A Pragmatic, Randomized, Controlled Trial Examining the Efficacy of a Hospital Discharge Follow-up Phone Call Program

Principal Investigator: Maame Yaa A. B. Yiadom, MD, MPH

NCT03050918

Protocol Date June 5, 2017

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Co-Investigators: Daniel Byrne, MS; Neesha Choma MD, MPH, FACP; Michele Hasselblad, RN, MSN, NE-BC; Johnston Morrison, MSN, RN, CPPS; Henry Domenico, MS; Sunil Kripalani, MD, MSc; Adam Lewis; Cheryl Gatto, PhD, CAPM; Frank Harrell PhD; Tina Hartert MD MSCI; Gordon Bernard, MD

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Principal Investigator: Maame Yaa Yiadom, MD, MPH
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Abbreviations
General Medical Services (GMS)
Intention to Treat (ITT)
Hospital Consumer Assessment of Healthcare Providers and Systems (HCHAPS)
Vanderbilt University Medical Center (VUMC)
Vanderbilt Institute for Clinical and Translational Research (VICTR)
Center for Clinical Quality and Implementation Sciences Research (CCQIR)
Post Hospital Discharge Follow-Up Phone Call Data Collection form (Phone Call Starform)
Research Derivative (RD)
Department of Quality, Safety and Risk Prevention (QSRP)
Application Program Interface (API)
Electronic Health Record (EHR)

Study Summary
Study Start: February 13, 2017 (1 week run-in period)
Accrual Start: February 20, 2017 (NCT03050918)
Primary Outcome: Readmission within 30 days

Primary Analysis: Intention to Treat

- Study length/accrual period: ~7 months
- Follow up: 45 days
- Sample size: 3556 (1778 per arm)
- Baseline event rate = 13.5%
- Target detectable difference of 3.5% (13.5% controls, 10% intervention)
- Power 90% (chi square)

Secondary Analyses:

- Subgroup Analysis of Primary Outcomes (forest plots + interaction analysis)
- **Survival/Frequency Plot of Readmission events (0-45 days)**
- Descriptive Demographics of *Controls*, *Reached*, *Not Reached*
- Heat Map of readmission rates by zip code

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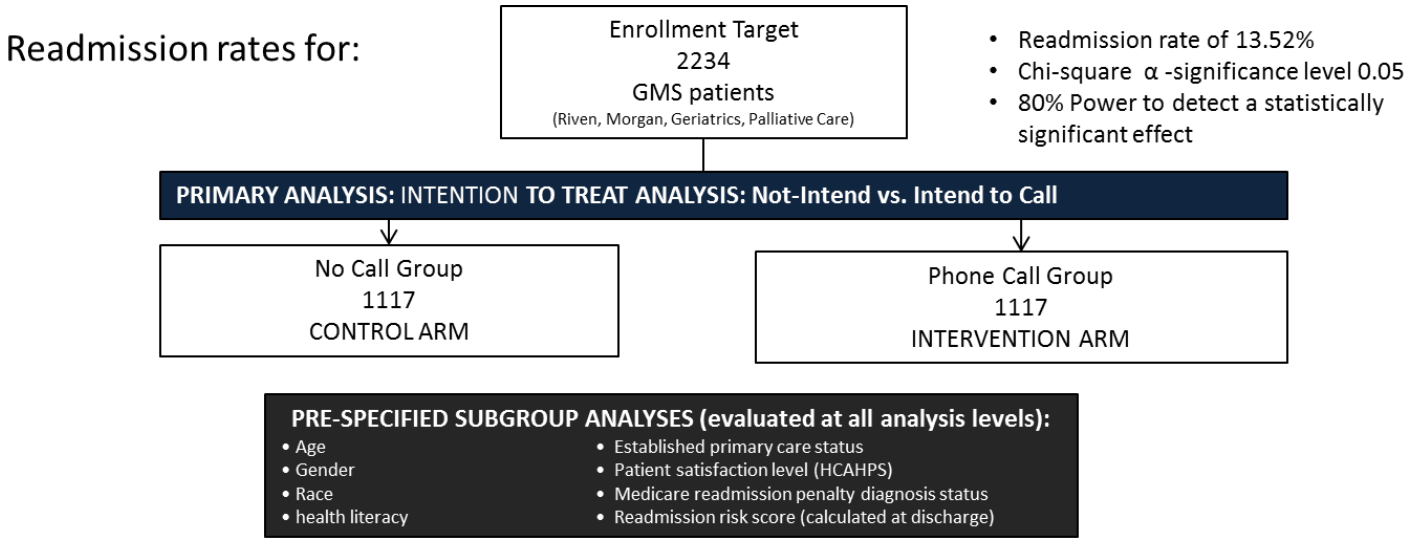
Figure 1 - Study Design Schematic and Enrollment Projection



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STUDY TIMELINE: UPDATED

1. Adult Executive Quality Committee 3 month Update - **June 21, 2017**
   a. Analysis: **Hank Domenico** (descriptive, no outcome data)
      - Table 1 - Patient demographics
      - Overall VUMC readmission rate
      - Summary of phone call nurse patient interventions
   b. Presenters: **Dr. Maya Yiadom, Dr. Gordon Bernard, Michele Hasselblad**

2. Blinded Interim Analysis – 50% patient enrollment – **~July 2017**
   a. Content (**Li Wang**)
      - 2 week analysis window: Alpha 0.005, no stopping/futility rules
      - Patient demographics (by study arm, Table 1)
      - VUMC readmission rate by study arm and assessment of significant difference
      - Pre-specified subgroup analysis for readmission yes/no
      - Will not include the reachability index at this time.
      - Will only use death data from VUMC and available Patient Satisfaction data
      - See Appendix V for details

   b. Safety Review – **August 2017**
      - Safety Committee Members: Mitch Edgeworth, Dr. Jerry Hickson, Dr. Tina Hartert
      - Review of Discharge Phone Call RN's daily reports to her supervisors for safety issues.
      - Interim Analysis Preparation and Presentation: **Dr. Tina Hartert**

3. Enrollment End – 100% patient enrollment end: **~Sept 20, 2017**
   a. Readmit f/u end: **~Nov 5, 2017**
   b. Freeze database after Patient Satisfaction data (2mo lag) included: **~Nov 20, 2017**
   c. Re-open database to add death + external hospital readmission data (6-8mo lag): **~May 20, 2018**
   d. Death date source: VUMC EHR
   e. External hospital readmission data source: Vanderbilt Health Affiliated Network (VHAN)

4. Adult Executive Quality Committee Presentation - Study End Early Findings – **Jan 2018**
   a. Final analysis findings, except for death data
   b. 2 week analysis window: Alpha 0.048

5. Final Analysis - **June 2018**
   a. Content (**Hank Domenico and Dan Byrne**)
      - 2 week analysis window: Alpha 0.048
      - Patient demographics (by study arm, Table 1)
      - VUMC readmission rate by study arm and assessment of significant difference
      - Pre-specified subgroup analysis for readmission yes/no
      - Identical to the Interim Analysis plan except all patient satisfaction, external hospital readmission, and mortality data will be included.

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BACKGROUND:

Implementing a post-hospital discharge follow-up phone call program at Vanderbilt University Medical Center (VUMC) is expected to support effective patient transitions to out-patient care,[1] improve patient satisfaction,[2] and elevate the quality of care delivered. It will, however, add to the existing care delivery workflow and involve hiring and training additional staff. Therefore, it is crucial to rigorously quantify the impact of this program before the existing program is scaled as a larger enterprise-wide health-system intervention.[3]

OBJECTIVE

The goal of this project is to quantify the impact of post-hospital discharge follow-up phone calls on hospital readmission within 30 days, emergency department (ED) visits, patient satisfaction, and mortality in a general medicine inpatient population. We will obtain exploratory information on patient sub-groups at high risk for readmission and those experiencing high benefit from the follow-up phone call intervention. In addition, we will obtain data on discharge plan implementation assistance needed to support a successful transition from inpatient to outpatient care amongst those reached by the intervention phone call.

RATIONALE

In the current medical literature, it is unclear how follow-up calls influence these outcomes in a general medical population. Some studies have attempted to address this question, but are limited in that they target very specific patient populations,[4] are of insufficient quality, or evaluated follow-up calls as part of a larger care bundle.[5] We will conduct a high quality, real-time clinical care study to determine the efficacy of a follow-up phone call program.

STUDY DESIGN

This is a single center, pragmatic, randomized, controlled clinical trial to investigate whether a structured post-hospital discharge follow-up phone call can improve patients' transition from in-hospital to outpatient care and improve satisfaction with their care. We will also identify the discharge implementation assistance given to those in the intervention (Phone Call) group.

Outcome Measures

Primary Outcome for this study is **readmission within 30 days**
Secondary Outcomes include evaluating: The primary outcome of readmission within 30 days within pre-specified subgroups (age, gender, race, health literacy level, established primary care status, patient satisfaction, Medicare readmission penalty diagnosis status, readmission risk score), patient satisfaction between the study arms measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient satisfaction scores, all cause VUMC ED visits, the need for assistance with discharge plan implementation, and mortality within 30 days.

Inclusion Criteria

The study will include VUMC patients discharged after an inpatient status hospital stay on the following General Medicine services: Riven, Morgan, Geriatrics, and Palliative Care.

Exclusion Criteria

We will exclude all patients who experience in-hospital death, leave the hospital against medical advice, are transferred to any post-acute care facility or are discharged to inpatient hospice.

Study Arms

VUMC Quality Committee's Post-Hospital Discharge Program is a quality initiative started in January of 2016 where a single study nurse calls as many patients after discharge as she can reach. Using a phone call intervention script and form (See ***Appendix I*** – Discharge Phone Call Starform) to guide the flow of each call

and screening for discharge intervention needs. After discharge, patients will be randomized to one of 2 study arms. Enrollment projections are included in ***Figure 1***.

Phone Call Group (Intervention Arm): Patients will first be called with a maximum of 3 call attempts by the study nurse made up until post-discharge day 7. The semi-structured script imbedded within the Discharge Phone Call Starform is used to guide a conversation to obtain information on potential causes of hospital readmission that can be identified and addressed to improve each patient's transition to outpatient care. We will collect data on 1) outpatient care support provided to intervention group patients exposed to the phone call intervention (coordinating the receipt of durable medical equipment, facilitating a connection with home health, referral to PCP, referral to ED, requesting the assistance of case management or social work assistance for the patient, medication change initiated by the Phone Call Nurse, requesting pharmacist assistance with discharge plan details, requesting other health providers assistance, reminding the patient of planned follow up appointments, scheduling expected follow-up appointments, providing self-care education (wound care, diet, activity), providing medication dosing and administration education), 2) whether findings from the call generate a visit to emergency department or a hospital readmission. (See Appendix I's *Starform Data* section)

Usual Care Group (Control Arm): Patients assigned to the Control Group receive standard discharge planning and follow-up per the usual care of their medical providers.

Data Collection

Every weekday morning, a report will be generated from the Vanderbilt electronic medical record identifying all patients discharged from the hospital the previous day. This list will be transmitted securely to the study team. The list will then be randomized and uploaded to the study database within Research Electronic Data Capture (REDCap). This will occur using code written in R linked with the application program interface (API) function of REDCap. (See ***Appendix II*** – Randomization and REDCap API Database Upload Code). The code will upload patients assigned to the 2 study arms into separate database locations. The Intervention Arm Database includes a work list queue for the Study Phone Call Nurse. In addition, she will document interventions delivered via a form (***Appendix III*** - Intervention Data Capture Form) for each patient's phone call encounter that will save this data as new variables within the database.

The Study Phone Call Nurse will continue to complete an existing form within the electronic health record, the Phone Call Starform (***Appendix I***) to document care provided via the phone call. For patients reached, the Study Phone Call Nurse will use the semi-structured script provided by the Starform to assess the patient's understanding of their discharge plan, screen for discharge assistance needs, and inquire about new symptoms requiring patient referral.

The majority of our study data will be obtained via Vanderbilt University Medical Center's Research Derivative. These variables include: 1) VUMC based primary outcome (hospital readmission to VUMC) data, 2) secondary outcome measures (patient satisfaction scores, all cause ED visits within 30 days, identified the need for assistance with discharge plan implementation, and 30 day mortality), 3) Hospital readmission risk score calculated for each patient before discharge which is included as part of the medical record, and 4) pre-specified subgroup identifiers (see Figure 1).

The Research Derivative (RD) is a database of clinical and related data derived from the Medical Center's clinical systems and restructured for research. Data is repurposed from VU's enterprise data warehouse, which includes data from StarPanel, Vanderbilt Perioperative Information Management System, ORMIS (Operating Room Management Information System), EPIC, Medipac, and HEO order entry records among others. The medical record number and other person identifiers are preserved within the database. Data types include reimbursement codes, clinical notes and documentation, nursing records, medication data, laboratory data, encounter and visit data, among others. Output may include structured data points, such as ICD-9 codes or encounter dates, semi-structured data such as laboratory tests and results, or unstructured data such as physician progress reports. The database is maintained by the Office of Research Informatics under the direction of Paul Harris, Ph.D.

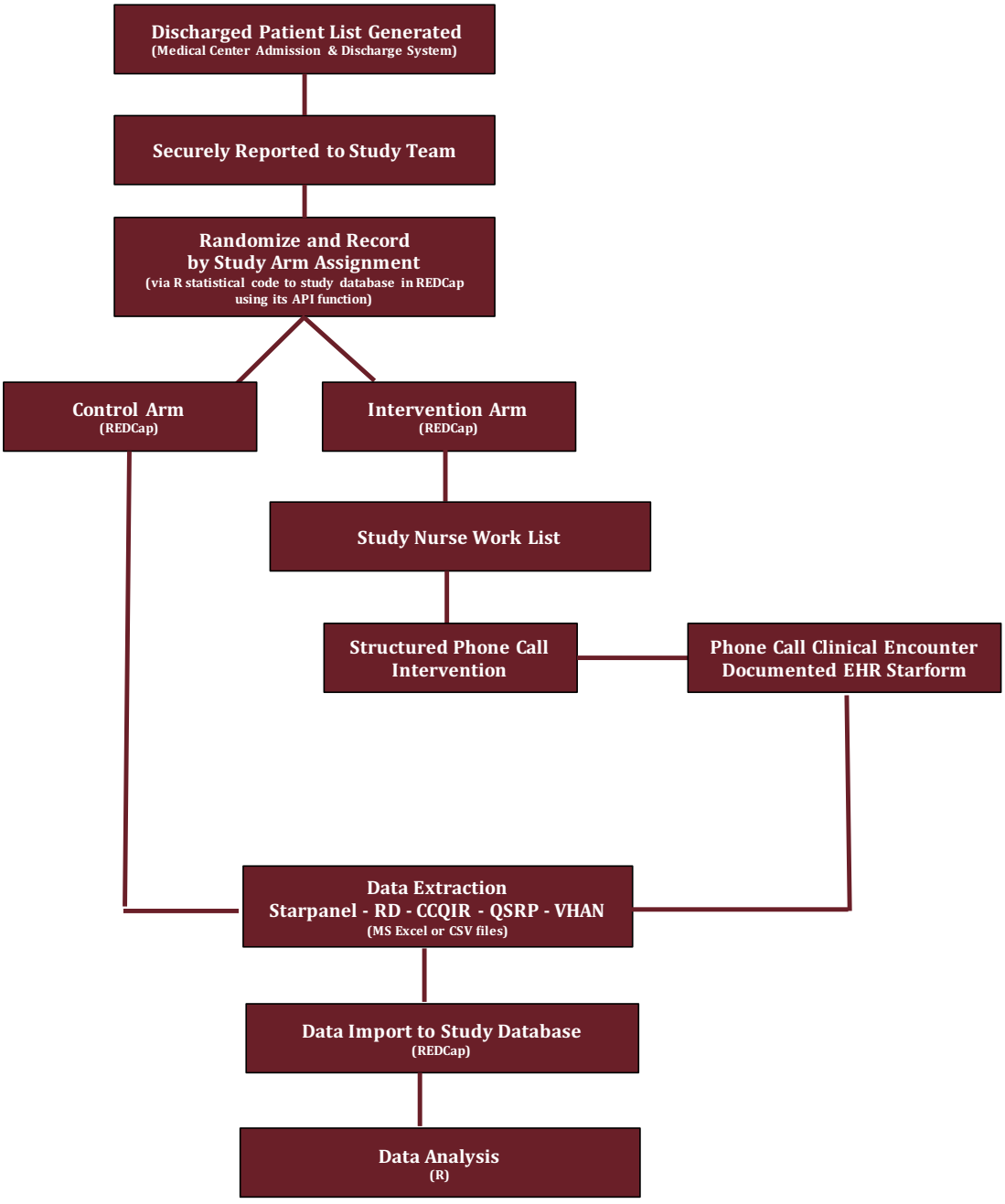
Not all patients returning to a hospital will be readmitted at Vanderbilt, and the Research Derivative data is limited to VUMC care. The inability to capture external health system readmission data is a major limitation of

readmission investigations. As a result, we have explored many methods to obtain external readmission data and found the use of the Vanderbilt Health Affiliated Network (VHAN) to be most feasible for this pragmatic study approach. We plan to overcome this obstacle, albeit in a limited way, by using the infrastructure of the Clinical Data Research Network (CDRN) to extract hospital admission and discharge data from VHAN.

Health Literacy Information will be procured from the Center for Clinical and Implementation Sciences Research Data Core.

A summary of all study variables is includes as ***Appendix IV*** – Study Data Summary.

Figure 2 – Flow of Discharge Phone Call Study Data Collection



Confidentiality and Source Data

Only key study personnel at the Data Coordinating Center, Vanderbilt University, will have access to the full study dataset which will be maintained in REDCap.

Data Safety and Monitoring

The interim analysis will be conducted by VICTR biostatistician Li Wang and Data Safety Monitor, Dr. Tina Hartert, Assistant Vice Chancellor for Translational Science. The results will be reviewed with the 3 member Safety Monitoring Committee including Dr. Hartert, VUMC Adult Enterprise Quality Committee: Mitch Edgeworth, CEO of Vanderbilt University Adult Hospital and Clinics; and Jerry Hickson, Chief Quality, Patient Safety and Risk Prevention Officer for VUMC. In addition to the study data analysis the Safety Committee will review 1) a 10% sample of the Phone Call Nurse's daily reports to her supervisors which is an element of clinical care reporting and 2) a summary of potential safety concerns from the office overseeing this clinical program, the Medicine Patient Care Center. The study team will remain blinded to outcome associated results.

Sample Size Considerations

Per inpatient hospital admission volume from October 2015 - September 2016, we estimate approximately 3048 patients will eligible for the study over the 6 month study period. Of those ½ will be randomized to each study arm. Based on the experience of a current pilot with calls made by 1 nurse, we anticipate attempting to call 1117 patients and reaching 334 patients in the phone call group each month. We will analyze the impact of the program on the phone call population with a pre-specified subgroup analysis of those actually reached (See Figure 1 – Study Design Schematic and Enrollment Projection).

Study Length and Timeline

The informatics run-in period will begin February 7th, 2017 to test the Study Data Flow and integrity of the randomization process. Official study enrollment will begin February 20th, 2017. Patients will be randomized the morning after hospital discharge. Those receiving a call will be contacted within 7 days of hospital discharge. We will obtain interim impact estimates of the discharge phone call intervention at 50% enrollment for 80% power (See the ***Study Timeline***, on page 2), and conduct the definitive analysis at 100% enrollment. In addition, the analyses will account for a 30 day re-admission observation window. Fifteen additional days will be added to the follow-up period to assure re-admissions are not minimally deferred to just after the 30 days period. Run-in period patient cases will be used to test the study data extraction and database upload process prior to the planned study analyses. This will permit us to troubleshoot unforeseen data collection challenges. Given the sample size considerations noted above, we estimate a study length of 7 months with enrollment completion in September of 2017, primary outcome follow-up ending in November of 2017, and data collection completed in (due to data lags for patient satisfaction, external hospital readmission, and mortality data) May of 2018.

ANALYSIS PLAN

General Approach

The study analysis will have 3 phases. The primary analysis will examine our primary outcome, hospital readmission within 30 days, via an intention-to-treat analysis where comparisons will be made between the 2 study arms. We will then examine secondary outcomes of all cause ED visits to Vanderbilt or VHAN ED and mortality. Given VUMC's interest in understanding characteristics of patients not reached via telephone, we will explore differences among those called and reached, called and not reached, and the control arm. In these 3 phases we will examine outcome differences by treatment assignment, age, gender, race, highest educational attainment, health literacy, established primary care status, patient satisfaction level, Medicare readmission penalty diagnosis status, and readmission risk score calculated at discharge as part of routine care at VUMC. Lastly, we will use descriptive statistics to quantify the need for patient assistance with discharge plan implementation (appointment scheduling or reminders, questions about new medications, durable medical equipment acquisition, referral for new symptoms, etc.) among patients in the intervention arm who are called and reached.

Statistical Analysis

In our univariate analysis, differences among these patient characteristic groups will be assessed using the continuity corrected chi-square test or Mann-Whitney test for continuous outcomes and the Kruskal-Wallis test for categorical outcomes. In our multivariate analysis, we will examine the relationship between treatment assignment and our secondary endpoints using logistic regression. The study is not powered for a time-to-event analysis; however, we will explore time-to-readmission using the Cox proportional hazard model to understand the timing of when readmissions occur. In order to provide VUMC Leadership with preliminary efficacy data, we will perform an interim analysis at 50% enrollment (~3.5 months) followed by the final analysis at study completion months (~7 months). See **Appendix V** for details. We have pre-specified an α-level of significance of 0.05 with penalties for a mid-study interim analysis per the O'Brian-Fleming alpha spending function allowing for an α-significance level of 0.005 for the interim analysis and 0.048 for the final analysis.

Power Calculation

The study design is targeted to achieve 80% power before October of 2017. Given our 0.048 alpha level for our final analysis, and controls anticipated to have a 13.52% readmission rate based on estimates, this requires approximately 320 patients enrolled per month (n = 2234). We assessed the feasibility of this target after observing there were approximately 508 eligible patients per month based on medical center data collected from 10/1/2015 - 9/30/2016. We noted approximately 11% of these patient would need to be excluded after randomization due to mis-categorized hospital discharge status affecting study eligibility reducing potential monthly enrollment to 452 (n = 3164, or 1582 patients per arm). In ***Table 1***, we illustrate conservative and ambitious enrollment scenarios with estimates for 80% and 90% power. Considering we have 1 Phone Call Study Nurse and will miss enrollment days for paid time off or sick days, we opted for a more conservative power target and detectable differences of 80% and 3.9% respectively. This carries an associated enrollment of 1117 patent per arm (n = 2234, or 11 patients per day).

Table 1 - Power and Sample Size Scenarios

	Conservative		Ambitious	
Control Group Readmission Rate†	13.52%	13.52%	13.52%	13.52%
Intervention Group Readmission Rate	9.60%	9.10%	10.20%	9.70%
Power	80%	90%	80%	90%
Detectable Difference	3.9%	4.4%	3.3%	3.8%
Projected Study Sample Size	1117	1117	1582	1582

*2 group X^2 test of equal proportions (equal n's), 2-sided text, final analysis α = 0.048
† Historical VUMC readmission rates

POTENTIAL RISKS AND BENEFITS

We anticipate minimal risk to patient as none will receive less than what was the VUMC standard discharge practice (no structured follow-up call) prior to the initiation of the phone call program in 2016. In addition, there are no invasive tests or sensitive questions. The phone call nurse currently is able to attempt calls for 75% of all discharged inpatient general medicine patients. She successfully reaches 30% after an average of 2.1 call attempts. With study call efforts focused on the intervention arm we anticipate she will attempt a call for all patients assigned to the Phone Call Group, and complete up to 3 call attempts. This may improve the intervention delivery rate. Patients that may have received a call before the study will not be exposed to potential benefits from the follow-up phone call. This, however, is anticipated to balance with the patients in the intervention arm that would otherwise have not been exposed to a call. Despite mixed results on the effectiveness of a discharge phone call program reported in the literature, we expect to observe a benefit from exposure to the phone call intervention,[6] particularly in those found to require discharge plan implementation assistance.[5] Other risks are related to potential breaches in confidentiality in the handling of patient protected health information (PHI). To avoid this, all PHI will be transferred among key study personnel and stored using REDCap. To avoid breaches in confidentiality induced by the Study Phone Call Nurse potentially sharing PHI with a friend, family member or stranger answering the patient's phone, she requests identifying information before initiating a discussion of the patient discharge care plan. Health proxies, caretakers or family members

may be spoken to with the explicit verbal permission of the patient. This is the current standard of medical care for follow-up phone call health service and not specifically implemented for the purpose of this study.

SIGNIFICANCE AND IMPACT

The results of the primary endpoint analysis of this study will inform an evidence-based VUMC decision on whether to invest in a hospital discharge follow-up phone call program for medical patients across the enterprise. If launched, our secondary outcome analyses results will inform the design of the program to maximize patient benefit. We intend to publish our result in the medical literature to contribute to knowledge on the efficacy of post-hospital discharge follow-up phone calls as a means of delaying hospital readmissions, improving patient's transition from inpatient to outpatient care, and improving patient satisfaction.

REFERENCES

1. Harrison PL, Hara PA, Pope JE, Young MC, Rula EY. The impact of postdischarge telephonic follow-up on hospital readmissions. Popul Health Manag. 2011 Feb;14(1):27-32. PMID: 21090991 PMCID: PMC3128446
2. Dudas V, Bookwalter T, Kerr KM, Pantilat SZ. The impact of follow-up telephone calls to patients after hospitalization. Am J Med. 2001 Dec 21;111(9B):26S–30S. PMID: 117903651. Weisman DS, Bashir L, Mehta A, Bhatia L, Levine SM, Mete M, Padmore JS. A medical resident post-discharge phone call study. Hosp Pract (1995). 2012 Apr;40(2):138–146. PMID: 22615088
3. Wong, F. K. Y. et al. Economic evaluation of the differential benefits of home visits with telephone calls and telephone calls only in transitional discharge support. Age Ageing 44, 143–147 (2015).Ashton CM, Del Junco DJ, Souchek J, Wray NP, Mansyur CL. The association between the quality of inpatient care and early readmission: a meta-analysis of the evidence. Medical care. 1997 Oct 1:1044-59.
4. Wong, F. K. Y., Chow, S. K. Y., Chan, T. M. F. & Tam, S. K. F. Comparison of effects between home visits with telephone calls and telephone calls only for transitional discharge support: a randomised controlled trial. *Age Ageing* **43,** 91–97 (2014).
5. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing Hospital Readmission: Current Strategies and Future Directions. *Annual review of medicine*. 2014;65:471-485. doi:10.1146/annurev-med-022613-090415.
6. O'Connor, C.M., and Fiuzat, M. (2010). Is Rehospitalization After Heart Failure Admission a Marker of Poor Quality? Time for Re-Evaluation. Journal of the AmericanCollege of Cardiology, 56(5), 369-371
7. Wong FKY, Chow SKY, Chan TMF, Tam SKF. Comparison of effects between home visits with telephone calls and telephone calls only for transitional discharge support: a randomised controlled trial. Age Ageing. 2014 Jan;43(1):91–97. PMCID: PMC3861338
8. Soong C, Kurabi B, Wells D, Caines L, Morgan MW, Ramsden R, Bell CM. Do post discharge phone calls improve care transitions? A cluster-randomized trial. PLoS ONE. 2014;9(11):e112230. PMCID: PMC4227814
9. Wong FKY, So C, Chau J, Law AKP, Tam SKF, McGhee S. Economic evaluation of the differential benefits of home visits with telephone calls and telephone calls only in transitional discharge support. Age Ageing. 2015 Jan;44(1):143–147. PMCID: PMC4255617
10. Melton LD, Foreman C, Scott E, McGinnis M, Cousins M. Prioritized post-discharge telephonic outreach reduces hospital readmissions for select high-risk patients. Am J Manag Care. 2012 Dec;18(12):838–844. PMID: 23286612
11. Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study. J Gen Intern Med. 2008 Aug;23(8):1228–1233. PMCID: PMC2517968
12. Goldman LE, Sarkar U, Kessell E, Guzman D, Schneidermann M, Pierluissi E, Walter B, Vittinghoff E, Critchfield J, Kushel M. Support from hospital to home for elders: a randomized trial. Ann Intern Med.

2014 Oct 7;161(7):472–481. PMID: 25285540

13. Mistiaen P, Poot E. Telephone follow-up, initiated by a hospital-based health professional, for postdischarge problems in patients discharged from hospital to home. Cochrane Database Syst Rev. 2006 Oct 18;(4):CD004510. PMID: 17054207
14. Chan B, Goldman LE, Sarkar U, Schneidermann M, Kessell E, Guzman D, Critchfield J, Kushel M. The Effect of a Care Transition Intervention on the Patient Experience of Older Multi-Lingual Adults in the Safety Net: Results of a Randomized Controlled Trial. J Gen Intern Med. 2015 Dec;30(12):1788–1794. PMCID: PMC4636586
15. Dudas V, Bookwalter T, Kerr KM, Pantilat SZ. The impact of follow-up telephone calls to patients after hospitalization. Dis Mon. 2002 Apr;48(4):239–248. PMID: 12021756

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APPENDIX I - Follow Up Phone Call Data Collection Form (Phone Call Starform)

Provider (indexing): Morrison, Johnstc (*** This will change the provider displayed in the all documents listing of StarPanel. ***)

***Standard Document Name**: Clinical Communication — Discharge Follow-up

Comment for Indexing (optional):

VANDERBILT UNIVERSITY MEDICAL CENTER
POST DISCHARGE TELEPHONE CALL

Date of Discharge: 12/12/2015

Patient Home Phone: (609) 122-2222

CALL INFO:

Call Attempt Date and Time: 01/28/2016 12:12

Contact Attempts:

Caller: Morrison, Johnstc

Pre-Call Prep Time:

Call Duration:

Pt Location:

- Call Successful
- Call Unsuccessful
- Call Unnecessary

Phone Call Occurred with:

INTRODUCTION:

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Hello, Barbara Ztest, this is Morrison, Johnstc from Vanderbilt. I am calling to follow-up with you after your recent visit to our hospital. I'd like to ask you a few questions to make sure everything is going ok. This could take 10 to 15 minutes - Is this a good time to talk?

- If Yes proceed;
- If No - can you give me a time that would be better and I will call you back?

I see you were in the Hospital for [x]. How are you feeling?

Comments:

DISCHARGE INSTRUCTIONS

Click HERE for Discharge Instructions

- I want to make sure the discharge instructions we gave you were clear and understandable... Can you please tell me in your own words how you are caring for yourself at home?

- What questions do you have about your discharge instructions?
  - If none... Great - if something were to come up, what would you do to get your questions answered?

- Are you having any unusual symptoms or problems? (Specific to problem *base this on the discharge summary* - i.e. dressing, PAIN, bruising or swelling, N/V; e.g., *Do your favorite pair of shoes still fit?*)

Patient can teach back self-care	○ Yes ○ No ○ Partial
Provider contacted for pain/symptoms/complications	○ Yes ○ No

Comments:

FOLLOW-UP APPOINTMENT

- When is your follow-up appointment?

Follow-up appointment change made based on this call	○ Yes ○ No
Able to teach back follow-up appointment related to hospitalization	○ Yes ○ No
Comments:	

MEDICATIONS:

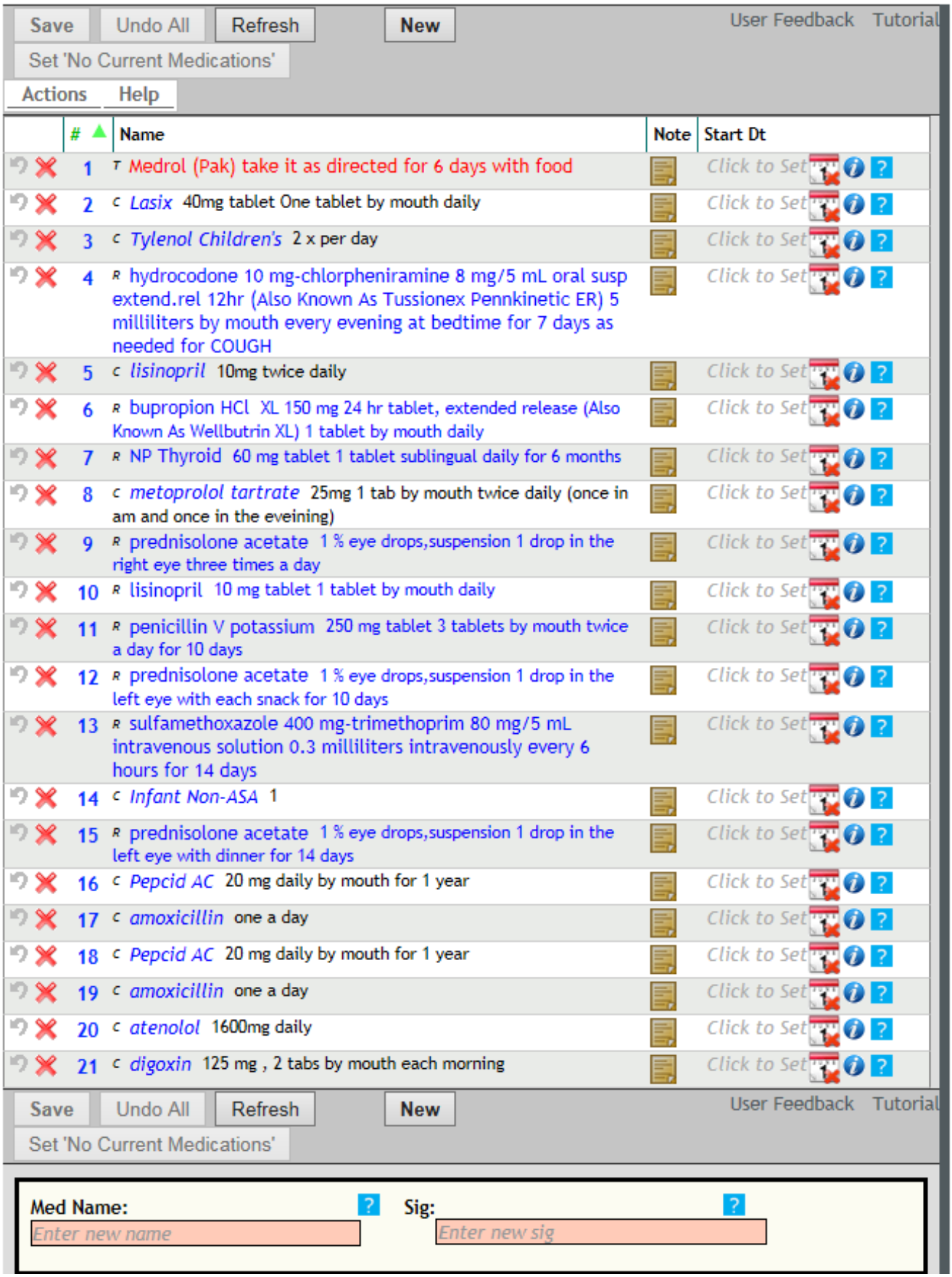
*Are new prescriptions identified on the discharge summary?

- **Yes** –
  - I see you have [number] new medicines from your hospital visit. How are you tolerating taking your [medication]? (follow protocol if you find patient has not filled prescriptions)
  - Would you talk through your daily plan for taking all your medicines
  - What questions do you have about your medicines
- **No** –
  - I see we didn't prescribe any new medicines when you left the hospital. Is that still correct?
  - Yes: Great – do you take any other medicines on a regular basis?
    - Would you talk through your daily plan for taking your medicines?
    - Do you have any questions about your medicines?
  - No: Ok, what medicines did you get? How are you tolerating taking your new medicines?
    - Would you talk through your daily plan for taking your new medicines and any others you take on a regular basis?
    - What questions do you have about your medicines?

Able to teach back medications	○ Yes ○ No ○ Partial
Has obtained medications prescribed at discharge	○ Yes ○ No

	○ Partial
Medication education or clarification was needed	○ Yes ○ No
Medication change made by caller/provider based on phone call	○ Yes ○ No
Comments:	

Meds Editor: (Click to expand/collapse)



Save | Undo All | Refresh | New | User Feedback | Tutorial

Set 'No Current Medications'

Actions | Help

	#	Name	Note	Start Dt
	1	T Medrol (Pak) take it as directed for 6 days with food		Click to Set
	2	C *Lasix* 40mg tablet One tablet by mouth daily		Click to Set
	3	C *Tylenol Children's* 2 x per day		Click to Set
	4	R hydrocodone 10 mg-chlorpheniramine 8 mg/5 mL oral susp extend.rel 12hr (Also Known As Tussionex Pennkinetic ER) 5 milliliters by mouth every evening at bedtime for 7 days as needed for COUGH		Click to Set
	5	C *lisinopril* 10mg twice daily		Click to Set
	6	R bupropion HCl XL 150 mg 24 hr tablet, extended release (Also Known As Wellbutrin XL) 1 tablet by mouth daily		Click to Set
	7	R NP Thyroid 60 mg tablet 1 tablet sublingual daily for 6 months		Click to Set
	8	C *metoprolol tartrate* 25mg 1 tab by mouth twice daily (once in am and once in the eveining)		Click to Set
	9	R prednisolone acetate 1 % eye drops,suspension 1 drop in the right eye three times a day		Click to Set
	10	R lisinopril 10 mg tablet 1 tablet by mouth daily		Click to Set
	11	R penicillin V potassium 250 mg tablet 3 tablets by mouth twice a day for 10 days		Click to Set
	12	R prednisolone acetate 1 % eye drops,suspension 1 drop in the left eye with each snack for 10 days		Click to Set
	13	R sulfamethoxazole 400 mg-trimethoprim 80 mg/5 mL intravenous solution 0.3 milliliters intravenously every 6 hours for 14 days		Click to Set
	14	C *Infant Non-ASA* 1		Click to Set
	15	R prednisolone acetate 1 % eye drops,suspension 1 drop in the left eye with dinner for 14 days		Click to Set
	16	C *Pepcid AC* 20 mg daily by mouth for 1 year		Click to Set
	17	C *amoxicillin* one a day		Click to Set
	18	C *Pepcid AC* 20 mg daily by mouth for 1 year		Click to Set
	19	C *amoxicillin* one a day		Click to Set
	20	C *atenolol* 1600mg daily		Click to Set
	21	C *digoxin* 125 mg , 2 tabs by mouth each morning		Click to Set

Save | Undo All | Refresh | New | User Feedback | Tutorial

Set 'No Current Medications'

Med Name: Enter new name

Sig: Enter new sig

CLOSING:

- Thank you for talking with me. We are always trying to get better at giving excellent care. Is there one thing that comes to mind for you that we can improve on?
- You will be getting a survey in the mail asking about your experience during your hospital stay. We would appreciate you taking the time to give us your feedback. It is very important to us and should only take you about five minutes.
- Do you need anything from us right now?
    - Ok we wish you all the best in your recovery. If you need anything, please contact us at [phone number]

Comments:

Save As Draft Complete

Form: post_discharge_telephone_call (Post Discharge Telephone Call)
Version: 2.4
Last modified: $Date: 2015/12/21 18:22:48 $

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Appendix II - R Code Template for Daily Patient Cohort Randomization and
Upload to the REDCap Study Database

```
#Load Necessary Libraries
library(RCurl)
library(readr)

#Set your file path to the folder where BOR report is stored
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization")

#Will upload BOR csv corresponding to today's date
filename <- paste("discharge_report_",format(Sys.Date(), "%m-%d-%Y"),".csv", sep = "")
filename <- paste("discharge_report_", Sys.Date(),".csv", sep = "")
data <- read.csv(file = filename)

#Sets a seed based on today's date for reproducibility
set.seed(floor(as.numeric(Sys.Date())^1.5))

#Samples a random 1/2 of rows to be included in the intervention group. Will randomly round up or down if an
odd number of rows.
sample_rows <- sample(1:nrow(data), sample(c(floor(nrow(data)/2), ceiling(nrow(data)/2)), 1), replace = F)
random_group <- rep("B", nrow(data))
random_group[sample_rows] <- "A"
data <- data.frame(data, random_group)

#Saves intervention and control patients to separate datasets
data_intervention <- data[data$random_group == 'A',]
data_control <- data[data$random_group == "B",]

#Change directory to store intervention patients in Intervention Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Intervention")

#Saves intervention patients with date stamp
write.csv(data_intervention, file = paste("data_intervention", Sys.Date(),".csv", sep = ""), row.names = F)

#Creates data object containing the intervention patients that can be uploaded to REDCap
Data.INT <- read_file(paste("data_intervention", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 2 below
result_intervention <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='0F5278ECF8493BDA2A5FB71EBE828110',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.INT,
  returnContent='count',
  returnFormat='json'
)

print(result_intervention)
```

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```
#Change directory to store Control patients in Control Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Control")

#Saves control patients with date stamp
write.csv(data_control, file = paste("data_control", Sys.Date(),".csv", sep = ""), row.names = F)

#Creates data object containing the Control patients that can be uploaded to REDCap
Data.Control <- read_file(paste("data_control", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 1 below
result_control <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='6EA859FA6C7F35B11CAAAA744ADAAC48',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.Control,
  returnContent='count',
  returnFormat='json'
)

print(result_control)
```

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Appendix III – Intervention Data Capture Form

Discharge Follow Up Phone Call

Editing existing Encounter Number **12345678901**

Encounter Number	**12345678901** To rename the record, see the record action drop-down at top of the Record Home Page.
Current Date and time	03-17-2017 11:33 Now M-D-Y H:M
Discharge Team	RIVEN HM 1
Discharge Team Group	RIVEN
MRN	5555555555
Name	DOE, JOHN
BHLS	
Education	12
Admit Date/Time	03-10-2017 16:30 Now M-D-Y H:M
Discharge Date and time	03-12-2017 11:55 Now M-D-Y H:M
Hours Since Discharge (auto-calculated, ineligible for call after 168 hours)	74 View equation
Tele	615XXXXXXX
PCP Name	SMITH, MARK
PCP ID	2520
Patients Preferred Language	ENGLISH

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Date of First Contact	03-14-2017 Today M-D-Y
Call Attempts	Patient currently Inpatient/Readmitted
Date of Last Contact	03-17-2017 Today M-D-Y
Status	Unnecessary - Patient in hospital
Interventions Delivered (check all that apply)	Durable Medical Equipment Facilitated Home Health Connection Referral to PCP (pt instructed to call) Referral to ED (pt instructed to go) Case Management/Social Work assistance requested Medication Change by Call RN Pharmacist assistance requested Provider assistance requested Planned Follow Up Appt Reminder Planned Follow Up Appt Scheduled Self-care teaching (wound care, diet, activity) Medication education provided Other
Notes	Expand
Form Status	
Complete?	Complete

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Appendix IV- Study Variable Summary

Phone Call Study Patient Variates

BASELINE PATIENT DATA

First name
Last name
Zipcode
Medical record number
Established Primary Care
- Yes
- No

Health Literacy
- BHLS
- Education level

Race
- Black
- White
- Latino
- Non-white Hispanic
- Multiple Races
- Unknown

Primary Language
- English
- Spanish
- Arabic
- Other

Number of Hospitalizations in Prior Year

Complicating Baseline Comorbidities (Natural Language Processing)
- Congestive heart failure
- COPD
- Readmission penalty dx - AMI, HF, PNA, COPD, CABG, Total hip/knee repair, and stroke
- Diabetes
- Outpatient hospice
- Substance abuse
- Depression

INDEX HOSPITALIZATION DATA

Intervention Arm
Encounter Number
Date of admission
Time of admission
Admission day of the week
Admission Diagnosis #1
Admission Diagnosis #2
Admission Diagnosis #X
Highest bed level
- Floor
- ICU

Discharge Service
- Riven
- Morgan
- Geriatrics
- Palliative Care

Discharge Diagnosis #1 (ICD-10)
Discharge Diagnosis #2 (ICD-10)
Discharge Diagnosis #3 (ICD-10)
Discharge Diagnosis #4 (ICD-10)
Discharge Diagnosis #X (ICD-10)
Discharge Date
Discharge Time
Discharge Location/Disposition
Readmission penalty dx cohort- AMI, HF, PNA, COPD, CABG, Total hip/knee repair, and stroke
Number of medications upon discharge
VUMC Cornelius Readmission Risk Score
Patient satisfaction (Press Ganey Score, 1-5)

READMISSION HOSPITALIZATION DATA

Date of admission
Time of admission
Admission Diagnosis #1
Admission Diagnosis #2
Admission Diagnosis #X
Highest bed level
- Floor
- ICU

Discharge Diagnosis #1 (ICD-10)
Discharge Diagnosis #2 (ICD-10)
Discharge Diagnosis #3 (ICD-10)
Discharge Diagnosis #4 (ICD-10)
Discharge Diagnosis #X (ICD-10)
Readmission penalty dx - AMI, HF, PNA, COPD, CABG, Total hip/knee repair, and stroke
Discharge Date
Discharge Time
Discharge Location
Patient satisfaction (Press Ganey Score, 1-5)

Extra-Institutional Data

Survival Data (at 30 days)
Non-VUMC TN Readmission (at 30 days post VUMC admit)
(minimum data = yes/no)

CALL INTERVENTION DATA

1st Contact
- Time of first call
- Date of first call

Final Contact
- Time of Final Contact
- Date of Final Contact

Call attempts
- 1
- 2
- 3
- Not eligible
- AMA
- Facility Placement
- Deceased
- Already seen in clinic
- CRC patient
- Patient currently admitted/readmitted

Call status
- Success
- Unsuccessful - Wrong Number
- Unsuccessful - Refused
- Unsuccessful - Patient Call Back Requested
- Unsuccessful - Patient Not Available
- Unsuccessful - No Answer
- Unsuccessful - Patient Never Admitted
- Unsuccessful - Left a Message
- Unsuccessful - Patient in Hospital
- Unnecessary (already seen in clinic)

Can teach back self care
- Yes
- No
- Partial

Pt aware of follow up appointment
- Yes
- No

Able to teach-back follow up appointment
- Yes
- No
- Partial

New Meds Upon Discharge
- Yes
- No

Able to teach-back current medications dosing
- Yes
- No
- Partial

Has obtained medications prescribed at discharge
- Yes
- No

Discharge Implementation Assistance Required
- Provider contacted for pain/symptom/complication
- Durable Medical Equipment
- Facilitated Home Health Connection
- Referral to PCP (pt instructed to call)
- Referral to ED (pt instructed to go)
- Case Management/Social Work Assistance Requested
- Medication Dose Change by Call RN
- Pharmacist assistance requested
- Provider assistance requested
- Planned Follow Up Appt Reminder
- Planned Follow Up Appt Scheduled
- Medication education provided

Total Intervention Time (call prep, phone time, care coordination)

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Appendix V – Interim Analysis Plan
INTERIM ANALYSIS PLAN

1. **Consort Diagram** (Consort Diagram – ***Figure 1***)
    a. Pts Enrolled
    b. Pts Randomized
    c. Post-Randomization exclusions by arm total count and rate (including reasons with counts)

2. **Adverse Events Summary**
    a. All Pts: Results of a debriefing with the Medicine Patient Care Center for incidents that
        i. Raised concerns that the phone calls may introduce harm or create and issue (i.e. – MVC s/p picking up call from the Phone call RN, d/c plan confusion introduced by phone call RN involvement, etc)
    b. Intervention Pts: Unmet need upon initial discharge (Summarized in ***Table 3,*** see below)

3. **Co-Variate Distribution** (***Table 1***)
    a. Patient: Age, sex, zip code, established primary care, BHLS, education level, race, primary language, VUMC admits in prior 6 mo, VUMC ED visits in prior 6 mo, PMHx (7 readmit penalty diagnoses, DM, outpatient hospice, substance abuse, depression)
    b. Index Admission: Admit diagnosis, # meds upon discharge, Cornelius score, Any ICU time, meds-to-beds program exposure, %weekend discharges, % discharges after 4pm, Hospital LOS

4. **Outcome Analysis** (ITT analysis for stat significant differences)
    a. VUMC Readmission Rate
        i. Rates (***Table 2*** – 2x2 Table)
        ii. Descriptives for proportion readmit penalty diagnosis
    b. Time to VUMC readmission
        i. Kaplan-Meier Curve (***Figure 2***)
    c. VUMC ED Revisit Rate
    d. Patient Satisfaction (Press Ganey)

5. **Intervention Delivery**
    a. Intervention Delivery Rate: Successful Calls
    b. Unsuccessful Calls and Reason (wrong number, refused, call back requetsed, no answer, never admitted, left a message, in hospital)
    c. #Call Attempts to success: proportion 1, 2, 3, mean, median
    d. Time-to-Successful Call (adjusted for first call?)
    e. Total Intervention Time: mean/SD, median/IQR
    f. Discharge Implementation Assistance Provide: (***Table 3*** - Frequencies, %)
        - Any (Count, % of Total)
        - Provider contact for a new symptom/complication
        - Durable medical equipment
        - Facilitate home health connection
        - Referral to PCP (pt to call)
        - Referral to ED (pt told to go)
        - Case mgmt./Social work assistance requested
        - Med dose change by Call RN
        - Pharmacist assistance requested
        - Planned F/U appt reminder
        - Planne F/U appt scheduled
        - Med Education provided

6. **VUMC Admission Trend** (***Figure 3*** – Admission Rates from Feb 20 – Sept 20 2017)

7. **Stopping Rules** (none)

8. **Checking Readmission Rate Assumption**
    a. adjusted sample size calculation (if needed)