization, poor health literacy, and adverse illness severity.[2] These patients are also subject to recurrent hospital readmissions due to *insufficient post-discharge follow-up and poor medication adherence rates*.[3] *There exists, therefore, a critical need for an intervention aimed at preventing hospital readmissions in this high-risk population*.

Pharmacist-led Meds-to-Beds programs effectively reduce hospital readmissions by providing *convenient prescription delivery and personalized medication counseling for patients prior to hospital discharge*.[4] As medication experts, pharmacists are well-equipped to educate patients on new medication regimens and encourage adherence, which can prevent future hospital readmissions. Meds-to-Beds programs have been shown to decrease the odds of 30-day unplanned hospital readmissions by 60% in patients suffering from common chronic conditions such as heart and pulmonary diseases.[4] Despite their proven success in these populations, *Meds-to-Beds programs have not been exclusively evaluated in patients with psychiatric disorders. This literature gap provides an ample opportunity to assess the impact of a Meds-to-Beds program on hospital readmissions in the adult psychiatric population*. Patients with psychiatric disorders may particularly benefit from a Meds-to-Beds intervention due to their history of vulnerability and heightened hospital readmission risk.

2. HYPOTHESIS AND SPECIFIC AIMS

The *objective* of this study is to measure the impact of a clinical pharmacist-led Meds-to-Beds program on unplanned hospital readmissions and patient understanding of medications in

patients with psychiatric disorders who are being discharged from our behavioral health unit with at least one new medication or dose change. The *central hypothesis* is that bedside delivery of new and dose-changed medications coupled with thorough patient counseling will reduce unplanned hospital readmissions and improve medication understanding in patients with psychiatric disorders. We hypothesize that our Meds-to-Beds intervention will *minimize treatment gaps, while reinforcing the importance of adherence and risk mitigation through tailored education efforts*. Patient counseling will be personalized to meet individual patient needs in order to *build a strong foundation of health literacy and empower patients to properly adhere to their medication regimens*. The *significance* of the proposed research is that, if proven effective, other health systems can leverage relationships with affiliated community pharmacies to incorporate similar Meds-to-Beds programs into discharge planning for patients hospitalized with a psychiatric disorder. The long-term goal is to encourage widespread application of Meds-to-Beds programs beyond patients with psychiatric disorders and common chronic diseases, with the hopes of decreasing hospital readmission rates across all populations. To test our central hypothesis and attain the objective of the study, we will pursue the following *specific aims*:

1. Evaluate the effect of a pharmacist-led Meds-to-Beds program on unplanned 30-day, 60-day, and 90-day hospital readmissions (clinical outcomes).
2. Evaluate the change in patient understanding regarding their new or dose-changed medication regimen (humanistic outcome).

We will define patient understanding as the degree to which patients are able to appropriately comprehend their medication regimen, correctly understand administration directions, and self-monitor for efficacy and side effects. This outcome will be evaluated by a validated medication knowledge assessment questionnaire, which is explained in detail under Treatment Procedures.[5]

Innovation: Medicare's Hospital Readmissions Reduction Program (HRRP) provides an incentive to reduce hospital readmission rates by enforcing payment reductions for excess readmissions in patients with one of six conditions: acute myocardial infarction, chronic obstructive pulmonary disease, heart failure, pneumonia, coronary artery bypass graft surgery, and elective primary total hip arthroplasty and/or total knee arthroplasty.[6] This financial incentive has led Meds-to-Beds programs to often focus on patients diagnosed with one of these six conditions. *Psychiatric disorders are not included in HRRP, which limits motivation to focus*

resources on reducing hospital readmissions among these patients. However, there still exists a dire need to explore interventions that will reduce hospital readmissions and disease burden in this high-risk population. Consequently, this study proposes a multi-faceted Meds-to-Beds approach to unplanned hospital readmission reduction in patients with psychiatric disorders by optimizing patient education efforts by the inpatient psychiatric pharmacy team and coordinating with the outpatient pharmacy to have discharge medications delivered to our behavioral health unit. *Our innovative intervention leverages both the convenience of bedside medication delivery and pharmacist medication expertise to improve post-discharge outcomes in patients with psychiatric disorders. Our novel approach expands on the success of Meds-to-Beds programs demonstrated in other chronic disease states by implementing the program in a unique and vulnerable population.*

3. PROPOSED STUDY DESIGN AND METHODS

Overview of study design: We propose an open-label randomized controlled trial executed in our inpatient behavioral health unit over an 18-month period (June 2025 through December 2026) that evaluates a pharmacist-led Meds-to-Beds program in patients with psychiatric disorders. The trial will follow the process outlined in **Figure 1**. Following approval by the Institutional Review Board, the inpatient psychiatric pharmacist will recruit patients in our behavioral health unit who meet our inclusion criteria and will be screened for eligibility. Eligible patients who provide informed consent will be randomized 1:1 into either the control group or the intervention group. Randomization will be conducted using a computer-generated block randomization scheme with a block size of 4. Randomization will also be stratified based on psychiatric disorder to ensure uniformity of baseline characteristics between both arms and to avoid biased

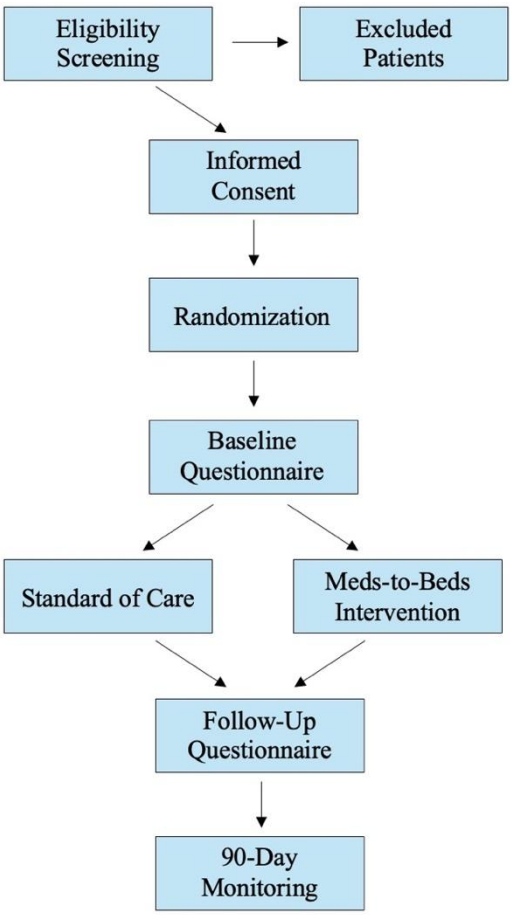

Figure 1. Overview of study design

results caused by psychiatric disorders that carry greater risk of unplanned hospital readmissions, such as schizophrenia.[2] Participants in the control group will receive the standard of care, with no psychiatric clinical pharmacy intervention. Patients in the intervention group will be provided their new or dose-changed medication(s) from the outpatient pharmacy upon discharge along with tailored patient education from a psychiatric pharmacy resident or pharmacist-supervised APPE student through our Meds-to-Beds program. All participants will complete a medication knowledge assessment questionnaire both at baseline and within 3-7 days of hospital discharge to evaluate our humanistic outcome of patient understanding. Patients in both arms will be observed for 90 days following discharge to monitor for unplanned hospital readmissions.

Study population: A total of 90 participants will be included in each arm during the 18-month duration of the study. The following eligibility criteria have been established to maintain participant safety and ensure ability to complete the study:

Inclusion criteria: Participants must be:

1. At least 18 years old and admitted to our inpatient behavioral health unit with a psychiatric disorder (i.e. anxiety, depression, bipolar disorder, schizophrenia, etc.).
2. Prescribed at least one new medication or dose change of an existing medication.
3. Prepared for discharge after spending at least two days in our inpatient behavioral health unit.

Exclusion criteria: Participants will be excluded if they:

1. Are incapable or unwilling to provide informed consent (i.e. dementia, Alzheimer's, etc.)
2. Are scheduled to have a planned hospital readmission in the next 90 days, such as a procedure, surgery, or psychiatric re-evaluation.

Study setting: The inpatient psychiatric pharmacist will identify and recruit subjects from our inpatient behavioral health unit who meet the appropriate criteria. The clinical research coordinator will conduct eligibility screening and obtain informed consent. We aim to recruit 90 participants for each arm over the course of 18 months for a total of 180 participants, which corresponds to about 10 new patients recruited each month. In terms of ***feasibility***, our inpatient behavioral health unit includes 20 beds and discharges an average of 10 patients per week. Due to these restrictions, we aim to include all eligible patients regardless of their psychiatric disorder

to obtain a sufficient population size for the purpose of statistical power. Additionally, we believe that patients suffering from any psychiatric disorder will benefit from our Meds-to-Beds program, therefore we do not intend to limit our approach to a smaller subset of this greater high-risk population. After considering our timeframe and bed space, we do not anticipate any difficulties in terms of reaching our recruitment goals.

Screening, recruitment, and informed consent: The inpatient psychiatric pharmacist will recruit potential participants in our behavioral health unit who are ready to be discharged in the next 48 hours with at least one new or dose-changed medication. Recruited participants will be screened by the clinical research coordinator to identify patients who satisfy our eligibility criteria. The clinical research coordinator will then meet with eligible patients prior to enrollment to explain the purpose, risks, and benefits of the study in detail. Patients who provide informed consent will be randomized into either the control group or the intervention group according to our proposed study design. We believe the inpatient setting of our behavioral health unit provides an ideal environment with sufficient time to recruit, screen, and randomize study participants.

Treatment procedures: All participants will complete a validated medication knowledge assessment questionnaire at baseline to assess their initial understanding of their new or dose-changed medication, which will be conducted immediately following informed consent.[5] This questionnaire will be administered in each participant's room by the inpatient psychiatric pharmacist or a psychiatric pharmacy resident. The flexibility of this role is intended to accommodate participants being discharged outside of traditional business hours when staffing may be limited. Questionnaire results will be recorded on an iPad in a password-protected spreadsheet. The standardized format of the questionnaire will provide the ability to quantify the patient's knowledge and level of understanding of their prescribed medication(s) including how the medication should be properly taken, important side effects, self-monitoring parameters, and the importance of adherence and its correlation with long-term treatment success. This validated medication knowledge assessment questionnaire consists of a series of questions outlined in **Figure 2**.[5] For each question, correct answers will receive a score of 1 and incorrect answers will receive a score of 0. Participants with a total score of 7-9 will be classified as having "Excellent"

medication knowledge, participants with a total score of 5-6 will be classified as having "Average" medication knowledge, and participants with a total score of 1-4 will be classified as having "Poor" medication knowledge.[5]

Patient knowledge on medication	Question asked
1. Knowledge of indication for use	Why are you taking this medication?
2. Knowledge of dosage regimen	How would you take this medication?
3. Knowledge of treatment duration	How long are you to take this medication?
4. Knowledge of form of administration	Is this drug a tablet or syrup or injection?
5. Knowledge of precautions to be adhered to	What special care would you take when taking this drug?
6. Knowledge of potential side/adverse effects of the drug	Do you know of any adverse effects or unfavorable effects of this medication?
7. Knowledge of drug effectiveness	What does this medication do in the body?
8. Knowledge of potential drug/food interactions	Are there any medications or food that you shouldn't take with this medication?
9. Knowledge of risk of missed dose	What do you think will happen if you don't take this medication as prescribed?

Figure 2. Medication Knowledge Assessment Questionnaire

Control group: After completing the baseline medication knowledge assessment questionnaire, patients in the control group will be discharged following normal hospital procedures. After discharge, patients will receive standard follow-up at the appropriate level of care established in coordination with their provider to meet their condition-specific needs.

Intervention group: The inpatient psychiatric provider will send any new or dose-changed prescriptions to the outpatient pharmacy, tagged with a specific code to indicate Meds-to-Beds program enrollment. The outpatient pharmacy will then fill and deliver a 30-day supply of the new or dose-changed medication(s) directly to our behavioral health unit. A psychiatric pharmacy resident or pharmacist-supervised APPE student will deliver the discharge medications to the patient's room. At this time, they will provide tailored patient education at an appropriate level of health literacy to fill in information gaps, emphasize medication adherence, equip the patient with tools for treatment success, and utilize teach-back methods to reinforce learning. This counseling session is designed to not only educate the patient about pertinent medication details, but to allow space for the patient to address any concerns or misconceptions. The patient will then be discharged according to standard procedures and will receive standard follow-up at the appropriate level of care indicated for their condition in coordination with their provider.

Follow-up and monitoring: Within 3-7 days of discharge, the inpatient psychiatric pharmacist or a psychiatric pharmacy resident will administer the same medication knowledge assessment questionnaire over the phone to all patients in both study groups. Questionnaire results will be recorded on an iPad in a password-protected spreadsheet. The questionnaire will be readministered to reevaluate participants' understanding of their medication regimen and provide an opportunity for patients to ask any lingering questions, which can be resolved by a member of the inpatient psychiatric team.

Participants will also be monitored for 30-day, 60-day, and 90-day unplanned hospital readmissions. This information will be gathered retrospectively from patients' electronic health records (EHRs) in Epic by the clinical research coordinator and documented in a password-protected spreadsheet. Relating to ***feasibility***, our hospital is a member of ABC health system, which encompasses 75% of hospitals and emergency rooms in the state. Therefore, despite patients having access to multiple health systems, we expect that most visits will be to ABC-affiliated sites. All patient and visit information will be documented in Epic, which will be accessible by any ABC Epic user. Since Epic information is synchronized with other health systems, our inpatient psychiatric team will still be able to access patient documentation, should patients choose to visit non-ABC sites.

Outcomes: Our *primary outcome measure* will be the number of unplanned 30-day hospital readmissions (clinical), which we expect will decrease in our intervention group. Our *secondary outcome measures* will include:

1. The number of unplanned 60-day and 90-day hospital readmissions (clinical), which we expect will decrease in our intervention group.
2. Patient understanding of new and dose-changed medication(s) (humanistic) evaluated by the validated medication knowledge assessment questionnaire. We anticipate that participants in the intervention group will have an enhanced understanding of their medication regimen and a higher follow-up questionnaire score compared to the control group.

Statistical analyses: A power calculation was performed based on an established unplanned 30-day hospital readmission rate of 45% in patients with psychiatric disorders.[1] A sample size of 84 participants in each arm will give us 80% power to detect a 60% reduction in unplanned 30-day hospital readmissions using an alpha of 0.05.[4] To account for potential loss to follow-up, we plan to recruit a slightly more conservative sample size of 90 participants in each arm to maximize statistical power. Differences in primary and secondary clinical outcomes between each arm will be compared using a logistic regression analysis, adjusted for known confounders. Differences in our secondary humanistic outcome between each arm will be analyzed using a proportional odds model adjusted for their baseline questionnaire score. Subgroup analyses will be conducted according to patients' primary psychiatric disorder using SPSS version 29 statistical software.

Responsibilities and staffing: The inpatient psychiatric pharmacist and psychiatric pharmacy residents will apply for Institutional Review Board (IRB) approval and will develop training session materials prior to trial kick-off. This training session will educate outpatient pharmacy and inpatient behavioral health unit staff on the logistics of the Meds-to-Beds program and will outline workflow responsibilities. Inpatient psychiatric providers will be trained to add an identifying code to all prescriptions for participants in the intervention group to indicate Meds-to-Beds enrollment. Staff from the outpatient pharmacy will be trained to adopt Meds-to-Beds program procedures, including filling and delivering discharge medications directly to the behavioral health unit for patients randomized to the intervention arm. The inpatient psychiatric pharmacist will be instructed to identify patients scheduled for discharge in the next 48 hours with new or dose-changed medication(s). The clinical research coordinator will be responsible for screening patients for eligibility. They will also be responsible for educating eligible patients on the purpose, risks, and benefits of the study and obtaining informed consent prior to enrollment. The clinical research coordinator will also retrospectively collect and document 30-day, 60-day, and 90-day unplanned hospital readmission data during the 18-month timeframe using Epic software. A psychiatric pharmacy resident or pharmacist-supervised APPE student will be assigned the role of delivering discharge medications to the patients' bedside and providing personalized patient counseling. The inpatient psychiatric pharmacist and psychiatric pharmacy residents will be adequately trained to administer, score, and document the results of

the medication knowledge assessment questionnaire. Data management for all primary and secondary outcomes will be handled by an independent statistician.

IRB justification for human subject involvement:

Recruitment and Informed Consent Process: Our anticipated demographic does not include participants that are considered high-risk (children, incarcerated, developmentally challenged, etc.), but rather includes participants that have varying levels of health literacy. For this reason, we will undergo the IRB Full Institutional Review. The psychiatric pharmacist and psychiatric pharmacy residents will submit an application to the ABC IRB detailing the following elements:

- Cover sheet
- Abstract
- Informed consent form:
    - Outline of study procedures
    - Risks and benefits of participating in the study
    - Rights to withdraw from the study

Data Integrity Management: To safeguard our data, all information will be documented in a password-protected spreadsheet only accessible through ABC-approved remote access programs. Study participant identifiers will be kept separate from other collected data, where study participants will only be referred to by their study identification number. Involved researchers, including the inpatient psychiatric pharmacist, psychiatric pharmacy residents, clinical research coordinator, and statistician will be provided password-protected access to this spreadsheet and thorough training to perform best documentation practices. All electronic documentation will be performed on password-protected hospital laptops or iPads. The statistician will only have access to data sheets that exclude patient-identifiable information.

Potential Limitations: 1) The primary limitation of this study would be insufficient sample size to detect a significant result due to lower-than-expected enrollment and the relatively limited bed space of our inpatient behavioral health unit. This limitation is addressed by including patients with any psychiatric disorder. 2) Potential inconsistency of results across different psychiatric disorders. This limitation is addressed by stratifying patients based on psychiatric disorder and

conducting the pre-planned subgroup analyses. 3) The risk of subjectivity associated with administering and scoring the medication knowledge assessment questionnaire as well as providing patient counseling. We acknowledge that each patient will have varying levels of health literacy and diverse condition-based circumstances, therefore counseling needs may look different from patient to patient. However, the validated and standardized format of the questionnaire adds structure and uniformity to our humanistic data collection reducing the risk of bias. 4) Potential loss to follow-up after hospital discharge. Patients may not be reachable by phone to complete the post-discharge medication knowledge assessment questionnaire and comply with standard follow-up procedures. We accounted for this limitation by establishing a slightly expanded population size, as explained under Statistical Analyses.

4. TIMELINE AND BUDGET ADHERENCE

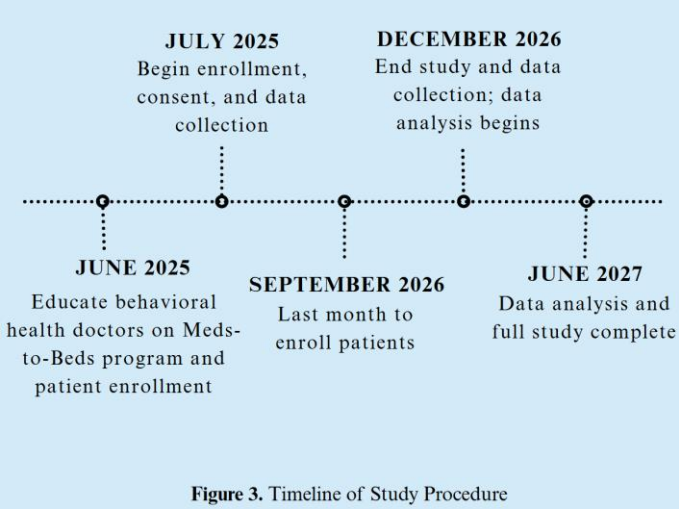

Figure 3. Timeline of Study Procedure

Timeline: As shown in **Figure 3**, our study will begin in June 2025 with an informative training session for the outpatient pharmacy and inpatient behavioral health unit staff to explain the features of the Meds-to-Beds program and associated responsibilities. The enrollment, informed consent, and data collection process will begin the following month. Enrollment will continue until the end of September 2026 to ensure optimal time for data collection and assessment. In December 2026, the study will officially conclude, and no further data will be collected. Between December 2026 and June 2027, data analysis will commence, and study results will be drafted. By June 30, 2027, data analysis and the study timeline will conclude, after which study results will be published and disseminated.

Budget Justification: We propose the following budget allocation, which totals $26,900, for the following staff and materials to pilot our Meds-to-Beds program:

1. Clinical Research Coordinator - $12,600 at $35/hour (360 hours)

2. Statistician - $6,000 at $75/hour (80 hours)
3. Training Budget - $5,000; for outpatient pharmacy and inpatient behavioral health unit staff to hold a pre-launch Meds-to-Beds training session. This includes compensation for the cost of training materials and the time the psychiatric pharmacist and psychiatric pharmacy residents spend developing the training materials and coordinating training.
4. iPad Pro 13" - $2,800; for administering and scoring the medication knowledge assessment questionnaire.
5. Paper education materials for counseling purposes - $500.

5. FUTURE IMPACT/DISSEMINATION PLAN

Future Impact: The results of this study will reinforce the demonstrated efficacy of pharmacist-led Meds-to-Beds programs by highlighting their effects in a previously understudied population. Beyond the short-term benefits of reducing hospital readmission rates in patients with psychiatric disorders, we hope this study has a long-term impact on the clinical utilization of Meds-to-Beds programs in all patient populations. While reducing hospital readmissions has financial advantages, it also facilitates improved patient outcomes. Therefore, this study features a novel setting in which pharmacists can positively impact patient outcomes. In addition to psychiatric disorders, there exists a myriad of other disease states in which Meds-to-Beds programs have not yet been explored. We hope that this study will not only encourage other institutions to implement this program but also justify the integration of a clinical pharmacist in patient care. We are optimistic that evidence-based success of a pharmacist-led Meds-to-Beds program will extend its influence across a broader spectrum of disease states.

Dissemination: We plan to present our results at a national pharmacy conference, such as the 2027 American College of Clinical Pharmacy Annual Meeting. We will also submit a manuscript for publication to a clinical pharmacy journal, such as the *Journal of the American College of Clinical Pharmacy* or a psychiatry-focused journal such as the *American Journal of Psychiatry.* We hope to highlight the impact that a clinical pharmacist-led intervention can have on patient outcomes in especially high-risk populations like psychiatry and emphasize the importance of recognizing pharmacists as important assets in patient care. Ideally, other institutions will

recognize the value of our disseminated results and implement similar Meds-to-Beds programs, both inside and outside of a behavioral health setting.

6. REFERENCES

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