Anticoagulation Medical Home for High-Risk Patients with Venous Thromboembolism: Patient Education, Anticoagulant Decision-Making, and Patient Self-Efficacy in the Home Coordinated by the UMass Anticoagulation Team

Grant ID 20405049

<u>Principal investigator</u>
Alok Kapoor

<u>Co-investigators</u>
Robert Goldberg
Joel Gore
Kathleen Mazor
Frederick Spencer
Bruce Barton
Wei Huang
Matthew Silva

Abstract

Overview: Initiation of anticoagulation for patients with venous thromboembolism (VTE) newly diagnosed in the hospital is an important patient safety threat. A multicomponent intervention including pharmacist inpatient consultation to choose between new oral anticoagulant versus warfarin, improvement of discharge medication instructions with illustrations, coordination of care across all settings, and pharmacist home visit holds the promise of better quality transition for the patient with VTE.

Goal: To improve the quality of care transitions for patients with new episodes of VTE.

Target population: Age 18+ with new VTE; patient must eligible for anticoagulation and prescribed anticoagulation on discharge.

Project methods: A research assistant will screen radiology records to identify 200 patients total with new cases of DVT or PE. Patients agreeing to participate will undergo initial interview and pharmacist consultation including discussion of choice of new oral anticoagulants versus warfarin. We will then randomize patients to the multicomponent intervention or usual care. For intervention patients, the pharmacist will write medication discharge instructions enhanced with illustrations. The intervention patients will also receive home visits within seven days of discharge and coordinated communication through nurse anticoagulation clinic provider. To measure the effectiveness of the intervention, we will compare mean scores on Care Transition Measure (CTM)-15. We will also analyze secondary outcomes including VTE recurrence and major hemorrhage.

Evaluation: We anticipate a 10% higher score on CTM-15 for intervention patients given that our multicomponent intervention focuses on information transfer of medications particularly medication side effects which are a current practice gap at UMass. We will track secondary outcomes by chart review as well as telephone calls to patients at 30 days or 90 days after discharge.

Table of Contents

C1. Overall Goals and Objectives

Overview: Anticoagulants have been identified as one of the top five drug types associated with patient safety incidents in the United States.[1] Venous thromboembolism (VTE), comprising the conditions of deep vein thrombosis (DVT) and pulmonary embolism (PE), require anticoagulant therapy. Despite initiation of therapy the risk (at 30 and 90 days) of recurrent VTE for treated patients is high (3.3% and 7.8% respectively) and the risk of hemorrhage from anticoagulation is also high (3.5% and 4.5% respectively).[2] Despite these high rates, there are few published care management interventions which have demonstrated effectiveness in reducing the risk of secondary episodes of VTE and hemorrhage. Part of the problem may lie in the choice of setting. Interventions have addressed medication education in the hospital or, separately, management in the clinic.[3] Few of these intervened in both settings or addressed the coordination of care. Providers differ between the hospital, clinic, and home settings. Including our anticoagulation team in interventions focused on each of these settings could overcome shortcomings of prior trials.

Another significant problem is that medication instructions provided by clinicians are often not understandable to the average patient being discharged from the hospital. Anticoagulant medication, particularly warfarin, is among the most common source of adverse drug events.[4] Well written patient instructions with illustrations can improve transition from hospital to home and patient adherence in the outpatient setting.[5,6] This can be particularly important in a medication like warfarin which requires frequent monitoring in the initial phase of usage and which has so many medication interactions and dietary restrictions.

Novel oral anticoagulants, although offering advantages with respect to fixed dosing, still pose issues for which patient education is critical (timing of administration, once versus twice per day, monitoring of renal function, storage of medication etc.) Including clinical pharmacists experienced with these medications early in the decision-making process could enhance choice of the anticoagulant and adherence with this choice.

Previous care transition interventions[7,8] including pharmacist consultation at the time of discharge or follow-up phone call by pharmacist have not been able to reduce medication errors. Home visits with direct observation of patient medication use can identify pitfalls including wrong dose, schedule, administration, or interaction with other medications, including over-the-counter medications missed in many medication reconciliation lists.[9] A multicomponent intervention including pharmacist inpatient consultation to choose between new oral anticoagulant versus warfarin, improvement of discharge medication instructions with illustrations, coordination of care across all settings, and pharmacist home visit holds the promise of better quality transition for the patient with VTE. *We therefore propose a randomized controlled study comparing a multicomponent intervention focused on improving the quality of transition compared with usual care for patients with new episodes of VTE.*

(**Overall goal:** Our primary study goal is to improve the quality of care transitions for patients with new episodes of venous thromboembolism (VTE).

Alignment of goal: Our proposed multicomponent intervention fits the Pfizer request for proposals that are "well-balanced and focus on key aspects of transitions of care, including: multidisciplinary collaboration … transitional planning, medication management, patient and family action/engagement and transfer of information."

Objectives:
(1) **Primary Outcomes:** To measure differences in the quality of care transition, as measured by the Care Transition Measure (CTM)-15 in *our target population* of patients with incident VTE randomized to either a multicomponent, anticoagulation medical home intervention or usual care.
(2) **Secondary Major Outcomes:** To measure the difference in recurrent VTE, major hemorrhage, all-cause readmissions, and mortality between our intervention and comparison groups at 30 and 90 days in our target population.
(3) **Secondary other outcomes:** To measure patient knowledge and attitudes, and health-related quality of life, time in the therapeutic range (TTR) for patients on warfarin in our target population.

Innovation: *Multidisciplinary team, illustrated instructions, and home visits are innovative.* Although studies exist on the individual components, there has not been an evaluation of a multicomponent intervention designed to improve transition from hospital to home for patients with VTE. Use of a multidisciplinary team (clinical pharmacists both in hospital and in the home and registered nurses supervised by cardiologist and hospitalist), illustrated medication instructions, and home visitation make this proposal innovative. Our notion of making the anticoagulation team in charge of coordinating patient care is also innovative.

C2. Technical approach: Our intervention in which the anticoagulation team at UMass will coordinate the transition of care from hospital to home and clinic among patients with newly diagnosed VTE will improve the communication of health goals, follow-up appointments and plans, patient knowledge of the underlying medical condition, and medications including side effects. The anticoagulation team will facilitate communication between inpatient and outpatient providers, make follow-up telephone calls to ensure adherence, and observe patients in their home setting to detect possible medication errors that might lead to an increase in adverse events including recurrent VTE or major hemorrhage.

Current assessment of target area: We derived baseline metrics from Transitions, Risks, and Action in Coronary Events – Center for Outcomes Research and Education

Information transfer about medication side effects is a quality

(TRACE-CORE), an NIH funded observational cohort study on transitions of care for the patient with acute coronary syndrome. Although the treatment plans and the indications for readmission are somewhat different for patients with acute coronary syndrome compared with VTE, there are similar adherence issues with antithrombotic, common age and facility quality variables that can be informative to our understanding of the current gap in care transitions in our setting. Members of our team (RG and JG) participated in the design and implementation of this trial which occurred between 2011 and 2013. The trial found that patients in this observational study had a CTM-15 score of 74.7 ± 16.2 (score ranges 0-100). The 30 day readmission rate was 15.1%. Although the overall score was high on the CTM-15, individual items of the CTM-15, which was developed by Eric Coleman et al. for profiling facility performance with quality of transition of care for Medicare and Medicaid beneficiaries, suggested problems with communication of information. In particular, 26.2% of patients disagreed with the statement "when I left the hospital, I clearly understood the possible side effects of each of my medications." Given the preponderance of readmissions related to

adverse drug events nationwide[10], we have focused development of our intervention on the improvement of knowledge of medications and their side effects by integrating clinical pharmacists in the inpatient and home settings.

Target audience / beneficiaries of project: The target audience for this project is hospitals and health systems looking to improve the quality of transition of care for patients with recently diagnosed VTE. We believe that patients with VTE will benefit from the project outcomes given the typical confusion that occurs during the transition from hospital to home, the lack of clear, useful information for patients about the proper use of anticoagulation, and the failure to educate patients about potential interactions with other medicines. In addition, patients with other indications for anticoagulation (e.g. atrial fibrillation) will also benefit from the lessons we learn through this proposed project.

METHODS

Population: Patients aged 18 years and older admitted to the hospital for VTE or alternate reason with development of a new diagnosis of deep vein thrombosis (DVT) (i.e. popliteal vein or more proximal) or pulmonary embolism (PE). In order to be eligible for the proposed study, the patient must be eligible for anticoagulation and prescribed anticoagulation on discharge. We will include patients with DVT of the leg or pelvis confirmed by ultrasound or CT scan and exclude those who develop a DVT in their arm or other site given those patients have a different risk of embolization and recurrence.[11,12] We will include patients with PE on the basis of a positive CT spiral exam, pulmonary arteriogram, CT angiogram, or high probability ventilation perfusion scan. We will include patients with first or subsequent episode of VTE.

Setting: UMass Memorial Hospital - University and Memorial campuses; any inpatient service.

Procedure: In order to identify potentially eligible patients, each day a research assistant will screen radiology records for inpatients to identify patients with positive CT pulmonary embolism and limb Doppler studies. Given that these radiological exams are virtually unique for the suspicion of new VTE event, this method will prove to be a highly efficient way to identify potential participants for our study. For those patients with positive studies, we will ask the attending physician in charge of this patient for permission to approach his or her patient about the study. In addition to screening radiology records, we will advertise widely among the other hospitalists in Dr. Kapoor's group as well as reach out to faculty and residents from other specialties along with nurses and case managers. Once we identify a patient, a research assistant will discuss the project and obtain informed consent. He / she will then collect baseline interview data on all consenting patients with this interview expected to last approximately 45 minutes.

Initial interview: At the initial interview, the research assistant will collect baseline demographic information and administer several data collection instruments (See Figure and Table 2) from which we will derive our outcomes and covariates. All responses will be recorded in the REDcap database specifically designed for this purpose. (page 14 for further details)

Initial anticoagulation pharmacist consultation: Dr. Gore, the Director of the anticoagulation service at UMass, and Dr. Kapoor will train 2 inpatient clinical pharmacists to participate in this trial. The clinical pharmacists will conduct his or her usual interview focused on reviewing the medical history and speaking to the patient about medication preferences regarding anticoagulation and other medications. Next, the pharmacist will share patient input and his or her own expertise to help make a decision regarding the choice of oral anticoagulant and the

6

timing of its initiation.   To assist in making this decision, the pharmacist will employ clinical prediction rules designed to estimate the risk of VTE recurrence and bleeding.[13] During training sessions, the pharmacist will review with Drs. Gore and Kapoor common patient scenarios and how decision making might be influenced by the clinical prediction rules.

Randomization: Once the pharmacist has completed initial consultation, we will then randomize those consenting to the intervention or control using Statistical Analysis Software (SAS) 9.3, Inc. random number generator procedure.[14] To avoid imbalance in the treatment and control groups within the type of oral anticoagulant prescribed, we will randomize in a stratified fashion according to type of novel oral anticoagulants versus warfarin, using a permuted block design. This randomization strategy forces a balance between treatment groups within each block of treatment allocations. The block size will vary between 2 and 4, due to the small sample size.

Figure 1: Timeline of Study Interventions, Study Administration and Data Collection
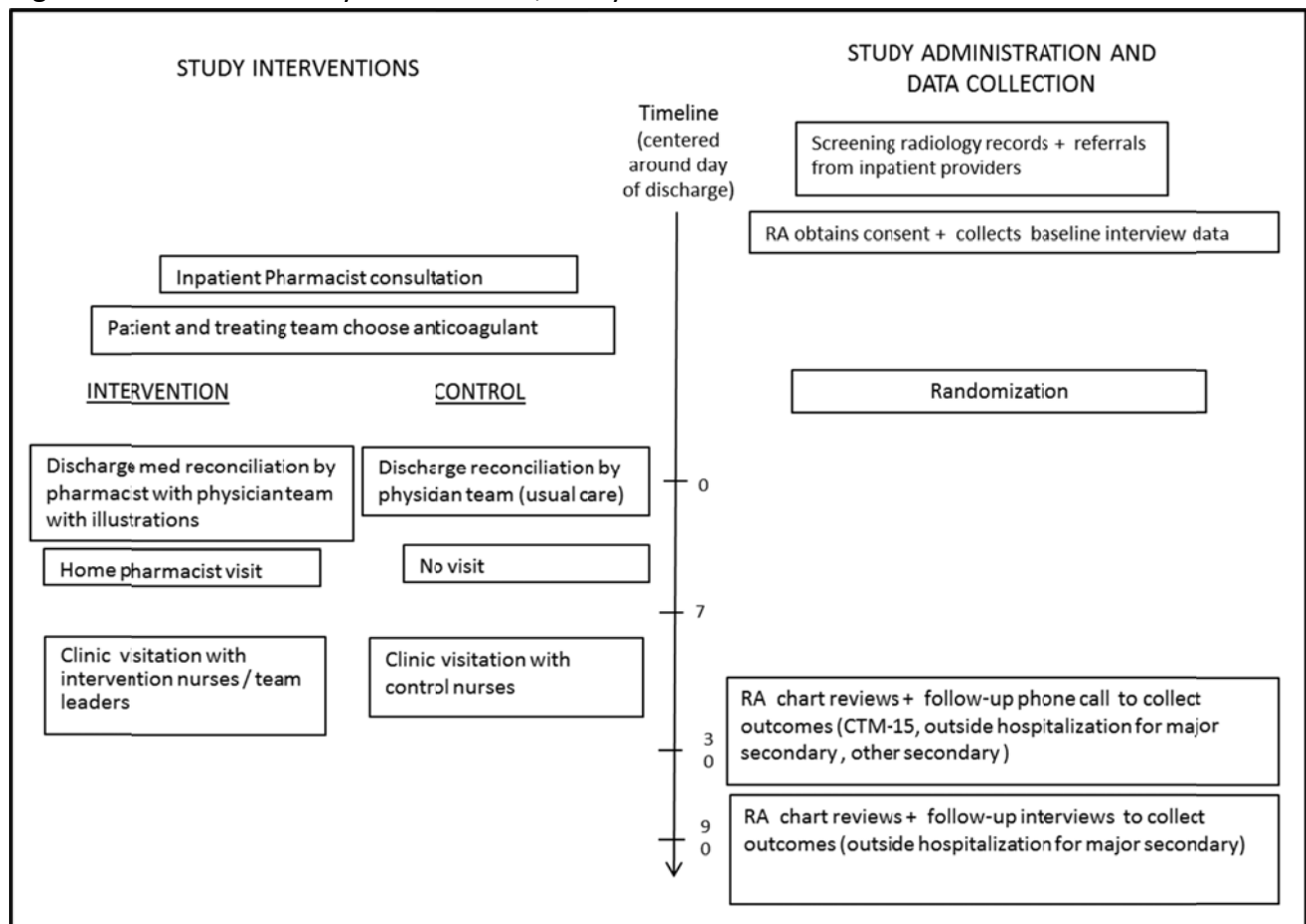
Multicomponent Intervention: We will intervene in multiple phases of the hospital to home transition.

Discharge: One of the inpatient pharmacists mentioned above will perform medication reconciliation for each intervention patient at the time of discharge. In addition, the pharmacist will compose illustrated medication instructions to accompany other hospital instructions using software of the International Pharmaceutical Federation.[15] (See Appendix 1

for example) The pharmacist will then discuss these instructions along with information about the patient's disease and follow-up appointments. The pharmacist will also highlight warning signs and symptoms that should trigger a call to the anticoagulation clinic or, in the case of a more severe situation, instructions to go to the hospital. He/she will also advise patients about potential medication side effects especially for anticoagulants. We will also ensure that the medication instructions provided by the pharmacist are sent to the anticoagulation clinic nurse who will be the patient's anticoagulation team leader. The anticoagulation clinic nurse will act as the patient's leader much in the same way that the primary care provider serves as the leader of the medical home model.[16]

Clinic: In the clinic, the anticoagulation team nurses will continue to provide excellent guidance for patients on warfarin, including selection of highly motivated patients for home self-testing in certain cases. For patients prescribed a new oral anticoagulant, study nurses will reinforce dosing changes required for rivaroxaban and apixaban at the 3 and 1-week mark, respectively. Anticoagulation nurses will also update medication and diet instructions using the same software mentioned above.

The nurse will communicate all interventions to the patient's PCP.   In order to prevent contamination across intervention and control groups, we will assign separate nurses to intervention patients as compared with patients randomly assigned to usual care. The leadership role for the nurse provider will not exceed three months which is the typical duration of anticoagulation for patients with first or provoked VTE. In cases in which patients will be continuing anticoagulant past 90 days, the nurse will continue to advise the patient regarding anticoagulant use but defer coordination role for other medications and issues to the patient's PCP.

Home: A clinical pharmacist will make a home visit to all intervention cohort patients within seven days of their discharge. In that home visitation protocol, the clinical pharmacist, who is part of our anticoagulation team, will assess the patient's proficiency in self-medication using the scorecard we developed and tested for reliability in a prior home visitation intervention we conducted[17] for the proposed study. The scorecard includes the following domains: identification (participant identifies pill bottle from others), explanation (understands approximately the biological purpose of the medication), organization (sorts pills appropriately into pillbox), administration (including cutting pills and drawing up and injecting the correct dosage of parenteral medication), and timing. (See Appendix 2 for scorecard) We will also use the home visit to perform another medication reconciliation. The total time for the home visit shall not exceed one hour. In our prior home visit project the average time was 35 minutes.

At the conclusion of our home visit, we will share our scorecard and medication reconciliation information with the patient's anticoagulation provider and PCP through secure email. The anticoagulation nurse provider will be in charge of calling the patient to remediate any medication errors and/or following up with the PCP - for example, to make a change in medication that might conflict with anticoagulation or other medications on the patient's list.

Chart review and follow-up phone calls: After 30 days have elapsed from the time of discharge, the research assistant will perform a limited chart review and make telephone calls for all enrolled patients telephone. The research assistant will receive training from Dr. Goldberg who has a wealth of experience tracking VTE and hemorrhage outcomes through his leadership of the Worcester VTE study. In the interview, the RA will administer the CTM-15 (primary

outcome) as well as the other instruments for secondary outcome detection detailed below. In addition, the RA will inquire about new health events and outside hospitalizations. After 90 days have elapsed, the RA will again review the chart and telephone the patient to ask about new health events and hospitalizations. Dr. Kapoor will serve as a clinical referee for any positive outcomes.

Outcomes:

Primary: Our primary trial outcome will be the CTM-15. The CTM-15 is a 15 item instrument which assesses discharged patients views on how well the care team communicated and supported the patient. (See table) Although other outcomes might be appropriate targets to measure quality of care transitions including some of our secondary outcomes, CTM-15 is the only established instrument for measuring care transitions. It also happens to be included (in the abbreviated version CTM-3) in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) routinely distributed to a subset of patients discharged from the hospital receiving payment from Medicare.[21] The measure has been shown to successfully discriminate between patients who did and did not have a subsequent emergency department visit or re-hospitalization for their index condition (which was any one of nine diagnoses commonly leading to skilled nursing facility discharge or discharge home with home health services).[22](Appendix 4)

Secondary, major outcomes:

VTE and major hemorrhage at 30 and 90 days: We list definitions for these events in Table 1.

Table 1: Outcomes with Description, Timing and Source

Item	Description	Timing of collection / Source of Data
Primary Outcomes		
CTM-15	15 questions which measure 4 aspects of quality of transitional care **-** Information Transfer - Patient and Caregiver Preparation - Support for Self-Management - Empowerment to Assert Preferences	30 day
Secondary Major Outcome		
VTE recurrence	- Proximal DVT or PE radiographically confirmed - lower extremity, pelvic (no upper extremity)	-30 day, 90 day - chart review, telephone calls
Major hemorrhage	- *ISTH 2005 medical* definition [18]- 2 unit drop in hemoglobin, 2 unit transfusion , or critical site bleed - *ISTH 2009 surgical* definition[19] - surgical site 2 unit drop or 2 unit transfusion with increase in LOS , hemodynamic compromise , delay in rehab	-30 day, 90 day - chart review , telephone calls
All cause readmissions	Any unplanned admissions	-30 day, 90 day -chart review, telephone calls
Mortality	Any death	-30 day, 90 day -chart review, telephone calls
Secondary Other Outcomes		
Patient knowledge	About VTE and antithrombotic medication	-baseline, 30 day
Health-related quality of life	Change in MCS and PCS	-baseline, 30 day
Attitude	Attitude toward anticoagulation queried through trust in clinician questionnaire [20]	- baseline, 30 day
Patient knowledge	Patient knowledge about VTE / antithrombotic medication	-baseline,30 day

Abbreviations: ISTH= International Society of Thrombosis and Haematosis, MCS, PCS = mental and physical component scores.

Secondary, other outcomes: <u>Knowledge</u>- We will measure change in knowledge from baseline to 30 days. For the patients receiving warfarin, we will distribute a modified version of a 22-item instrument (see Appendix 3) previously developed and tested by our group.[23] For the patients receiving new oral anticoagulants, we will develop a similar knowledge assessment tool. Finally for VTE as a disease entity, we will develop additional questions leveraging our expert consultant. Questions will include items regarding warning signs of new VTE, complications of VTE, prevention of recurrent VTE.

<u>Attitude</u> - We will measure change in patient attitude toward anticoagulation team from baseline to 30 days. And compare across groups. Specifically, we will adapt an existing instrument[20] with items assessing patient trust in doctors, health insurance, and the medical profession in general. (Appendix 4)

<u>Health-Related Quality of Life</u>- We will measure the difference in mean change between 30 day and baseline measurements of the SF-12 inventory[28] for intervention versus control patients. We will measure this difference for both summary measures from the SF-12, i.e. physical component score (PCS) and mental component score (MCS). (Appendix 4)

<u>Time in the therapeutic range</u>- UMass Memorial contracts with DoseResponse, Inc. to track and report patient INR data.[29] We will export these data into Microsoft Excel documents and calculate a TTR for each patient using the Rosendahl method consistent with prior work.[30] Multiple studies[31,32] have shown that time in the therapeutic range predicts both recurrent VTE and major hemorrhage rates.

Covariates: We have chosen each of the variables in Table 2 because of their clinical significance and association with our outcomes. In

Table 2: Covariates

Covariates	Description
Demographics	Age, race, sex, insurance type, educational level
Comorbidities	TRACE-CORE[24] custom instrument
Medications	Number of medication classes based on VA national formularoy[25]
Health literacy	2 screening questions[26]
Caregiving support	TRACE-CORE custom instrument
Access to healthcare	TRACE-CORE custom instrument
Patient activation	PAM6 assesses knowledge, skill, and confidence for self-management[24]
Depression	PHQ-9[27]

Abbreviations: TRACE-CORE = Transitions, Risks, and Action in Coronary Events – Center for Outcomes Research and Education, PAM6 = Patient Activation Measure – 6, PHQ-9 = Patient Health Questionnaire-9

addition to patient interviews, in order to verify previously diagnosed comorbidities and medications in our study sample, we will have trained our RA to review patient charts in a standardized manner.

Analysis: For all of our analyses, we will initially generate descriptive statistics (e.g., for continuous outcomes: mean, standard deviations, medians; for categorical outcomes, proportions and standard deviations) in each treatment group. Our initial analyses will be an unadjusted analysis to compare the outcome between the two treatment groups in an Intention-to-Treat analysis. We will then build multivariable models for each outcome, keeping in mind that, with a small sample size, we will have to limit the number of predictor variables. We will typically fit a model with variables of interest (including interactions) and then manually remove non-significant (p≤0.05) predictors, one at a time, with interactions being considered for removal first.

For the initial model for each outcome, we will include the study design predictors:

treatment group and anticoagulant stratification and, initially, the interaction of these two to determine if the treatment has a differential effect within either anticoagulant group. Building on the results of this initial model, we will then include covariates as a group, utilizing the manual step-down procedure described above. In general we will include all covariates mentioned in Table 2 except in cases where a certain covariate is not relevant -i.e. The model fit will be assessed by the standard R^2 for continuous outcomes and generalized R^2 (coefficient of determination) for binary outcomes. For logistic models, we will also use the -2 log likelihood statistic (and its adjusted forms).

Sample size: We aim to recruit 100 patients in each arm. Based on data from the Worcester VTE study, we estimate more than 500 patients discharged over 15 months from UMass Memorial which would require a 40% participation rate. We believe that we can achieve this level of participation given that research staff will be approaching the patient in the hospital and able to interview the patient without typical constraints of interviewing patients in ambulatory care settings or over the phone.

For the primary outcome, CTM-15, we assume a mean of 74.7 and s.d. of 16.2 (from TRACE-CORE at one month post discharge) in the usual care group. To be conservative, we will also assume a somewhat higher standard deviation in the intervention group (20% higher, or s.d. = 19.7) for a two-sided two-sample t-test with unequal variances at alpha=0.05. With these parameters, with 100 patients in each group, we will have 80% power to detect a difference of 7.2 in the mean CMT-15 score between the two groups. Although there is little published about the magnitude of a clinically important difference, a difference of 7 points on this measure correlated with fewer adverse events for elders recently discharged from the hospital.[33]

Data and Safety Monitoring Plan Organization: The DSMB will consist of three experienced external investigators, including clinicians and a biostatistician/epidemiologist, to exercise oversight of the safety of trial participants and of the conduct of the study. The board will be appointed by the study investigators with approval from the IRB. It will review periodic safety reports prepared by the trial biostatistician, request additional data/information (if necessary), and advise the trial leadership regarding continuation/discontinuation of the study. In the event of an adverse effect, from disease or drug, the clinical presentation will be immediately reviewed by the study leadership. Management will be chosen on the basis of the collective clinical decision-making of the investigators and the other physicians involved in the patient's care.

Method and Timing: All fatal events, unanticipated problems and other serious adverse events and suspected adverse reactions will be reported to the Data Safety Monitoring Board (DSMB) and IRB by secure email **within 24 hours of first knowledge of the event**.

Evaluation:

Determination of practice gap achieved: We will have addressed our practice gap if the CTM-15 is significantly higher for the intervention patients. In particular, if patients report having better understanding of side effects we anticipate scoring better in the intervention group. In addition we will have addressed the gap if intervention patients report higher knowledge about medications and VTE, medication adherence higher, health-related quality of life change score is higher, and time in the therapeutic range longer in the intervention group compared with the control group. We also hope that the recurrent VTE and hemorrhage, all-cause readmissions,

and mortality rates are lower although we do not anticipate having sample size to demonstrate this.

Data Sources for evaluation: Tracking of outcomes with chart review and direct telephone inquiry with the patient/survey as specified in the Methods section above.

Data collection and analysis for evaluation: Chart review and direct inquiry again.

Control for bias: The randomized controlled trial design we have chosen accounts for other factors outside of this project. In addition, we will perform multivariable regression on our primary outcome controlling for covariates which are confounders of the associations we find.

Amount of change expected: given that there has not been a previous investigation of this type of multicomponent intervention using the CTM-15 it is unclear the exact amount of improvement. Our original gap analysis indicated that patients at UMass report not receiving sufficient information about medication side effects. Given the number of touches we provide with clinical pharmacists, we anticipate at least 10% increase (i.e. 7 points) in the score on the care transitions measure. Given that our intervention targets the patient at the time of discharge, in the home and in the clinic with pharmacy and nursing expertise and attention, we believe our intervention participants will favorably review their experience.

Engagement of target audience: *Staff engagement:* We will assess the extent of engagement for anticoagulation team nurses and pharmacists by tracking participation in specific study activities, including consultation totals for each pharmacist, attendance at monthly research meetings for nurses and pharmacists, and other monthly contributions which we will log in a separate REDcap database. The form will include optional open-ended questions about barriers to full engagement, and recommendations for adaptations to study procedures. The form will be designed to take $\leq$ 3 minutes to complete.

Patient engagement: We will assess patient engagement through recruitment rates (i.e., percentage of eligible patients approached for participation who agreed to participate), study completion rates (i.e., percentage of enrolled patients who completed the study, excluding those who died or suffered readmission. We will also examine the number of intervention patients who had a home visit, those who scheduled a home visit but did not complete it, and those who did not schedule or complete a home visit. In a follow-up phone call at 30 days and 90 days we will also record patient views on the illustrated medication instructions.

Dissemination of project outcomes: We will disseminate project outcomes at major professional meetings and in scholarly journals. More specifically, the principal investigator will present his findings at the annual meetings for the Society of Hospital Medicine and the American Hospitals Association. Similarly we will submit articles to the Journal of Hospital Medicine as well as health services journals for cardiovascular outcomes, Circulation: Cardiovascular Quality Outcomes. We will also post our findings online through Dr. Kapoor's personal webpage at UMass as well as on the North American Thrombosis Forum webpage.[34]

C3. Workplan and Deliverables: The deliverables include training documents and data collection forms that precede actual results published in conference proceedings and scientific journals. In particular we anticipate having one publication for the primary with secondary, major outcomes and another based on the secondary, other outcomes.

Figure 2 - Workplan and Deliverables

	Year 1				Year 2			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

Task	1	2	3	4	5	6	7	8	9
IRB, Hiring	▓								
Training staff , database construction, pictogram development		▓							
Deliverable: sample pictograms for hypothetical patients		▓							
Deliverable: staff script for approaching patients		▓							
Deliverable: REDcap database blank form		▓							
Patient recruitment			▓	▓	▓	▓	▓		
Analysis			▓	▓	▓	▓	▓		
Interim analysis: descriptive statistics, bivariate results						▓			
Deliverable: final analysis								▓	
Deliverable: podium or poster presentation SHM, AHA								▓	
Manuscripts 1 and 2									▓

Strengths and limitations: The strength of our proposal is the number of settings in which we intervene on the patient's behalf - hospital, time of discharge, clinic, and home. We also incorporate several innovations including coordination of care by anticoagulation provider, illustrated medication instructions, pharmacist home visits, and expansion of current scope with anticoagulation nurse supervision of warfarin use alone to nurse supervision of all anticoagulants. Finally the team that will conduct the proposed research brings together expertise in hospital, cardiovascular medicine and epidemiology, patient communication and clinical trial design, and pharmacist home visits.

We also have several limitations. We don't have sufficient sample size to detect important differences in our secondary major outcomes. We therefore have chosen the CTM-15 as our primary measure. Although there has been no formal study linking change in CTM-15 and reduction in our secondary major outcome endpoints, change in CTM of the magnitude for which we have powered our study has previously been shown to correlate with prevention of other adverse events occurring after the time of discharge.[33] Moreover, the constructs that the CTM-15 attempts to measure including information transfer, preparation of patient and caregiver, support for self-management, and empowerment have strong face validity to predict our outcomes after discharge.

Our intervention also may not generalize to other settings. We propose empowering a nurse working in an academic hospital-based anticoagulation clinic as an anticoagulation care team leader. In other settings, a community based PCP or cardiologist may deliver this care. These latter clinicians may not be able to devote the same level of attention as we anticipate from our nurses. Similarly, outcomes achieved by our inpatient and home pharmacist who are affiliated with our academic medical center may not resemble those which can be achieved by other providers. We hope to investigate the role of hospital type (academic versus nonacademic) in our future efforts.

References

1.   The Joint Commission. High-Alert Medications and Patient Safety. 1999;
        http://www.jointcommission.org/assets/1/18/SEA_11.pdf.
2.   Huang W, Goldberg RJ, Anderson FA, Kiefe CI, Spencer FA. Secular trends in
        occurrence of acute venous thromboembolism: the Worcester VTE study (1985-2009).
        American Journal of Medicine. Sep;127(9):829-839.e825.
3.   The Joint Commission. 2014 National Patient Safety Goals. 2014;
        http://www.jointcommission.org/assets/1/6/ncc_npsg_chapter_2014.pdf.
4.   Budnitz DS, Shehab N, Kegler SR, Richards CL. Medication use leading to emergency
        department visits for adverse drug events in older adults.[Summary for patients in Ann
        Intern Med. 2007 Dec 4;147(11):I24; PMID: 18056655]. *Annals of internal medicine.*
        Dec 4 2007;147(11):755-765.
5.   Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health
        communication: a review of research on attention, comprehension, recall, and adherence.
        Patient Education & Counseling. May 2006;61(2):173-190.
6.   Katz MG, Kripalani S, Weiss BD. Use of pictorial aids in medication instructions: a
        review of the literature. *American Journal of Health-System Pharmacy.* Dec 1
        2006;63(23):2391-2397.
7.   Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to
        decrease rehospitalization: a randomized trial. *Annals of internal medicine.* Feb 3
        2009;150(3):178-187.
8.   Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically
        important medication errors after hospital discharge: a randomized trial. *Annals of
        internal medicine.* Jul 3 2012;157(1):1-10.
9.   Walsh KE, Stille CJ, Mazor KM, Gurwtiz JH. Advances in Patient Safety: New
        Directions and Alternative Approaches. In: Henriksen K, Battles JB, Keyes MA, eds.
        Using Home Visits to Understand Medication Errors in Children. Vol 4. Rockville, MD:
        Agency for Healthcare Research and Quality; 2008.
10.   US Department of Health and Human Services. National Action Plan for Adverse Drug
        Event Prevention. 2014; http://www.health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf.
        Accessed July 8, 2015.
11.   Munoz FJ, Mismetti P, Poggio R, et al. Clinical outcome of patients with upper-extremity
        deep vein thrombosis: results from the RIETE Registry. *Chest.* Jan 2008;133(1):143-148.
12.   Joffe HV, Kucher N, Tapson VF, Goldhaber SZ. Upper-extremity deep vein thrombosis:
        a prospective registry of 592 patients. *Circulation.* Sep 21 2004;110(12):1605-1611.
13.   QxMD Software Inc. CHA2DS2-VASc Score Calculator.
        http://www.qxmd.com/calculate-online/cardiology/cha2ds2-vasc-stroke-risk-in-atrial-
        fibrillation.
14.   *Statistical Analysis Software (SAS) 9.3* [computer program]. Cary, North Carolina2011.
15.   (FIP) IPF. Development, references and publications. 2014;
        http://www.fip.org/pictograms.
16.   National Committee for Quality Assurance. NCQA Patient-Centered Medical Home.
        http://www.ncqa.org/Portals/0/PCMH%20brochure-web.pdf.
17.   Alok Kapoor. Show Back: A Partnership with the VNA Care Network to Improve on the
        Teach Back Paradigm When Assessing Older Adult Medication Self-Management. 2014.

18.   Schulman S, Kearon C. Definition of major bleeding in clinical investigations of antihemostatic medicinal products in non-surgical patients. *Journal of thrombosis and haemostasis : JTH.* Apr 2005;3(4):692-694.

19.   Schulman S, Angeras U, Bergqvist D, Eriksson B, Lassen MR, Fisher W. Definition of major bleeding in clinical investigations of antihemostatic medicinal products in surgical patients. *Journal of thrombosis and haemostasis : JTH.* Jan 2010;8(1):202-204.

20.   Dugan E, Trachtenberg F, Hall MA. Development of abbreviated measures to assess patient trust in a physician, a health insurer, and the medical profession. *BMC health services research.* 2005;5:64.

21.   Centers for Medicare and Medicaid. The HCAHPS Survey - Frequently Asked Questions. 2015; http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/downloads/HospitalHCAHPSFactSheet201007.pdf.

22.   Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *Journal of the American Geriatrics Society.* Nov 2004;52(11):1817-1825.

23.   Mazor KM, Baril J, Dugan E, Spencer F, Burgwinkle P, Gurwitz JH. Patient education about anticoagulant medication: is narrative evidence or statistical evidence more effective? *Patient education and counseling.* Dec 2007;69(1-3):145-157.

24.   Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health services research.* Dec 2005;40(6 Pt 1):1918-1930.

25.   U.S. Department of Veterans Affairs. Pharmacy Benefits Management Services, VA National Formulary. 2015; http://www.pbm.va.gov/nationalformulary.asp.

26.   Powers BJ, Trinh JV, Bosworth HB. Can this patient read and understand written health information? *Jama.* Jul 7 2010;304(1):76-84.

27.   Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine.* Sep 2001;16(9):606-613.

28.   SF-12v2 Health Survey. https://www.optum.com/optum-outcomes/what-we-do/health-surveys/sf-12v2-health-survey.html.

29.   Dose Response. http://doseresponse.com/.

30.   Rosendaal FR, Cannegieter SC, van der Meer FJ, Briet E. A method to determine the optimal intensity of oral anticoagulant therapy. *Thrombosis and haemostasis.* Mar 1 1993;69(3):236-239.

31.   Veeger NJ, Piersma-Wichers M, Tijssen JG, Hillege HL, van der Meer J. Individual time within target range in patients treated with vitamin K antagonists: main determinant of quality of anticoagulation and predictor of clinical outcome. A retrospective study of 2300 consecutive patients with venous thromboembolism. *Br J Haematol.* Feb 2005;128(4):513-519.

32.   Oake N, Jennings A, Forster AJ, Fergusson D, Doucette S, van Walraven C. Anticoagulation intensity and outcomes among patients prescribed oral anticoagulant therapy: a systematic review and meta-analysis. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne.* Jul 29 2008;179(3):235-244.

33.   Hung WW, Ross JS, Farber J, Siu AL. Evaluation of the Mobile Acute Care of the Elderly (MACE) service. *JAMA internal medicine.* Jun 10 2013;173(11):990-996.

34.   North American Thrombosis Forum. http://www.natfonline.org/patients/support-group/online-support-group/.
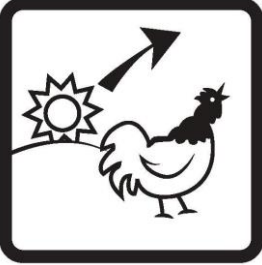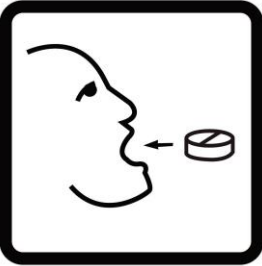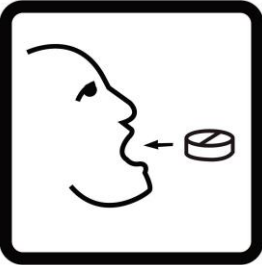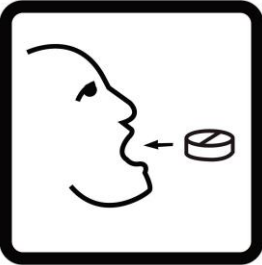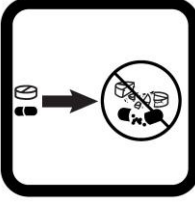
35.   Anticoagulation Forum. Examples of Excellence. 2014;
http://excellence.acforum.org/?page=examples_of_excellence.

36.   Kapoor A, Labonte AJ, Winter MR, et al. Risk of venous thromboembolism after total
hip and knee replacement in older adults with comorbidity and co-occurring
comorbidities in the Nationwide Inpatient Sample (2003-2006). *BMC geriatrics.*
2010;10:63.

37.   Kapoor A, Chew P, Silliman RA, et al. Venous Thromboembolism After Joint
Replacement in Older Male Veterans with Comorbidity. *Journal of the American
Geriatrics Society* 2013; n/a-n/a. Available at: http://dx.doi.org/10.1111/jgs.12161.

38.   Kapoor A, Chuang W, Radhakrishnan N, et al. Cost effectiveness of venous
thromboembolism pharmacological prophylaxis in total hip and knee replacement: a
systematic review. *PharmacoEconomics.* 2010;28(7):521-538.

39.   Cook NL, Bonds DE, Kiefe CI, et al. Centers for cardiovascular outcomes research:
defining a collaborative vision. *Circulation. Cardiovascular quality and outcomes.* Mar 1
2013;6(2):223-228.

8. Hanchate AD, Lasser KE, **Kapoor A**, et al. Massachusetts reform and disparities in inpatient care utilization. *Med Care.* Jul 2012;50(7):569-577**.**

9. Cook NL, Bonds DE, Kiefe CI, Curtis JP, Krumholz HM, Kressin NR, Peterson ED; National Heart, Lung, and Blood Institute Centers for Cardiovascular Research (CCOR) Writing Group. Circ Cardiovasc Qual Outcomes. 2013 Mar 1;6(2):223-8. doi: 10.1161/CIRCOUTCOMES.0b013e31828e8d5c. Epub 2013 Mar 12.

10. **Kapoor A,** Chew P, Silliman RA, et al. Venous Thromboembolism After Joint Replacement in Older Male Veterans with Comorbidity. *Journal of the American Geriatrics Society.* 2013.

11. Freund KM, Isabelle AP, Hanchate AD, et al. The impact of health insurance reform on insurance instability. *Journal of Health Care for the Poor & Underserved.*25(1 Suppl):95-108.

12. **Kapoor A**, Battaglia TA, Isabelle AP, et al. The Impact of Insurance Coverage during Insurance Reform on Diagnostic Resolution of Cancer Screening Abnormalities. *Journal of Health Care for the Poor & Underserved.*25(1 Suppl):109-121.
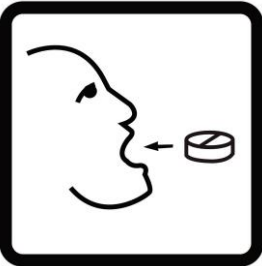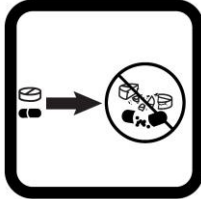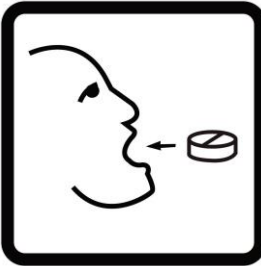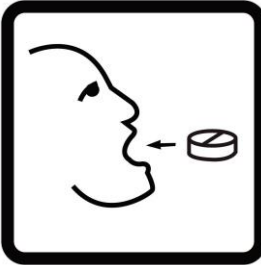
Appendix 1 Illustrated Discharge Medication Instructions

Date:

Patient's ID:	Morning	Noon	Evening	Night	Precautions
Amlodipine 5mg	1 tablet				Take with water
Celexa 20mg	1 tablet				Take with water
Metoprolol XL 100mg	1 tablet				Take with water Do not crush

Omeprazole 20mg	1 tablet				Take with water Do not crush
Simvastatin 20mg				1 tablet	Take with water
Warfarin 5mg				1 tablet	Take with water

Appendix 2: Medication Management Assessment Scorecard

Study ID _____

Medication Information		Patient Task Domains Scoring: • 1 – Proficient • 0 – Not Proficient • X – Not observed (N/A)					
Medication Type (Circle one)	**Medication Name, Dose, and Schedule**	**Identification**[*]	**Explanation**[**]	**Organization**[†]	**Administration**[***,^]	**Timing**	**Comments**
Pill Inject pre-filled Inject not pre-filled Inhaler/nebulizer							
Pill Inject pre-filled Inject not pre-filled Inhaler/nebulizer							
Pill Inject pre-filled Inject not pre-filled Inhaler/nebulizer							
Pill Inject pre-filled Inject not pre-filled Inhaler/nebulizer							
Pill Inject pre-filled Inject not pre-filled Inhaler/nebulizer							

[*]   Patient can actually correctly identify the medication among all set of meds in possession. Also includes identifying duplicate medication.
[**]   Patient can identify the purpose of the medication
[***]   Includes splitting medication and opening pill bottle or removing medication from blister pack, cleaning site and injecting at the correct angle for subcutaneous injection, correct timing with breathing, breath hold, exhalation and then subsequent inhalation if indicated.
[^]   Pills without special instructions should be marked as "X"
[†]   Only for patients who use pillboxes, all others should be marked as "X"

Appendix 3: Outcome Questionnaires

Care Transition Measure (CTM)-15

Patient Name: _____   Date:_____

Who completed interview?   ___ Patient   ___ Caregiver

The first few statements are about the time you were in the hospital…

1. Before I left the hospital, the staff and I agreed about clear health goals for me and how these would be reached.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

2. The hospital staff took my preferences and those of my family or caregiver into account in deciding **what** my health care needs would be when I left the hospital.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

3. The hospital staff took my preferences and those of my family or caregiver into account in deciding **where** my health care needs would be met when I left the hospital.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

The next set of statements are about when you were preparing to leave the hospital…

4. When I left the hospital, I had all the information I needed to be able to take care of myself.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

5. When I left the hospital, I clearly understood how to manage my health.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

6. When I left the hospital, I clearly understood the warning signs and symptoms I should watch for to monitor my health condition.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

7. When I left the hospital, I had a readable and easily understood written plan that described how all of my health care needs were going to be met.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

8. When I left the hospital, I had a good understanding of my health condition and what makes it better or worse.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

9. When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

10. When I left the hospital, I was confident that I knew what to do to manage my health.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

11. When I left the hospital, I was confident I could actually do the things I needed to do to take care of my health.

Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**	**Don't Know/ Don't Remember/Not Applicable**

The next statement is about your follow-up doctors' appointments…

12. When I left the hospital, I had a readable and easily understood written list of the appointments or tests I needed to complete within the next several weeks.

Strongly Disagree   **Disagree**   **Agree**   **Strongly Agree**   **Don't Know/ Don't Remember/Not Applicable**

The next set of statements is about your medications…

13. When I left the hospital, I clearly understood the **_purpose_** for taking each of my medications.

Strongly Disagree   **Disagree**   **Agree**   **Strongly Agree**   **Don't Know/ Don't Remember/Not Applicable**

14. When I left the hospital, I clearly understood **_how_** to take each of my medications, including how much I should take and when.

Strongly Disagree   **Disagree**   **Agree**   **Strongly Agree**   **Don't Know/ Don't Remember/Not Applicable**

15. When I left the hospital, I clearly understood the possible **_side effects_** of each of my medications.

Strongly Disagree   **Disagree**   **Agree**   **Strongly Agree**   **Don't Know/ Don't Remember/Not Applicable**

Short Form-12 Version 2

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

---

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
b Climbing <u>several</u> flights of stairs	☐	☐	☐

---

3. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	Yes	No
a <u>Accomplished less</u> than you would like	☐	☐
b Were limited in the <u>kind</u> of work or other activities	☐	☐

4. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

		Yes	No
a	<u>Accomplished less</u> than you would like	☐	☐
b	Did work or other activities <u>less carefully than usual</u>	☐	☐

5. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

6. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the <u>past 4 weeks</u>...

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
b	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐

c   Have you felt downhearted and blue?   ☐   ☐   ☐   ☐   ☐   ☐

---

7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

Attitude toward Anticoagulation Team

For the next few questions, tell me whether you strongly agree, agree, disagree, strongly disagree or are neutral with each statement.

Trust in physicians

1. **Sometimes doctors care more about what is convenient for them than about their patient's medical needs. Would you say that you…**
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree, OR
   - ☐ Strongly disagree

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

2. **Doctors are extremely thorough and careful. Would you say…**
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree, OR
   - ☐ Strongly disagree

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

3. **You completely trust doctors' decisions about which medical treatments are best. Would you say…**
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree, OR
   - ☐ Strongly disagree

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

4. **Doctors are totally honest in telling their patients about all of the different treatment options available for their conditions. Would you say…**
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree, OR

☐ Strongly disagree

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

5. **All in all, you trust doctors completely. Would you say…**
   ☐ Strongly agree
   ☐ Agree
   ☐ Neutral
   ☐ Disagree, OR
   ☐ Strongly disagree

   ☐ DON'T KNOW [DO NOT READ]
   ☐ REFUSED [DO NOT READ]

Warfarin Knowledge Questionnaire

(from Mazor *Patient Education and Counseling* 69 (2007) 145–157)

Below are a number of questions about your views on warfarin therapy. Some questions are factual. Most people will not know the answer to at least some of these questions. If you are not sure of your answer, please mark "I don't know".

Note: warfarin is also known as Coumadin; both refer to the exact same medicine.

Why do you take warfarin?

I take warfarin…	Yes ▼	No ▼	I Don't Know ▼
to treat high blood pressure.	Y	N	DK
because I have an artificial heart valve	Y	N	DK
to treat osteoporosis.	Y	N	DK
to prevent blood clots.	Y	N	DK
because I have heart disease.	Y	N	DK
because I have arthritis.	Y	N	DK
because I have an irregular heart rhythm.	Y	N	DK
to prevent stroke.	Y	N	DK
because I have high blood sugar.	Y	N	DK
because I have (or had) a blood clot.	Y	N	DK

For each of the following medicines, mark whether you think it could cause a problem if you started, stopped, or changed your dose of that medicine while taking warfarin.	Yes, might cause a problem ▼	No, probably wouldn't cause a problem ▼	I Don't Know ▼
Antacids (Tums…).. Y .... DK	Y	N	
Beta blockers (Lopressor, Toprol, Atenolol...) .... Y .... DK	Y	N	
Diuretics (Lasix, Hydrochlorothiazide(HCTZ)...) .... Y .... DK	Y	N	
Acetamenophen (Tylenol)... Y .... DK	Y	N	
Anti-depressants (Prozac, Paxil, Zoloft...) .... Y .... DK	Y	N	
Statins (Lipitor, Zocor, Prevachol...)... Y .... DK	Y	N	
Aspirin .... Y .... DK	Y	N	
Antibiotics (Bactrim, Flagyl, Amoxicillin, Keflex…).................. Y .... DK	Y	N	
Steroids (Prednisone, Hydrocortisone...).. Y .... DK	Y	N	

For each of the following foods and drinks, mark whether you think it could cause a problem if you started, stopped, or changed how much you ate/drank while taking warfarin.

	Yes, might cause a problem ▼	No, probably wouldn't cause a problem ▼	I Don't Know ▼
Beer/Wine	Y	N	
....	DK		
Bran cereals	Y	N	
....	DK		
Dried fruits	Y	N	
....	DK		
Coffee (with caffeine)..	Y	N	
....	DK		
Dairy products	Y	N	
....	DK		
Green leafy vegetables..	Y	N	
....	DK		
Green tea	Y	N	
....	DK		
Hard liquor (like whiskey, gin, vodka...)	Y	N	
....	DK		

ease mark whether each statement is true or false.

I Don't

	True ▼	False ▼	Know ▼

Too little warfarin in my blood could cause me to…

become forgetful. ....T   F
.... DK

have a stroke..T   F
.... DK

lose weight. ....T   F
....DK

Too much warfarin in my blood could cause…

me to bruise easily. ....T   F
....DK

me to feel dizzy. ....T   F
.... DK

me to have a stroke. ....T   F
.... DK

my stomach to bleed. ....T   F
.... DK

I should call the anticoagulation clinic if I …

notice any unexplained bruising..T   F
.... DK

have a loss of appetite...T   F
.... DK

have a severe headache..T   F
.... DK

have a cut that won't stop bleeding. ....T   F
.... DK

have constipation...T   F
.... DK

notice blood in my urine/stool ....T   F

.... DK

Taking my warfarin exactly as prescribed is...	Strongly Agree ▼	Agree ▼	Neutral ▼	Disagree ▼	Strongly Disagree ▼
Easy	SA	A	N	D	SD
Confusing	SA	A	N	D	SD
Inconvenient	SA	A	N	D	SD
Expensive	SA	A	N	D	SD
Important	SA	A	N	D	SD

Getting my blood tested is…					
Easy	SA	A	N	D	SD
Confusing	SA	A	N	D	SD
Inconvenient	SA	A	N	D	SD
Expensive	SA	A	N	D	SD
Important	SA	A	N	D	SD

Please mark whether you agree or disagree with the following statements:	Strongly Agree ▼	Agree ▼	Neutral ▼	Disagree ▼	Strongly Disagree ▼

I sometimes take a little extra warfarin when I

feel it's too low. .... SA   A   N   D   SD

I worry about my health more since I started

    taking warfarin. .... SA   A   N   D   SD

I don't always mention to the nurses if I've made

    mistakes taking my warfarin. .... SA   A   N   D   SD

Missing a lab appointment once in a while is not

    a big deal. .... SA   A   N   D   SD

I sometimes worry a bit about the side effects of

    taking warfarin. .... SA   A   N   D   SD

Taking warfarin is important to keeping me
    healthy. .... SA   A   N   D   SD

Taking warfarin prevents me from doing some

    things I like to do. .... SA   A   N   D   SD

If the doctor recommended that I get my blood

    tested every day, I would do it. .... SA   A   N   D   SD

	Strongly Agree ▼	Agree ▼	Neutral ▼	Disagree ▼	Strongly Disagree ▼
I sometimes skip a dose of warfarin because I feel better without it.	SA	A	N	D	SD
Often things come up that are more important to me than getting my blood tested.	SA	A	N	D	SD
I feel that warfarin is really a good medicine for me	SA	A	N	D	SD

If the doctor recommended that I get my blood

    tested every week, I would do it. .... SA   A   N   D   SD

Sometimes I get confused about how much

    warfarin I should take.. SA   A   N   D   SD

I feel better now than I did before I started on

    warfarin. .... SA   A   N   D   SD

I rarely have side effects from taking medicines. .... SA   A   N   D   SD

I always tell the clinic nurses when there are

    changes in any of my other medicines................................ SA   A   N   D   SD

Taking a medicine for months or years is not

    good for you.. .... SA   A   N   D   SD

The nurses at the clinic think getting my blood

    tested is much more important than I do .... SA   A   N   D   SD

Some days I can't remember whether I've already

    taken my warfarin. .... SA   A   N   D   SD

I dislike taking any medicines .... SA   A   N   D   SD

If I miss lab appointments I am taking a chance

    with my health.. SA   A   N   D   SD

I have to be a lot more careful about what I do

    since I started taking warfarin.. SA   A   N   D   SD

I'm more sensitive than most people in how I

    react to medicines... SA   A   N   D   SD

I worry about my health less since I started

    taking warfarin. .... SA   A   N   D   SD

I can tell if my warfarin is at the right level by

how I feel .... SA   A   N   D   SD

I would never miss an appointment to get my

    blood tested except in an emergency .... SA   A   N   D   SD

I wish I didn't need to take any medicine .... SA   A   N   D   SD

	Strongly Agree ▼	Agree ▼	Uncertain ▼	Disagree ▼	Strongly Disagree ▼
My health, at present, depends on warfarin.	SA	A	U	D	SD
Having to take warfarin worries me.	SA	A	U	D	SD
My life would be impossible without warfarin	SA	A	U	D	SD
Without warfarin I would be very ill	SA	A	U	D	SD
I sometimes worry about the long-term effects of warfarin	SA	A	U	D	SD
Warfarin is a mystery to me	SA	A	U	D	SD
My health in the future will depend on warfarin	SA	A	U	D	SD
Warfarin disrupts my life	SA	A	U	D	SD

Please tell us a little about yourself:

Are you male or female?

What is your age now?
- ❑ 18-24 years
- ❑ 25-34 years
- ❑ 35-44 years

- ❏ Male
- ❏ Female

How would you describe yourself?
- ❏ American Indian or Alaska Native
- ❏ Asian
- ❏ Black or African American
- ❏ Hispanic or Latino
- ❏ Native Hawaiian or Pacific Islander
- ❏ White
- ❏ Other _____

What is the highest grade or level of school that you have completed?
- ❏ 8th grade or less
- ❏ Some high school, but did not graduate
- ❏ High school graduate or GED
- ❏ Some college or 2 year degree
- ❏ 4 year college graduate
- ❏ More than 4 year college degree

- ❏ 45-54 years
- ❏ 55-64 years
- ❏ 65-74 years
- ❏ 75 years or older

In general, how would you rate your overall health now?

- ❏ Excellent
- ❏ Very Good
- ❏ Good
- ❏ Fair
- ❏ Poor

How do you usually take your warfarin?
- ❏ Exactly as prescribed.
- ❏ Mostly as prescribed, but sometimes I get confused or make mistakes.
- ❏ Mostly as prescribed, but sometimes I adjust how much or how often I take it.

What, if anything, makes it difficult for you to have your blood tested as often as you need to?

What would make it easier for you to have your blood tested as often as you need to?

Please feel free to comment, either about this study, or about warfarin therapy in general.

Appendix 4: Other Questionnaires

Demographics

1. Do you have any trouble seeing, even when wearing glasses or contact lenses?
- ☐ Yes
- ☐ No

- ☐ REFUSED [DO NOT READ]

2. Do you have any trouble hearing, even when wearing your hearing aid?
- ☐ Yes
- ☐ No

- ☐ REFUSED [DO NOT READ]

3. Do you consider yourself to be Hispanic or Latino?
- ☐ Yes
- ☐ No

- ☐ DON'T KNOW [DO NOT READ]
- ☐ REFUSED [DO NOT READ]

4. Which of the following best describes your racial background?
- ☐ Asian or Pacific Islander
- ☐ Black
- ☐ Native American or Alaska Native
- ☐ White
- ☐ More than one race

- ☐ DON'T KNOW [DO NOT READ]
- ☐ REFUSED [DO NOT READ]

5. What is the highest level or grade in school that you have completed? I will read you a list of possible choices.

- ☐ 8th grade or less
- ☐ More than 8th grade but less than high school graduate
- ☐ High School Graduate
- ☐ Post High School trade or technical school
- ☐ 1-3 years of college or junior college
- ☐ College graduate
- ☐ Some post graduate work
- ☐ Higher post graduate degree

- ☐ REFUSED [DO NOT READ]

6. What is your current marital status?
- ☐ Married or living as married
- ☐ Separated
- ☐ Widowed
- ☐ Divorced
- ☐ Single/Never married

- ☐ REFUSED [DO NOT READ]

7. What is your current living situation?
- ☐ Live alone
- ☐ Live with spouse
- ☐ Live with family other than spouse
- ☐ Live with people other than family members
- ☐ Live in a Nursing Home

- ☐ REFUSED [DO NOT READ]

8.   (if Q7 not equal 1, ask Q8) Including yourself, how many people live in your household?
_____

- ☐ REFUSED [DO NOT READ]

9. (select proper probing based on the answer of Role Functioning question 8) What is your current job [if retired or unemployed/laid off or unemployed/health reasons], use phrasing "the job you had for most of your life")? _____

- ☐ REFUSED [DO NOT READ]

10. What is your total annual household income (before taxes)?
- ☐ less than $10,000
- ☐ $10,000 to $19,999
- ☐ $20,000 to $34,999
- ☐ $35,000 to $49,999
- ☐ $50,000 to $74,999
- ☐ $75,000 to $99,999
- ☐ $100,000 to $149,999
- ☐ $150,000 or more

- ☐ DON'T KNOW [DO NOT READ]
- ☐ REFUSED [DO NOT READ]

Health literacy

1. **How confident are you filling out medical forms by yourself?**
   Would you say…[READ RESPONSES]
   ☐ Extremely
   ☐ Quite a bit
   ☐ Somewhat
   ☐ A little bit, OR
   ☐ Not at all

   ☐ DON'T KNOW [DO NOT READ]
   ☐ REFUSED [DO NOT READ]

For the next statement, please tell me if you strongly agree, agree, disagree, or strongly **disagree**

2. **I have a hard time understanding when people speak quickly.**
   ☐ Strongly agree
   ☐ Agree
   ☐ Disagree, OR
   ☐ Strongly disagree

   ☐ DON'T KNOW [DO NOT READ]
   ☐ REFUSED [DO NOT READ]

CAREGIVER Support

1. **Have you received assistance from one or more caregiver(s) in the past 4 weeks?**
   - ☐ Yes → Go to # 2 [PROMPT: A caregiver is someone who helps you with daily activities or with medications for pay or not
   - ☐ No → Go to # 3

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

2. **Was the assistance you received formal (paid help) or informal (unpaid help)**
   - ☐ Formal
   - ☐ Informal

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

3. **Was there any time in the past 4 weeks that you didn't get the caregiving support that you needed?**
   - ☐ Yes
   - ☐ No

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

Access to Health Care
---

1. **Is there a place that you <u>usually</u> go to when you are sick or need advice about your health?**
   - ☐ Yes [→go to 2]
   - ☐ There is <u>no</u> place [-> go to 3]
   - ☐ There is <u>more than one place</u> [-> go to 2a]

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

2. **What kind of place is it – a clinic, doctor's office, emergency room, or some other place?**
   - ☐ Clinic or health center
   - ☐ Doctor's office or HMO
   - ☐ Hospital emergency room
   - ☐ Hospital outpatient department
   - ☐ Some other place (specify) _____

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

   2a. What kind of place do you go most often – a clinic, doctor's office, emergency room, or some other place?
   - ☐ Clinic or health center
   - ☐ Doctor's office or HMO
   - ☐ Hospital emergency room
   - ☐ Hospital outpatient department
   - ☐ Some other place (specify) _____
   - ☐ Does not go to one place most often

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

3. **Overall, how difficult is it for you to get medical care when needed?**
   - ☐ Extremely difficult
   - ☐ Moderately difficult
   - ☐ Somewhat difficult
   - ☐ Not very difficult, OR
   - ☐ No problem at all

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

4. **In the past twelve months, have you avoided obtaining any health care services because of the cost?**
   - ☐ Yes
   - ☐ No

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

5. **During the past 12 months, have you had any problems paying medical bills?**
   - ☐ Yes

☐ No [→go to 6]

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

5a. Was the medical condition(s) or event(s) that caused the medical bills you had difficulty paying… ([READ ALL RESPONSES] **CODE ALL THAT APPLY)**
☐ An accident or injury
☐ An illness
☐ A medical test or surgical procedure
☐ A birth of a child
☐ Routine health care, OR
☐ Something else (SPECIFY)

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

6. In general, how do your finances usually work out at the end of the month? Do you usually end up with:
☐ Some money left over
☐ Just enough to make ends meet, OR
☐ Not enough to make ends meet

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

7. How do you <u>usually</u> get to the health care appointments?

a. Do you drive yourself in private vehicle (car, truck, motorcycle, etc.) ?
☐ Yes
☐ No

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

b. Does someone else drive you in a private vehicle [such as a car, truck, motorcycle, etc.] ?
☐ Yes
☐ No

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

c. Do you take public transportation?
☐ Yes
☐ No

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

d. Do you use paratransit services (such as dial-a-ride or medical taxi service)
☐ Yes
☐ No

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

e. OR, do you walk or bike

☐ Yes
☐ No

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

8. **Overall, and in terms of transportation, how difficult is it for you to get to your health care appointments?**
   ☐ Extremely difficult
   ☐ Moderately difficult
   ☐ Somewhat difficult
   ☐ Not very difficult, OR
   ☐ No problem at all

   ☐ DON'T KNOW [DO NOT READ]
   ☐ REFUSED [DO NOT READ]

9. **Within the past 12 months, have you missed a medical appointment or been unable to obtain needed health care because of problems with your transportation?**

   ☐ Yes
   ☐ No

   ☐ DON'T KNOW [DO NOT READ]
   ☐ REFUSED [DO NOT READ]

Next, I will read some statements that people sometimes make when they talk about their health. Please tell me whether you disagree strongly, disagree, agree, or agree strongly with each statement as it applies to you personally. Your answers should be what are true for you. If the statement does not apply to you, just let me know and we will move on to the next one. The first one is...

1. **When all is said and done, I am the person who is responsible for taking care of my health. Would you say…**
   - ☐ Disagree strongly
   - ☐ Disagree
   - ☐ Agree
   - ☐ Agree Strongly

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

2. **Taking an active role in my own health care is the most important thing that affects my health. Would you say…**
   - ☐ Disagree strongly
   - ☐ Disagree
   - ☐ Agree
   - ☐ Agree Strongly

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

3. **I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself. Would you say…**
   - ☐ Disagree strongly
   - ☐ Disagree
   - ☐ Agree
   - ☐ Agree Strongly

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

4. **I know what treatments are available for my health problems. Would you say…**
   - ☐ Disagree strongly
   - ☐ Disagree
   - ☐ Agree
   - ☐ Agree Strongly

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

5. **I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising. Would you say…**
   - ☐ Disagree strongly
   - ☐ Disagree

☐ Agree
☐ Agree Strongly

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

6. **I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress. Would you say…**
☐ Disagree strongly
☐ Disagree
☐ Agree
☐ Agree Strongly

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. **Little interest or pleasure in doing things. Would you say…**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

2. **Feeling down, depressed, or hopeless. Would you say …**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

3. **Trouble falling or staying asleep, or sleeping too much. Would you say…**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

4. **Feeling tired or having little energy. Would you say…**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

5. **Poor appetite or overeating. Would you say…**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

   - ☐ DON'T KNOW [DO NOT READ]
   - ☐ REFUSED [DO NOT READ]

6. **Feeling bad about yourself---or that you are a failure or have let yourself or your family down. Would you say...**
   - ☐ Not at all
   - ☐ Several days
   - ☐ More than half the days, OR
   - ☐ Nearly every day

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

7. **Trouble concentrating on things, such as reading the newspaper or watching television. Would you say…**
☐ Not at all
☐ Several days
☐ More than half the days, OR
☐ Nearly every day

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

8. **Moving or speaking so slowly that other people could have noticed. Or the opposite--- being so fidgety or restless that you have been moving around a lot more than usual. Would you say…**
☐ Not at all
☐ Several days
☐ More than half the days, OR
☐ Nearly every day

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

9. **Thoughts that you would be better off dead, or of hurting yourself in some way. Would you say…**
☐ Not at all
☐ Several days
☐ More than half the days, OR
☐ Nearly every day

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]

*** If answered anything except "Not at all" – notify patient's Resident after survey***

10. [If Q1-9 above > 0) **how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?**

☐ Not difficult at all
☐ Somewhat difficult
☐ Very difficult , OR
☐ Extremely difficult

☐ DON'T KNOW [DO NOT READ]
☐ REFUSED [DO NOT READ]