High Tech and High Touch (HT2): Transforming patient engagement throughout the continuum of care by engaging patients with portal technology at the bedside

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Statistical Analysis Plan

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Version 3.0 (April 8, 2021)	Updated to reflect request from external reviewer to include sensitivity analysis.
Version 3.1 (November 7, 2023)	Updated to correct randomization and factor protocol deviations within analytic populations.

Table of Contents

Section 1: Statistical analysis

1.1 Confidence intervals and p-values

For all statistical tests, a p-value of 0.05 was used to assess significance and 95% confidence intervals were reported. No adjustment was done for multiple hypothesis testing.

1.2 Missing data

All available data was used for the analysis. Missing data was treated as missing completely at random (MCAR). No imputation was used.

1.3 Statistical software

All analyses were conducted using Stata MP 14.2.

1.4 Assumptions and testing

1.4.1 Analysis populations

Estimates of the intervention effects were calculated on two analytic populations. The main analytic population of the study used an *intention-to-treat (ITT)* approach. Using this paradigm, participants were analyzed on the basis of the study group to which they were randomized, regardless of their eventual receipt of that intervention.

The effects of the intervention were additionally evaluated on a *per-protocol* population, composed exclusively by those participants who were administered their randomized intervention. The analysis of the data from the per-protocol population was weighted by the inverse of their probability to receive the intervention to which they were originally randomized, computed on the basis of the following demographic and clinical characteristics: sex, race, age at time of enrollment, Charlson Comorbidity Index, length of stay.

1.4.2 Analytic framework

A review of factorial randomized control trials identified that the appropriate analytics model, in general, would adhere to Equation 1 (see below), assuming that the basic functional form for regression is the appropriate approach. This approach was used per Montgomery et al.[1] Variations to this functional form are noted below.

Eq. 1: $$y = X_{Tech} + X_{Touch} + X_{Tech*Touch}$$

To address potential differences in variance associated with the multi-site and pragmatic aspects of the study (e.g., expansion of the study after it was originally conceptualized and operationalized, differences in policies and procedures across hospitals and units), we performed cluster-robust standard errors in the estimation of the outcomes.[2] The analysis clusters study participants by the hospital where the study participant was enrolled. To validate this assumption, a sensitivity analysis was performed on patients transferred to different hospitals within the medical center.

Further, to account for heterogeneity in duration of patient access to the inpatient portal, we included the length of tablet provisioning, measured in days, as an offset parameter in all models.

1.4.3 Sub-sample analysis

We performed sub-sample analysis on the study participants who received the Full-Tech intervention (see Equation 2). Instances where this sub-sample analysis was not conducted is noted in the description of that outcome.

Eq. 2: $$If\ X_{Tech} = Full;\ y = X_{Touch}$$

1.4.4 Distributional assumptions

Prior to analysis, we will conduct an examination of the data to assess model fit for each hypothesis (i.e., Poisson, Negative Binomial, etc.).[i]

[i] Preliminary analysis revealed wide variance in the length of time that patients had a tablet, which we termed 'provision length'. This provision length was included as an exposure in the model fitting process. Analysis after data collection suggested that the ANOVA model was a poor choice for the distribution of the data. Poisson models were excluded because of the foundational assumption–namely that the mean and variance of the response variable are the same. In the data, the variance was significantly greater than the mean, leading this model to significantly underestimate true variability in the data. Subsequent outlier analysis suggested no improvement. The negative binomial model was specified four ways: (1) negative binomial; (2) negative binomial with the provision length adjustment; (3) zero truncated; (4) zero truncated with the provision length adjustment. The zero truncated model with length of provision as an exposure variable provided the best relative fit when comparing information criteria values. However, this improvement was viewed as marginal relative to the negative binomial model specification. For this reason and to account for the heterogeneity in provision length, all count outcomes were fit using a negative binomial model with the provision length adjustment.

1.4.5 Defining MyChart Bedside use sessions

A new MyChart Bedside use session was identified in the log files in two ways: (1) a "identify user with lock" action; or (2) any user action that occurred more than 15 minutes after the previous action. Some session periods contained no active tasks as defined in Section 6.3.5 in the Final Protocol. These inactive sessions were dropped from analyses. The "identify user with lock" action that marked the beginning of a session sometimes occurred multiple times sequentially without any other actions occurring. Retaining these recurring actions would create sessions with only a login action. To eliminate this problem, sequential "identify user with lock" actions were dropped.

1.4.6 Defining MyChart use sessions

MyChart log files contained timestamped records of patient actions on the outpatient portal. This data was processed to obtain information about the number of sessions associated with each unique study participant. For MyChart, a session was defined by a sequence of actions linked to a patient's medical record number (MRN), with the first action typically being a 'login' and the last one a 'logout'. In the case of MyChart sessions, at times patients did not actively logout of the application. Using the protocol described by Huerta, et al.,[3] we imposed a limit of 22 minutes as the length of time a patient was allowed to stay inactive before a 'logout' was imputed into the data. All actions occurring after the time limit were considered part of a new session. Additionally, sessions of length zero were discarded from the dataset.

1.4.7 Scaling analysis for Likert items

For Likert scale survey items, each survey item was modeled using one of three approaches:

1. An ordinary least squares (OLS) linear regression model with each Likert scale response treated as a continuous variable;
2. A logistic regression model with the Likert scale dichotomized to two "positive" responses versus three "not positive" responses; and
3. A logistic regression model with the Likert scale dichotomized to one "most positive" response versus all other responses.

The OLS model was assumed to be the most parsimonious model, making it the default model choice. However, OLS model assumptions were tested to confirm that this choice was appropriate. Between the two logistic models, Model #3 was considered to be the more restrictive model choice and thus provided a more conservative estimate of the effect of the study on the outcome. Model choices are specified below in relation to each outcome.

1.4.8 Cutoff date determination

Two options were considered for both the pre-study enrollment and post-discharge cutoff dates as specified in subsequent sections: 90 days (approximately three months) and 180 days (approximately six months) before/after the hospital encounter in which an individual was enrolled in the study. The actual cutoff date was determined after examining the cumulative distribution of MyChart adoption over the course of the year preceding/following hospital discharge to identify a meaningful endpoint.[ii]

1.4.9 Facility Transfer Sensitivity Analysis

Baseline characteristics were summarized, including age (median), gender (male, female percentages), race (White, Black, Other percentages), length of stay (days), and the Charlson comorbidity index (median, treated as a continuous score). Baseline characteristics were compared using analysis of variance (ANOVA) or t-tests, as appropriate, to examine equivalence between the four study arms and the impact on the model estimates for patients who were transferred between facilities was negligible.

1.5 Hypothesis 1: Inpatient portal use

H1: Individuals assigned to the High intervention levels for Tech and Touch will demonstrate higher use of MyChart Bedside.

We operationalized higher use in this hypothesis in three ways:

1. Frequency of use
2. Comprehensive use

1.5.1 Outcome 1 – Number of MyChart Bedside sessions within the enrollment admission was dependent on treatment

Dependent variable specification: The count of MyChart Bedside sessions for the admission associated with study enrollment.

- Enrollment admission was defined as the admission when the patient was enrolled in the study.

Statistical model: Negative binomial model with non-interacted and interacted study arms as binomial predictors.

[ii] Preliminary analysis of adoption rates for the outpatient portal revealed a rapid decrease in the numbers following the first few months, which motivated us to set the value for the cutoff date at 90 days in order to more conservatively attribute portal use to an individual's participation in the study.

Covariates: No covariates were added to this analysis.

1.5.2 Outcome 2 – Comprehensive use was dependent on treatment

Dependent variable specification: A binary variable identifying participants that used all available functions based on their Tech arm assignment (1 = comprehensive functions user; 0 = not a comprehensive functions user).

- The definition of "comprehensiveness" was tested in two different ways:
    - **Definition 1: Based on use of all available functions**: Users were considered comprehensive functions users when they reached a threshold number of functions used based on their Tech Arm. For Lite-Tech users, this threshold was three selectable functions available–Bedside Tutorial, Dining on Demand, and To Learn. For Full-Tech users, this threshold was eight of the 10 functions available, including the three functions available to Lite-Tech users.
    - **Definition 2: Based on use of the functions available to all users**: Users were considered comprehensive functions users when they used the three functions that were available to all users.

Statistical model: Logistic regression model with non-interacted and interacted study arms as binomial predictors.

Covariates: No covariates were added to this analysis.

1.5.3 Outcome 3 – MyChart Bedside use (by function) was dependent on Touch arm.

Sub-sample specification: As a function of the hypothesis and outcome specification, this analysis was not subject to sub-sample analysis as described in section 1.4.2. This analysis only used the Full-Tech arms, and therefore only used the Touch predictor in the statistical model.

Outcome specification: Proportion of total use, calculated for each user by dividing the sum of actions in a given function from the total sum of user actions during their enrollment admission accounted for by each function.

Statistical model: For each function, a fractional logistic regression model was performed, with use proportion as the response variable and Touch status as the explanatory variable.

Covariates: No covariates were added to this analysis.

1.6 Hypothesis 2: Patient satisfaction and involvement

H2: Individuals assigned to the High intervention levels for Tech and Touch will demonstrate higher levels of satisfaction with (H2a) and involvement in (H2b) their care experience.

Questions from the satisfaction and experience domains of the Admission, 15-day, and 6-month Post-discharge surveys were used to test H2. Below we describe the specific questions that were included in these analyses and how these outcomes were specified and tested.

1.6.1 Outcome 1 – Patient satisfaction was dependent on treatment

Outcome specification: Variations of this outcome were available in each survey. The following 5-point Likert scale survey items were explored as individual items dichotomized to one "most positive" response versus all other responses:

- **15-day Post-discharge survey:** In your most recent hospital experience, how satisfied were you with the interactions you had with your healthcare professionals?
- **15-day Post-discharge survey:** In your most recent hospital experience, how satisfied were you with how well your healthcare professionals responded to your concerns?
- **6-month Post-discharge survey:** In the past six months, how satisfied were you with the interactions you had with your healthcare professionals?
- **6-month Post-discharge survey:** In the past six months, how satisfied were you with how well your healthcare professionals responded to your concerns?

Statistical Model: Logistic regression models with and without an interaction of Tech and Touch were reported.

Covariates: The corresponding survey item from the Admission Survey was used as a covariate for the items listed above. The two relevant survey items were:

- **Admission survey:** In the past 12 months, how satisfied were you with the interactions you had with your healthcare professional?
- **Admission survey:** In the past 12 months, how satisfied were you with how well your healthcare professionals responded to your concerns?

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

1.6.2a Outcome 2a – Patient involvement was dependent on treatment

Outcome specification: In the 15-day Post-discharge survey, the following 5-point Likert scale survey items were explored as individual items dichotomized to one “most positive” response versus all other responses:

- **15-day Post-discharge survey:** All of my questions about managing my health, including my medications, were addressed before I left the hospital.

Statistical Model: Logistic regression models with and without an interaction of Tech and Touch were reported.

Covariates: No covariates were added to this analysis.

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

1.6.2b Outcome 2b – Patient involvement was dependent on treatment

Outcome specification: In the 15-day Post-discharge survey, a binary variable identifying whether the participant marked the item:

- **15-day Post-discharge survey:** If you had a question about your care while you were in the hospital, what steps did you take to find an answer? (mark all that apply)
    - I asked my doctor
    - I asked a nurse
    - I asked another hospital staff member
    - I searched online
    - Other
    - I did not have questions

- **15-day Post-discharge survey:** What kinds of activities did you use the tablet for? (mark all that apply)

    - Email
    - Research health issues
    - Social media
    - Watch movies/ TV
    - Communicate with my family
    - Play games
    - MyChart Bedside
    - None of the above

Statistical Model: Logistic regression models with and without an interaction of Tech and Touch were reported.

Covariates: No covariates were added to this analysis.

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

1.7 Hypothesis 3: Outpatient portal adoption and use

H3: Individuals assigned to the High intervention levels for Tech and Touch will demonstrate higher rates of outpatient portal adoption (i.e., of Epic's MyChart) for those admitted without prior outpatient portal use (H3a), and higher use of MyChart for those admitted who had previously used the outpatient portal (H3b).

MyChart adoption was inferred by evidence of use of the application and timed around the first recorded session for each individual. Study participants were classified into one of four groups, based on the presence of non-zero length sessions associated with the participant's usage of MyChart prior to enrollment in the study.

- **Group 1 – Prior MyChart User**: A record of MyChart sessions prior to study enrollment.
- **Group 2 – New MyChart User**: No record of MyChart sessions prior to study enrollment and a record of subsequent MyChart use within the cutoff period.
- **Group 3 – Never MyChart User**: No record of MyChart sessions prior to study enrollment and no record of subsequent MyChart use within the cutoff period.

MyChart frequency of use indicated the number of MyChart sessions (see section 1.4.5.) on record for a given study participant. The number of MyChart sessions that occurred before the cutoff date (see section 1.4.7) was used to quantify MyChart frequency of use.

1.7.1 Outcome 1 – MyChart adoption among participants without outpatient portal usage prior to enrollment was dependent on treatment

Outcome specification: A categorical variable identified whether the participants used the portal before the end of the cutoff period (1 = Admission New User or Post-Discharge New User; 0 = Never MyChart User). Prior MyChart Users were not included in the analysis for this outcome.

Statistical model: Logistic regression model with non-interacted and interacted study arms as binomial predictors.

Covariates: No covariates are added to this analysis.

1.7.2 Outcome 2 – MyChart adoption among participants without outpatient portal usage prior to discharge was dependent on treatment

Outcome specification: A categorical variable identified whether the participants used the portal before the end of the cutoff period (1 = Post-Discharge New User; 0 = Never MyChart User). Prior MyChart Users and Admission New Users were not included in the analysis for this outcome.

Statistical model: Logistic regression model with non-interacted and interacted study arms as binomial predictors.

Covariates: No covariates were added to this analysis.

1.7.3 Outcome 3 – MyChart adoption among participants who began using the outpatient portal during enrollment admission was dependent on treatment

Outcome specification: A categorical variable identified whether the participants used the portal before the end of the cutoff period (1 = Admission New User; 0 = Never MyChart User). Prior MyChart Users and Post-Discharge New Users were not included in the analysis for this outcome.

Statistical model: Logistic regression model with non-interacted and interacted study arms as binomial predictors.

Covariates: No covariates were added to this analysis.

1.7.4 Outcome 4 – Frequency of use for New MyChart Users.

Outcome specification: The count of MyChart sessions occurring between the date of enrollment in the study and the cutoff date. This variable was specified as a count variable. Prior MyChart Users and Never MyChart Users were not included in the analysis for this outcome.

Statistical model: Negative binomial regression model for counts of sessions with non-interacted and interacted study arms as binomial predictors (see Equation 3).

Equation 3: If New MyChart User=1; $y = X_{Tech} + X_{Touch} + X_{Tech*Touch}$

Covariates: No covariates were added to this analysis.

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

1.7.5 Outcome 5 – Frequency of use for Prior MyChart Users

Outcome specification: The count of MyChart sessions occurring between the date of enrollment in the study and the cutoff date. This variable was specified as a count variable. New MyChart Users and Never MyChart Users were not included in the analysis for this outcome.

Statistical model: Negative binomial regression model for counts of sessions with non-interacted and interacted study arms as binomial predictors (see Equation 4).

Equation 4: If Prior MyChart User =1; $y = X_{Tech} + X_{Touch} + X_{Tech*Touch}$

Covariates: The count of pre-enrollment sessions was included as a covariate in the model to control for previous use.

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

1.8 Hypothesis 4: Self-efficacy

H4: Individuals assigned to the High intervention levels for Tech and Touch will demonstrate higher levels of self-efficacy.

1.8.1 Outcome 1 – Self-efficacy

Outcome specification: The self-efficacy scale[4] was scored as the mean of six individual 5-point Likert scale survey items and was promulgated in each of the surveys (i.e. Admission, 15-day Post-discharge, 6-month Post-discharge). The six items were:

1. I am confident I can change my behaviors to improve my health.
2. I am confident that I can work with my provider to improve my health.
3. I am confident that if prescribed a new medication, I can take it appropriately.
4. I am confident that I can do the different tasks and activities needed to manage my health condition(s).
5. I am confident that I can keep symptoms or health problems from interfering with the things I want to do.
6. I am confident that I know how to take care of my health.

Statistical Model: OLS regression model with and without an interaction of Tech and Touch were reported.

Covariates: No covariates were added to this analysis.

Sub-sample analysis: No sub-sample analyses were considered for this outcome.

Section 2: Changes to the Statistical Analysis Plan

The original statistical analysis plan was specified based on assumptions about the data collection and distributions of the data, and was designed to be exploratory and flexible to account for violation of modeling assumptions. The final statistical analysis plan reflects a more detailed description of how the analyses were performed.

Section 3: References

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