

**Rural Options at Discharge Model of Active Planning (ROADMAP):**

**Protocol and Statistical Analysis Plan**

## ***Methods***

### ***Settings***

This study was conducted in Montana, a state with a population of 989,417 people living on 145,546 square miles for an average density of 6.8 persons per square mile. St. Patrick Hospital (SPH) was the central site for this study. SPH, a member of the Providence Health and Services System, is a regional referral hospital (RRH) serving Western Montana and Eastern Idaho. SPH is located in Missoula, Montana, a city of 66,768 in a county of 109,299 people. SPH uses the Epic® electronic medical record system. This study focused on patients discharged from the RRH to one of four Montana counties served by critical access hospitals (CAH) that also used the Epic® electronic medical records system, including Beaverhead, Lake, Powell, and Sanders Counties.

The Montana Department of Public Health and Human Services designated all four of the counties involved in this study as rural counties (counties with less than 50 people per square mile). Furthermore, all four were non-metropolitan counties and three of the counties met the criteria of being a frontier county (population of less than 6 people per square mile). Travel time to Missoula from the principal town of the four counties ranged from 79 (76 miles) to 145 (172 miles) minutes. Portions of Lake and Sanders Counties are included in the Flathead Reservation, which is home to the Salish, Pend d'Oreille and Kootenai Tribes. Table 1 provides basic demographic data from the most recent U.S. Census for each of the four counties included in the present study.

**Table 1**  
**Characteristics of Geographic Area**

County	Beaverhead	Powell	Lake	Sanders
Land Area (sq. miles)	5,541	2,326	1,490	2,760
Population	9,246	7,027	28,746	11,413
Density/Sq. Mile	1.7	3.0	19.3	4.1
White	94.9%	92.4%	68.2%	92.1%
Native American	1.8%	4.6%	23.4%	4.3%
Hispanic or Latino	3.7%	2.3%	4.0%	2.6%
Households	4,110	2,411	11,829	5,149
Mean Number in Household	2.11	2.31	2.38	2.17
Median Household Income	\$41,614	\$40,802	\$38,019	\$32,881
Per Capita Income	22,872	\$19,736	\$21,521	\$19,188
Percent Below Poverty	15.1%	15.3%	22.4%	22.0
Principal City Population	4,134	3,111	4,488	1,313

### ***Patient Population***

All patients from these four selected counties admitted to SPH for treatment and at least one overnight stay during the period of October 19, 2015 through November 30, 2016 were eligible. Patients were included if they were being discharged home or to a swing-bed arrangement in their home county critical access hospital. Researchers excluded patients, if they were younger than 18 years old or older than 75 years old, were prisoners of the State correctional facility in Powell County, came from or were being discharged to a nursing home or other long-term care facility, were admitted with a primary diagnosis of a psychiatric impairment or substance abuse, were actively dying, or presented cognitive impairments that would significantly limit their ability to consent or to complete the measurement instruments (Flesch-Kincaid Reading Level = 7.5). Figure 1 presents a patient flow diagram.

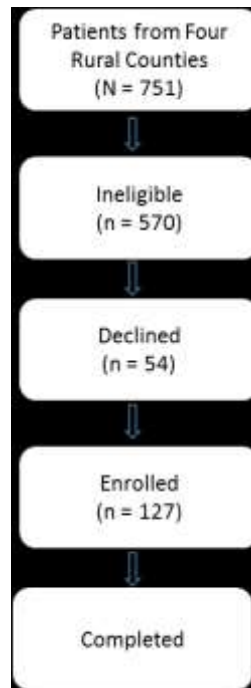


Figure 1: Patient flow diagram of the ROADMAP study.

**Enrollment.** A Research Transitions Coordinator (RTC) received a daily report of patients admitted into SPH. She reviewed the report to identify eligible patients. Based on the review, she developed a list of eligible patients. She then reviewed the list to identify patients who met any of the exclusion criteria; this produced a list of patients who met inclusion criteria to recruit into the study. Next, the RTC went to each patient's room to explain the study, to identify any additional factors that might exclude the patient, and to determine a patient's willingness to participate. If a patient met inclusion criteria and expressed interest, the RTC reviewed the informed consent material and enrolled the patient.

The RTCs screened 751 patients from the four counties. Of those, 570 patients were excluded as ineligible based on exclusion criteria, 54 who met the inclusion criteria declined to participate in the study, and 127 enrolled in the study. Table 2 presents demographic information of participants by experimental condition as required by ClinicalTrials.gov.

Table 2

## Demographic Characteristics of Study Sample Required for Clinical Trials

	Baseline A	Intervention	Baseline B	Totals
Enrolled	63	50	14	127
Completed	62	47	13	122
Lost to Follow-up	1	3	1	5
Under 18 Years of Age	0	0	0	0
Between 18 and 65	37	26	10	73
Over 65	26	24	4	54
Female	28	21	6	55
Male	35	29	8	72
American Indian, Alaskan	5	6	2	13
Asian	0	0	0	0
Hawaiian or Islander	1	0	0	1
Black or African American	0	0	0	0
White	56	43	11	110
More than one race	0	0	0	0
Unknown or Not Reported	1	1	1	3
<b>Subtotal</b>	<b>63</b>	<b>50</b>	<b>14</b>	<b>127</b>
Hispanic or Latino	0	0	0	0
Not Hispanic or Latino	61	47	11	119
Unknown or Not Reported	2	3	3	8
<b>Subtotal</b>	<b>63</b>	<b>50</b>	<b>14</b>	<b>127</b>

In addition, Table 3 presents the number of patients excluded by criterion and Table 4 shows the number of patient enrolled in the study from each county by experimental condition.

**Table 3**

**Number of Patients Excluded by Criteria**

Exclusion Criteria	Number of Patients
Age	242
Not an Inpatient	41
Substance Abuse – Mental Illness	65
Prisoner	29
Extended Care Facility	12
Not Going Home	26
Extended Observation	28
Cognitive Impairment	24
Actively Dying	16
Other	65
<b>Total</b>	<b>570</b>

Table 4  
Participants by County

	Baseline	Intervention	Baseline	Total
Sanders	10	21	4	35
Beaverhead	8	8	0	16
Powell	11	6	2	19
Lake	34	15	8	57
Total	63	50	14	127

### ***Procedures***

SPH's established discharge planning procedures and practices served as the standard comparator. From the patient's perspective, this involved three elements, including verification of financial means, discharge planning, and patient instructions. Generally, patients who lacked health insurance or other means for paying medical and hospital costs were "flagged" at admission. This alerted the Medical Assistance Program (MAP). Staff from MAP went to the patient's room to discuss options and outline a plan for payment. For example, a MAP staff member might work with a patient to enroll in Medicaid so that his or her costs might be covered. Six Discharge Planners (DP) served patients in the hospital. When a Discharge Planner initiated work with a patient, she reviewed the patient's file to determine what treatment the patient was to receive and examined any history that may be relevant to recovery. Next, the DP typically visited the patient in the hospital room to assess the patient's situation. This included determining if the patient had a place to go after treatment (e.g., home, shelter, etc.) and if they had someone to provide transportation there when discharged. Depending on the patient's situation, the DP might consult with the patient's physicians, nurses, or other care providers, and might work to arrange transportation or temporary shelter. The DP entered findings and actions into the patient's EPIC file. Finally, treatment staff used information in EPIC to prepare an After Visit Summary (AVS) for the patient that included a description of the patient's treatment, a list of medications and instructions for their use, and patient educational

materials about the treatment and self-care. Depending on the patient's condition and treatment, the AVS might include a follow-up referral (and sometimes a scheduled appointment for the patient). Finally, the AVS was given to the patient when they left the hospital. All patients enrolled in the study received these standard services.

**Enhanced discharge and rural transition planning.** Researchers engaged patients and other stakeholders in a structured process of contextual assessment and innovation to develop an Enhanced Discharge and Rural Transition model, protocol, and procedures (separate manuscript that can be cited). Figure 2 outlines the components of both the standard practice and the enhanced model. Researchers added 11 components to the standard practices, including: a Rural Transitions Needs Assessment, a resource bank for each rural community linked to categories of the needs assessment, a Patient Transition Agenda, an electronic episode of care in Epic® to support patient transition, patient-centered communication procedures between SPH staff and Local Community Transition Coordinators (LCTC), a discharge orders verification procedure, a transitions planning protocol, transitions follow-up procedures, a long-range goals assessment also linked to community resources, communication procedures to alert the patient's PCP of their hospitalization and transition home, and a coordination mechanism between LCTCs at the CAHs and the Research Discharge Coordinators at the RRH to facilitate teamwork.



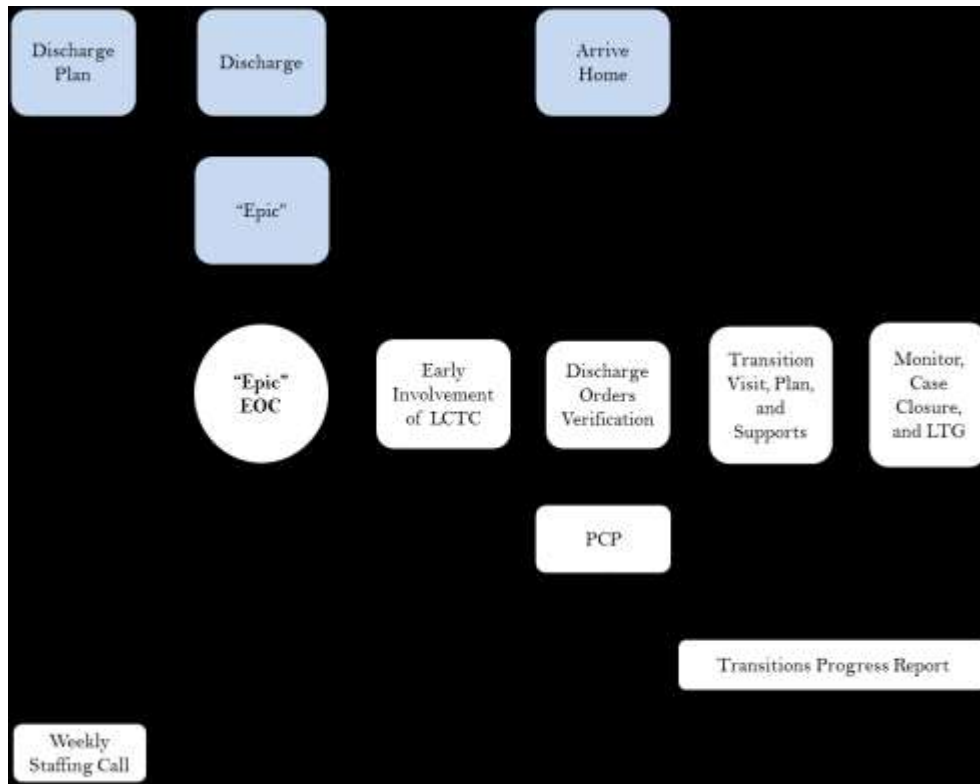


Figure 2: Tentative model describing the Enhanced Discharge and Rural Transitions Process. The shaded boxes at the top of the figure represent the standard practice. The open boxes at the bottom represent the experimental procedures. All patients received the standard procedures. Patients in the experimental conditions also received the enhanced procedures.

In general, the enhanced model was based on the existing discharge planning protocol but extended it by creating new roles and functions that focused on addressing patient needs that might interfere with recovery at home. Procedurally, a Research Transitions Coordinator located at the regional referral hospital used a tablet computer to conduct a Rural Transitions Needs Assessment with a patient. The patient's identified needs were linked to services and supports listed in a Community Resource Bank. Together, these formed a patient's Transition Agenda. The RTC posted the Agenda in an Episode of Care (EOC) tab in Epic®.

The RTC then notified the LCTC in the patient's home community that SPH had admitted and was treating a patient from their community. The LCTC reviewed the Transition Agenda and prepared for the patient's return to the community. Once home, the LCTC contacted the patient to check on his or her status, and to work with the patient to develop and execute a Rural Transition Plan.

**Needs Assessment and patient transitions agenda.** The RTC reviewed the Epic® medical record for patients meeting inclusion criteria to familiarize herself with the patient’s situation before visiting them in their room. For patients in the intervention condition, once a patient was enrolled in the study, the RTC worked with the patient (and caregivers as deemed appropriate by the patient) to complete a structured Rural Transitions Needs Assessment using an electronic tablet to rate his or her confidence in their ability to meet each of 18 transition needs (e.g., housing, groceries and meals, medications, self-care, etc.). The RTC read an item from a tablet computer screen and asked the patient to rate it. Then the RTC recorded the patient’s rating by checking the relevant box. These rating were stored electronically in the tablet. The assessment was structured to provide brief educational information about the need and asked the patient to rate their confidence in meeting the need on a scale of "0" to "4," where "0" meant not confident and "4" meant very confident. A patient could also rate the need as not applicable (NA). Figure 3 presents an example of two such items.

	Not Confident		Very Confident			NA
A safe and comfortable place to live contributes to your healing and recovery. How confident are you that you have a safe and comfortable place to live when you leave the hospital?	0	1	2	3	4	<input type="checkbox"/>
You should eat a healthy diet to provide the nutrients your body needs to heal. You may need someone to help you get groceries or prepare meals for a while. How confident are you that you have someone you can count on to help you get groceries and prepare meals when you get home?	0	1	2	3	4	<input type="checkbox"/>

Figure 3: Sample of items from the Rural Transition Needs Assessment and rating scale.

Items rated "2" or less were treated as potential patient needs. If a patient rated an item as "2" or less, the RTC would ask, “Can you tell me a bit more about this?” She would record responses as additional information. If a patient rated an item as 3 or higher (or NA) but that rating seemed incongruent with information learned from the file review or discussion with the patient, the RTC would ask, “Can you tell me more about how you will meet that

need?” This prompt sometimes led to a change in rating. Again, these explanatory responses were recorded as additional information. LCTCs used this additional information in preparing the draft Transitions Plan.

The patient’s endorsed needs were linked to a database of resources, the Local Resource Bank, known to provide services and supports in identified areas of need. Together, the needs and linked services created a patient Transition Agenda (PTA). Figure 4 shows a sample Patient Transition Agenda.



Figure 4: A screen shot of a patient's Transition Agenda listing services available in his hometown that he could use to address each identified need in the areas of medication, home modifications, and rehabilitation services.

**Electronic Episode of Care.** The RTC posted the patient's Transitions Agenda in the EOC tab in Epic® and notified (via EPIC® in-basket email and phone) the LCTC serving the county to which the patient was scheduled to return that a patient from the county was being treated at SPH and provided an estimated date of discharge. This early involvement, a component insisted on by the key stakeholders from the CAHs, allowed the LCTC to review a patient's treatment, risk factors, likely needs, and available resources to meet those needs while the patient was still in the hospital. In addition, the LCTC reviewed the patient’s AVS in EPIC and prepared a Discharge Orders Verification Checklist that listed orders and recommendations for the patient's recovery at home (e.g., medications, oxygen orders, etc.).

**Verifying discharge orders and scheduling a Transitions Conference.** Once discharged home (or to a swing bed placement), the LCTC contacted the patient to check on his or her status and to schedule a Transition Conference. The LCTC used the brief Discharge Orders Checklist to review the status of each discharge order with a patient. This was completed simply by asking the patient to indicate that an order had been implemented or not. If the checklist revealed any immediate gaps in implementation, the LCTC could take action to help the patient address any obstacles in securing the services. If no immediate gaps were identified, the LCTC scheduled a Transitions Conference with the patient. Then, the LCTC notified the patient's primary care provider (PCP) that one of their patients had been treated at SPH, had enrolled in the Enhanced Discharge and Rural Transitions study, and provided directions for locating the patient's Episode of Care tab in Epic<sup>®</sup>.

**Patient Transitions Conference.** The Patient Transition Conference involved the LCTC meeting with the patient in their home to review the Transitions Agenda and develop a Transitions Plan. While the preferred setting for the Transitions Conference was the patient's home, this meeting could also take place at the local CAH or even over the phone. Meeting at the patient's home was preferred because it was seen as helping the LCTC to understand a patient better and thought to lead to recognition of needs not previously identified. It was also seen as helping the LCTC judge what types of supports are most likely to fit the patient's context; thus, be more likely to be followed by the patient and caregivers. Furthermore, the Patient Design Team unanimously and strongly encouraged its inclusion in the model.

**Patient Centered Transitions Plan and Supports.** During the Transitions Conference, the LCTC reviewed the patient's Transition Agenda with the patient. She confirmed the identified needs, dropped ones that the patient felt no longer applied, and added any that had emerged from the patient's experience in returning home. Together, they reviewed the patient's personal resources (e.g., family, friends, etc.) and services available locally to address the needs, considered their utility and acceptability for the patient, and developed a plan for securing needed supports. The steps were recorded in a Transition Plan form that listed the need discussed, the services chosen, and the person responsible for executing each element of the plan (e.g., patient to call senior center to arrange transportation).

In general, the LCTC provided support to the patient for up to 30 days but could extend support for up to 90 days. During that time, the LCTC completed the steps to which she had committed and monitored the patient's progress in achieving other objectives. Progress was recorded in the Episode of Care. After 30 days, the LCTC discussed closing the case with the patient. If the patient agreed, the LCTC discussed a patient's long-range goals and together they identified other community supports that the patient might find useful in achieving any related objectives. The LCTC prepared a case summary letter that was sent to the patient, posted in the Episode of Care, and sent to the patient's PCP.

***Instructional manual, orientation and training.*** Researchers developed a written manual using a behavioral instructional format (e.g., Merkel, 1980) to orient and train all staff involved in the project. This involved conducting a detailed task analysis to specify the major jobs and tasks required to implement and maintain the experimental procedures. Each job was further analyzed into its component steps. Researchers prepared behavioral instructions that described each step. These instructions also presented examples of how to perform each step and explained the function or outcomes associated with completing each step.

Staff serving as RTCs and LCTCs read the manual and participated in a day-long orientation and training session to review and discuss the procedures. In addition, SPH Information Technology staff trained all research staff in the use of Epic® and the newly created Episode of Care component. Finally, the RTCs and LCTCs participated in weekly teleconferences during which they discussed the program's implementation.

### ***Design***

We used a quasi-experimental time series design with switching replications (Cook & Campbell, 1984). This design involved starting enrolled patients from each of the four counties in a baseline condition. Then, once a stable rate of enrollment had been reached, the introduction of the experimental procedures was staggered across patients from each county over time. That is, all patients from one county were enrolled into the intervention while those from the other counties remained in baseline. Later, patients from a second and third county were added to the intervention condition while those from the remaining county remained in baseline; and so on. Finally, a return to baseline condition was initiated for patients from all

four counties. This design protects against most threats to the internal validity of findings and many threats to their external validity. It is particularly helpful in protecting against threats posed by seasonal variables. A final "return to baseline" phase was also included in the study to add to protections from threats posed by interactions.

**Baseline and experimental conditions.** Patients in baseline conditions received the standard discharge services. Patients enrolled in the experimental condition received the standard discharge services and the Enhanced Discharge Planning and Rural Transition Supports.

**Measures.** All patients completed the PAM10 (Hibbard & Mahoney, 2005) and provided selected demographic information at the time of enrollment. Other demographic information was collected from each enrolled patient's medical record. In addition, we collected the LACE+ rating from the medical record and the rating of needs from our Rural Transition Needs Assessment. The LACE+ is a compilation of medical and treatment factors (e.g., chronic conditions, previous hospitalizations) derived from a patient's medical record that are used to assess risk for re-hospitalization (van Walraven, Wong, & Forster, 2012).

Researchers prepared an evaluation package that included the three-item Care Transition Measure (Coleman, Mahoney, & Parry, 2005), the 12 item Short Form of the Medical Outcome Study (Stewart and Ware, 1992), and a Rural Transitions Measure (RTM14; Montana Team, 2016). The RTM14 asked patients to report whether they strongly agree, agree, disagree, or strongly disagree with each of 14 statements reflecting services provided after discharge to facilitate an effective transition home. Researchers also asked patients to report the number of times that they had seen a PCP, visited an emergency department of any hospital, been admitted to SPH, or been admitted to any other hospital since they were discharged or since their last report.

**Data collection.** We asked patients to complete the instruments in the evaluation package at 3, 7, 14, 21, 30, 60, and 90 days after they were discharged from the RRH. RTCs gave patients the 3 and 7 day evaluation packages in the RRH to complete at home. The research staff mailed the remainder of the evaluation packages to patients three days before the end of each measurement period. Each evaluation package included an instrument and a

self-addressed stamped envelope for returning a completed questionnaire. In addition, the first six instruments included a \$10 honoraria and the last packet included a \$40 honoraria.

Finally, we used information in the Epic® patient records to collect demographic data and information on emergency department visits, outpatient admissions, and hospitalizations at the participating hospitals. Finally, RTCs and LCTC kept notes detailing the patient situation and experiences that were posted in the EOC tab in Epic®.

### ***Statistical Analysis Plan***

The primary hypotheses address the question of whether the intervention makes a difference in the frequency of hospitalizations and emergency department visits. There are at least two ways to view the measurement of these outcomes. The first is to examine the total number of hospital or emergency department visits in each condition. The second is to examine the proportion of patients who have at least one hospital or emergency department visits in each condition.

In addition, there are several intermediary outcomes we anticipate. These relate to the physical and mental health of patients, the rating of the quality of discharge planning services, and the rating of the delivery of rural transition services. We will test the following hypotheses using specified procedures:

#### 1) Hospital re-admissions

##### a) Number of hospital admission

i) H0i: There is no difference in the cumulative number of hospital admissions for day i (null hypothesis); H1i: The cumulative number of hospital admissions for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .

ii) We will assess the groups for differences using Poisson regression model.

##### b) Proportion of patients with at least one hospital admission

i) H0i: There is no difference in the proportion of patients who report a hospital readmission for day i (null hypothesis); H1i: The proportion of patients who report a hospital readmission for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .

- ii) We will assess the groups for differences using logistic regression.
- 2) Emergency department visits
- a) Number of emergency department visits
    - i) H0i: There is no difference in the cumulative number of ED visits for day i (null hypothesis); H1i: The cumulative number of ED visits for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .
    - ii) We will assess the groups for differences using Poisson regression model.
  - b) Proportion of emergency department visits
    - i) H1i: The proportion of patients who report at least one ED visits for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .
    - ii) We will assess the groups for differences using logistic regression model.
- 3) Primary care provider (PCP) visits
- a) Number of PCP visits
    - i) H0i: There is no difference in the cumulative number of PCP visits for day i (null hypothesis); H1i: The cumulative number of PCP visits for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .
    - ii) We will assess the groups for differences using Poisson regression model.
  - b) Proportion of PCP visits
    - i) H0i: There is no difference in the proportion of patients who report at least one PCP visits for day i (null hypothesis); H1i: The proportion of patients who report at least one PCP visits for the standard discharge group is greater than that for the enhanced discharge group; for days  $i = 3, 7, 14, 21, 30, 60, 90$ .
    - ii) We will assess the groups for differences using logistic regression model.
- 4) Physical health as measured by the Short Form (SF12) functional health score



- a) Hoi: There is no difference in mean SF-12 Physical Health scores between the standard and enhanced discharge groups (null hypothesis); H1i: The mean SF-12 Physical Health scores differ between the standard and enhanced discharge groups.
  - b) We will use a repeated measures ANOVA model (over the 7 time periods) to model the SF-12 Physical Health score as a function of treatment group.
- 5) Mental Health as measured by the Short Form (SF12) Mental Health Score
- a) Hoi: There is no difference in mean SF-12 Mental Health scores between the standard and enhanced discharge groups (null hypothesis); H1i: The mean SF-12 Mental Health scores differ between the standard and enhanced discharge groups.
  - b) We will use a repeated measures ANOVA model (over the 7 time periods) to model the SF-12 Mental Health score as a function of treatment group.
- 6) Care Transition Measure (CTM3) of discharge coordination services
- a) Hoi: There is no difference in mean CTM3 scores between the standard and enhanced discharge groups (null hypothesis); H1i: The mean CTM3 scores differ between the standard and enhanced discharge groups.
  - b) We will use a repeated measures ANOVA model (one time period at 3 days post discharge) to model to assess these hypotheses.
- 7) Rural Transition Measure (RTM14) of the delivery of transition services and supports
- a) H0: There is no difference in the mean RTM14 score between the standard and enhanced discharge groups (null hypothesis); H1: Patients in the enhanced discharge group will have a higher mean RTM14 rating than patients in the standard discharge group.
  - b) We will use a repeated measures ANOVA model (over the 6 time periods) to model the RTM14 score as a function of treatment group.

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