Published in final edited form as:

Contemp Clin Trials. 2016 March ; 47: 165–171. doi:10.1016/j.cct.2016.01.005.

Engaging hospitalized patients in clinical care: Study protocol for a pragmatic randomized controlled trial

Ruth Masterson Creber[a], **Jennifer Prey**[b], **Beatriz Ryan**[c], **Irma Alarcon**[b], **Min Qian**[d], **Suzanne Bakken**[a], **Steven Feiner**[e], **George Hripcsak**[b], **Fernanda Polubriaginof**[b], **Susan Restaino**[f], **Rebecca Schnall**[a], **Philip Strong**[g], and **David Vawdrey**[c]

[a]Columbia University, School of Nursing, 617 W 168th St., New York, NY 10032, United States

[b]Department of Biomedical Informatics, 20, Presbyterian Building, 622 W 168th St., New York, NY 10032, United States

[c]The Value Institute at New York Presbyterian Hospital, 622 W 168th St., New York, NY 10032, United States

[d]Mailman School of Public Health, 722 W. 168th St. R645, New York, NY 10032, United States

[e]Department of Computer Science, Columbia University, 500 W. 120th St., 450 CS Building, New York, NY 10027, United States

[f]New York Presbyterian Hospital, 622 W 168th St. #137, New York, NY 10032, United States

[g]El Camino Hospital, 2500 Grant Rd., Mountain View, CA 94040, United States

Abstract

Background—Patients who are better informed and more engaged in their health care have higher satisfaction with health care and better health outcomes. While patient engagement has been a focus in the outpatient setting, strategies to engage inpatients in their care have not been well studied. We are undertaking a study to assess how patients' information needs during hospitalization can be addressed with health information technologies. To achieve this aim, we developed a personalized inpatient portal that allows patients to see who is on their care team, monitor their vital signs, review medications being administered, review current and historical lab and test results, confirm allergies, document pain scores and send questions and comments to inpatient care providers. The purpose of this paper is to describe the protocol for the study.

Methods/design—This pragmatic randomized controlled trial will enroll 426 inpatient cardiology patients at an urban academic medical center into one of three arms receiving: 1) usual care, 2) iPad with general internet access, or 3) iPad with access to the personalized inpatient portal. The primary outcome of this trial is patient engagement, which is measured through the

Correspondence to: Ruth Masterson Creber.

Authors' contributions

All members of the writing committee contributed to the study design and/or study recruitment and everyone critically revised this manuscript. DV, GH, SB, FS, SR, and RS participated in the study design. RMC and JP drafted the article. BR leads site management. BR and IA recruit study participants and organize study meetings. RMC, JP, MQ, IA, SB, SF, GH, FP, SR, BR, RS and DV participate in routine study meetings. MQ is conducting data management and statistical analyses. PS leads the West Coast hospital collaboration. All authors read, edited and approved the final manuscript.

Patient Activation Measure. To assess scalability and potential reach of the intervention, we are partnering with a West Coast community hospital to deploy the patient engagement technology in their environment with an additional 160 participants.

Conclusion—This study employs a pragmatic randomized control trial design to test whether a personalized inpatient portal will improve patient engagement. If the study is successful, continuing advances in mobile computing technology should make these types of interventions available in a variety of clinical care delivery settings.

Keywords

Patient-centered care; Randomized controlled trial; Pragmatic clinical trial; Patient engagement; Patient activation; Medical informatics; Inpatient portal

1. Introduction

Individuals who are better informed and more engaged in their health care have higher satisfaction with their health care and better health outcomes [1–7]. Interventions that provide patients with clinical information have been effective in promoting patient participation in health-related decision-making, reducing decisional conflict, and increasing patient adherence to their care plans [8–10]. Studies have shown that patients remember less than half of what physicians explain to them in the hospital [11,12], and they may be uncertain of what actions are required of them. A study by Cumbler et al. discovered considerable deficits in patients' understanding of their hospital medications, even among patients who believed they knew, or desired to know, what was administered to them in the hospital [13]. The Institute of Medicine recommends that health-care delivery should prioritize and respond to individual patient preferences, needs, and values, and that these values should guide all clinical decisions [14]. Nevertheless, patients' information needs and preferences are rarely prioritized or addressed by providers in the acute care environment [15–19]. Given the complexity of the inpatient environment, allowing patients to see their information may help them be more engaged in their care.

Advocacy for patients to review their medical records and even participate in writing clinical notes has been occurring since the 1970s [20–23]. Although the 1996 Health Insurance Portability and Accountability Act guaranteed patients' rights to review their health records [24], information access has been hindered by barriers such as time delays and photocopying costs.

Current Federal health information technology (HIT) initiatives, including Meaningful Use, incentivize providers to offer patients electronic access to their clinical records [25]. The growth of this sharing of information is slowly occurring, but has not been implemented on a widespread scale. Many institutions are implementing personal health records to provide access to certain clinical information [26,27]. In the OpenNotes initiative, patients were invited to read their doctors' office notes [28,29]. Nearly all patients and approximately three-fourths of participating primary care physicians felt that open visit notes were "a good idea" [29]. After a year long trial, 99% of patients wanted OpenNotes to continue, with 77%

stating that they felt more empowered by having access to their notes and 60% reporting improved medication adherence [30].

To date, few hospitals have focused on providing patients within the hospital access to their health records. Prior to beginning this trial, we completed three pilot studies involving providing hospital patients with access to their information [31–35]. In the first study, we provided clinical information on tablet computers to a small number of patients in order to inform the design process for the inpatient portal and have a better understanding of patients' information needs [31]. In the second study, we conducted interviews with patients after they used the tablet application to discover what features they liked and disliked, to inform the usability and design of software used in the randomized controlled trial (RCT) [32]. In the third study, patients received full access to a daily paper copy of their medical records while they were in the hospital [19]. Our current study design was developed based on the results of these pilot studies in the context of the framework that we developed focusing on HIT-enabled engagement [19]. The purpose of this paper is to provide an overview of the study protocol.

2. Materials and methods

2.1. Study design and specific aims

2.1.1. Study aims—The primary aim of this study is to evaluate the effect of a personalized inpatient portal intervention on patient engagement. The secondary aims are to characterize information needs of hospital patients, assess clinicians' attitudes toward patient engagement in the hospital setting, and evaluate the salience of patient-entered information to issues of care quality and safety. Additionally, we are assessing scalability and potential reach of the intervention by deploying the inpatient engagement technology in a community hospital on the West Coast.

2.1.2. Study design—The study is a pragmatic randomized controlled trial (RCT). We are recruiting 426 patients into three study arms, which receive: 1) usual care, 2) iPad with general Internet access, or 3) iPad with access to the personalized inpatient portal (see Fig. 1). Participants in Arm 1 (Usual Care) receive the hospital's standard admission packet and discharge instructions. Participants randomized to Arm 2 are given an iPad with general Internet access. Participants in Arm 3 receive an iPad with access to the personalized inpatient portal that is available in both English and Spanish. This health portal contains information relevant to the patient's hospital stay, sourced directly from the hospital's electronic health record (EHR), such as: names and photos of care team members, medications being administered, comprehensive medication information, documented allergies, diagnostic tests being performed, diet, vital signs, test and lab results (Table 1). In addition, the personalized inpatient portal offers patients the ability to enter comments and questions, as well as their pain level, all of which are visible to care providers in the handoff tab of the EHR.

The study protocol is registered with ClinicalTrials.gov (NCT01970852) and is being conducted in accordance with the principles outlined in the CONSORT 2010 Statement: Extension to Pragmatic Trials [36]. Pragmatic trials are designed to evaluate real-world

effectiveness of interventions in routine practice environments [37,38]. A pragmatic trial design was used in the current study to accommodate the rapidly changing nature of technology, both at a global level (i.e., rapid improvements in tablet technology) and at the local level (i.e., iterative enhancements and hospital-wide changes to the outpatient portal application). Unlike a strictly controlled pharmaceutical trial, participants in our study cannot be constrained to receive a controlled "dose" of the intervention. Out of necessity, participants, family members and clinicians are not blinded to the intervention, and we do not attempt to control patients' communication or information-seeking behaviors beyond the three-group randomization described above.

2.1.3. Recruitment—The inclusion criteria for the study are English- or Spanish-speaking individuals who are 18 years or older and are admitted as patients to one of two medical and surgical cardiac units at NewYork-Presbyterian Hospital/Columbia University Medical Center. Patients are screened for cognitive impairment using the Mini Mental Status Examination [39], and those scoring below nine on the exam are excluded from the trial. Patients are also excluded from participating if they are currently in a separate research study, unable to provide written informed consent, in contact isolation with an infectious disease or have been admitted to the hospital for more than two weeks.

2.1.4. Ethics and consent—The Columbia University Medical Center Institutional Review Board approved the study. Participants provide written informed consent prior to enrollment and all data-management procedures are conducted in accordance with national and state regulations and local policies and procedures.

2.1.5. Recruitment protocol—Potential participants are identified within the EHR based on the date of admission to one of the study units. Research coordinators invite participants to participate in the study as close to admission to the study unit as possible, usually within 1–2 days. There are generally two patients per room on the study units, and patient assignment to a room is based upon the unit census, as well as patient factors such as infection status (e.g., requiring isolation) and gender. When there are two patients in a room, the study is explained to each patient individually and they are both recruited to the same study arm. If the patient is interested, he/she provides written informed consent.

2.1.6. Randomization and blinding—The unit of randomization is by room in the cardiac units. Randomization based upon room assignment was done to minimize the potential for a crossover effect of the interventions among patients sharing a room. Patients, clinicians, and researchers are not blinded, due to the obvious nature of the intervention.

2.1.7. Personalized inpatient portal—Participants randomized to the intervention arms (2 and 3) are provided with an iPad for the duration of their length of their stay on the study unit. A brief training session is offered if the participant is not familiar with a tablet. All participants in these arms are given printed instructions describing the features and use of the iPad, as well as an iPad power cord. Participants are informed that tablet devices are connected to a secure network and can also be used to navigate the internet. Arm 2 participants are informed that websites such as WebMD and MayoClinic.org are available for their use if they desire; however, they are not given access to the personalized inpatient

portal. There are also games installed on the device for entertainment, and patients can access Netflix or other video streaming platforms if they have existing accounts.

Arm 3 participants are oriented to the personalized inpatient portal and a brief tutorial on available features is provided. Participants sign into the personalized inpatient portal using a username and password of their choice. If they forget their password they are prompted to generate a new one.

Participants in all three arms are visited each day by a member of the study team. During these visits, the research coordinator checks to see if participants in Arms 2 and 3 are having any issues with device usability (ie: password, username, network connection). For participants in the control group, the research coordinator checks to make sure they will not be discharged prior to the end of the study period. After participants complete the study, the iPads are thoroughly cleaned using tablet-friendly antibacterial wipes to ensure infection control between patient rooms.

2.1.8. Data collection and management—Research coordinators collect baseline and follow-up data 3 to 5 days later using survey instruments. Data are managed using Qualtrics Survey Software (Qualtrics, Provo, UT). Research coordinators are trained on the study protocol prior to interaction with participants. They are also introduced to front-line medical and nursing staff and familiarized with the floor plans and room randomizations. Research coordinators follow specific guidelines and checklists to ensure that all data are collected and managed in a consistent manner.

2.2. Measurements

2.2.1. Patient activation—At baseline and 3–5 days follow-up, we administer the Patient Activation Measure (PAM)-13 [40]. The PAM assesses the knowledge, skills and confidence essential to managing one's own health and healthcare [40]. The PAM-13 is a uni-dimensional, 13-item measure that reflects a developmental model of activation. The PAM-13 segments consumers into one of four progressively higher activation levels: 1) Disengaged and overwhelmed, 2) Becoming aware, but still struggling, 3) Taking action, or 4) Maintaining behaviors and pushing further. The PAM-13 has good psychometric properties [41–45] and has been validated in multiple outpatient settings. Tests of construct validity for the PAM-13 have strong associations with functional status (SF-36 [17] and SF-12 [18]). The PAM-13 score has been used to predict health-care outcomes including medication adherence, emergency room utilization and hospitalization [46–50]. A recent observational study of the PAM-13 found that levels were associated with many health outcomes including better clinical indicators, more healthy behaviors, and greater use of women's preventive screening tests, as well as with lower costs [51].

2.2.2. Patient survey—In addition to the PAM-13, we administer a Patient Survey that includes two scales that measure: 1) satisfaction with the hospitalization and perceived engagement with healthcare providers; and 2) perceived usefulness of the personalized inpatient portal. The perceived usefulness scale is administered only to patients in Arms 2 and 3 of the study (those who received tablet computers). The Patient Survey includes 21 items on satisfaction and engagement and 5 items on perceived usefulness. All questions are

measured on a 5-point Likert-type scale and both scales will be summarized as a mean score and standard deviation. The Patient Survey was derived from the 26-item Telemedicine Satisfaction and Usefulness Questionnaire [52]. The Telemedicine Satisfaction and Usefulness Questionnaire includes two sub-scales, satisfaction/engagement and usefulness, which have internal consistency reliabilities of 0.96 and 0.92, respectively [52].

The time that participants spend using the personalized inpatient portal application is quantified using system audit logs. We also measure usage of the hospital's outpatient portal at 30-days post-discharge (Table 2). At this time, we are not tracking the use of other medically related applications on the tablet computers.

2.2.3. Taxonomy of information needs—The personalized inpatient portal allows participants to record questions and comments that are visible to their care team in the EHR on the handoff tab. These messages will be analyzed to catalog and understand patient information and communication needs.

2.2.4. Clinician surveys—We are also administering a survey to assess clinicians' opinions about the personalized inpatient portal—whether they believe patient-entered questions and concerns are useful, and in what ways the application positively or negatively impacted their workflow and the care-delivery process. The survey was originally developed for the pilot study for this grant based on the Telemedicine Questionnaire and adapted for clinicians. The survey includes 21 items on "Satisfaction and Perceived Engagement," and 5 items on "Perceived Usefulness." All questions are measured on a 5-point Likert-type scale ranging from "Strongly disagree to Strongly agree." The survey also provides space for clinicians to enter comments, which are being explored through thematic analysis.

2.2.5. Covariate and clinical outcome measurements—At the time of enrollment, patients are asked to complete a questionnaire containing information on socioeconomic status, living situation, marital status, ethnicity, education level, health literacy and technology use. Health literacy is assessed using the simplified screening technique developed by Chew et al. [53]. This technique requires little time and compares favorably against the gold standard Short Test of Functional Health Literacy in Adults (area under the curve 0.87; 95% CI = 0.78–0.96) [53]. Technology-use questions ask whether the patient uses the Internet generally, for how long, and through which modes (e.g., laptop, smartphone, and tablet computer). The Charlson Comorbidity Index will be used as a measure of comorbidity. The score will be extracted from the EHR. We are also using the EHR to collect data on participant mortality, hospital readmissions and length of stay.

2.3. Statistical analysis

2.3.1. Sample size estimation—We hypothesized that the change in patient satisfaction between Arm 1 (usual care) and Arm 2 (with access to general consumer health information) would be one-half of the difference between the generic consumer health information and Arm 3 (personalized inpatient portal). In part, we based this assumption on a study measuring differences in patient satisfaction among patients using a tailored Internet-based tool for diabetes management compared with patients accessing general Internet resources

[54]. In that study, the satisfaction score was 4.9 out of 6 for the tailored group and 3.7 out of 6 for the generic group, with a pooled standard error of 1.56. For this study, we estimated that a sample size of 142 per arm was required to detect a difference in satisfaction of 0.6 [(4.9–3.7) / 2] (standard error of 1.56) with a power of 80% and a significance level (alpha) of 0.05/3 (using the Bonferroni method) [54]. With three arms in the proposed study, 426 total patients are required. Patients are randomized equally to the three arms. To date 140 participants have been recruited and are enrolled in the study between March 2014–January 2016.

2.3.2. Data analysis for RCT—Patients' baseline characteristics will be compared using Analysis of Variance (ANOVA) F-tests for continuous variables and Chi-squared tests for categorical variables among the three treatment arms. For the primary outcome, patient engagement, the change in PAM scores (from baseline to follow-up) will be calculated and compared using Kruskal–Wallis test across the three groups.

In Arm 3, we will describe the total time on the personalized inpatient portal per day (there is an auto log-off function after 20 min of idle time). Generalized linear models, or survival models, depending on the type and distribution of the outcome variables, will be the primary analytic approaches. In particular, linear regression models will be used to assess the effect of treatment on summary scores describing levels of activation, satisfaction, and the rate of refusal by patients to accept medications (calculated as number of refusals divided by number of times asked per patient). If data do not follow a normal distribution, an appropriate transformation will be used on the outcome variables.

Logistic regression models will be used to assess the association between treatment and frequency of login to the hospital outpatient portal. If the proportional odds assumption holds, proportional odds logistic regression models will be used to evaluate the association between treatment and change in PAM-13 scores; otherwise, multinomial logistic regression will be used. Cox proportional hazard models will be used to examine the association between treatment and time to mortality or hospital readmission (first event).

All of the above analyses will adjust for patient variables, including socioeconomic status, living situation, marital status, ethnicity, education level, age, sex, admitting diagnosis, health literacy, technology use and the Charlson Comorbidity Score. Appropriate statistical methods, such as imputation or inverse-probability weighting, will be used where missing data are present.

2.3.3. Data analysis for patient-entered information—We will perform thematic analysis to code patient-documented questions and concerns. Two members of the research team will independently code the comments using a coding framework. Each person will independently examine 20% of the sample of comments. Inter-rater reliability will be calculated for these data. If a high level of agreement is reached, a single rater will categorize the remainder of the data and any equivocal items will be discussed among raters for final categorization. We anticipate that the themes will be classified with the categories identified in the Centers for Medicare & Medicaid Services' Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which include: communication

with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, and quietness of the hospital environment.

2.3.4. Partnering in dissemination activities—In 2006, the Agency for Healthcare Research and Quality released a report that summarized the evidence base regarding benefits and costs of health information technology systems [55]. The report explained that widespread implementation of HIT is limited by the lack of generalizable knowledge about what types of HIT and methods for its implementation will prove most useful for specific health organizations [55].

In addition to the randomized trial, we are demonstrating the generalizability of the inpatient portal by deploying it at a West Coast community hospital. This site, demographically speaking, treats a very different population from the primary study site, an academic medical center in New York City. Deploying the patient engagement technology at a community hospital and collecting patient engagement data, including patient activation and satisfaction, will help us assess sustainability, reach, and adoption [56,57].

The study design at the West Coast community hospital is a cohort study, not a randomized controlled trial. Participants in the intervention group receive a tablet computer with a similar inpatient engagement portal. The total target sample size for the West Coast community site is 160 participants (80 in the usual care group and 80 in the intervention group). Participants are recruited from a surgical recovery unit. Due to the shorter average length of stay, participants in both groups are given the PAM-13 and demographic questionnaire at enrollment. Prior to the same day discharge, participants in the intervention group are re-administered the PAM-13 as well as the patient satisfaction questionnaire. For the statistical analysis, the demographic characteristics, PAM-13 scores and patient satisfaction will be summarized with traditional descriptive statistics. We will compare the baseline PAM scores between the control and intervention groups using a Wilcoxon rank sum test. In the intervention group, we will compare the baseline and follow-up PAM and satisfaction scores using the Wilcoxon signed-rank test.

3. Discussion

Increasingly, health-care delivery organizations are focusing on improving patient engagement and the patient experience. Patient engagement has been compared to a “blockbuster drug” [58], and the Centers for Medicare and Medicaid Services recently began reporting the HCAHPS results using a star rating system. With the primary aim of improving overall patient engagement among hospitalized cardiology patients, our pragmatic randomized controlled trial is part of a growing area of research in this area.

To our knowledge, this will be the first and largest randomized trial of cardiology patients to test a personalized inpatient portal in medical and surgical inpatient units. Dykes and colleagues have developed an electronic bedside communication center prototype, as well as a web-based patient-centered toolkit prototype to improve access to health information and engage hospitalized patients in their plans of care [59–61]. One of the differences between

their web-based toolkit and this personalized health portal, is that caregivers of patients in the medical intensive care units were recruited to the study, whereas we did not specifically recruit caregivers [59]. Similarly, the Veteran's Administration has tested a paper-based daily plan for patients in the inpatient setting and found that among patients who responded to the survey, the majority found it increased their understanding of their treatment, and improved care and satisfaction [62]. O'Leary and colleagues [63] have also conducted a study showing that the provision of a mobile patient portal application to hospitalized patients was able to increase the patients' knowledge of physician names and roles. This study had an intervention group that received an inpatient portal including information about the care team, medications, and plan for the day. The PAM was administered to participants in the control and intervention group at a single point in time. Some of the differences between our studies are that the difference in the PAM score was not reported in the O'Leary study and the inpatient engagement portal in our study provided more comprehensive information from the medical record. Pell et al. [64] also gave hospitalized patients tablet computers to access test results and active medication schedules. In this study, they asked patients and clinicians before and after administering the tablet about perceived beliefs of sharing information with patients. They found that the concerns patients and clinicians had about sharing information did not bear out, there was not an increased workload for clinicians and it did not increase confusion or worry by patients [65]. In the inpatient pediatric setting, parental engagement was studied by Palma et al. [66] by providing parents of children in the neonatal intensive care unit with a daily, printed care plan. Families found these daily updates useful, and showed trends toward improved communication with providers [67].

Overall, most of the studies that have evaluated the impact of inpatient portals were cohort or cross-sectional studies. Our study is one of the first to study an inpatient portal intervention systematically in a pragmatic randomized controlled trial. Additionally, we are the first to discretely measure patient engagement changes as affected by the use of inpatient technology.

Our study also has several design features that merit attention. As a pragmatic clinical trial, this intervention provides a good example of what is feasible in an urban, academic-medical center environment in a multilingual, multi-ethnic patient population. The results of this study will be relevant to hospital administrators and other stakeholders who are making decisions about the types of technology in which to invest to engage patients and improve the quality of their care.

As a pragmatic trial, there are also inherent limitations, including trade-offs between internal and external validity. For example, in pragmatic clinical trials, it can be difficult to detect when the intervention is not delivered uniformly across all participants [68]. Though we can measure use of the personalized inpatient portal to some extent, we may not know if the portal or some other source of information was responsible for changes in patient activation and satisfaction. For instance, family members were allowed to use the patient portal and access the internet from the tablet for medical information.

4. Conclusions

In conclusion, our study has the potential to yield new knowledge regarding the impact of a personalized inpatient portal on improving overall patient engagement, including patient activation and satisfaction. The study will illuminate hospital patients' information needs. If the study is successful, continuing advances in mobile computing technology should make these types of interventions possible in a variety of clinical care delivery settings.

Acknowledgments

Funding support

This study is funded by the Agency for Healthcare Research and Quality [R01-HS021816]. The authors also gratefully acknowledge the post-doctoral funding for Ruth Masterson Creber by NIH/NINR [T32NR007969] at Columbia University School of Nursing.

We would like to acknowledge Jungmi Han, the computer programmer of the personalized inpatient portal, and Niurka Suero-Tejeda for her assistance with recruiting patients for this study.

References

1. Bird AP, Walji MT. Our patients have access to their medical records. Br Med J (Clin Res Ed). 1986; 292:595–596.
2. Cohen RN. Whose file is it anyway? Discussion paper. J R Soc Med. 1985; 78:126–128. [PubMed: 3973872]
3. Fisher B, Britten N. Patient access to records: expectations of hospital doctors and experiences of cancer patients. Br J Gen Pract. 1993; 43:52–56. [PubMed: 8466775]
4. Jimison H, Sher P. Consumer health informatics: health information technology for consumers. J Am Soc Inf Sci. 1995; 46:783–790.
5. Maly RC, Bourque LB, Engelhardt RF. A randomized controlled trial of facilitating information giving to patients with chronic medical conditions: effects on outcomes of care. J Fam Pract. 1999; 48:356–363. [PubMed: 10334612]
6. Moehr JR, Grant A. Medical informatics and medical education in Canada in the 21st century. Clin Invest Med. 2000; 23:275–280. [PubMed: 10981541]
7. Stein EJ, Furedy RL, Simonton MJ, Neuffer CH. Patient access to medical records on a psychiatric inpatient unit. Am J Psychiatry. 1979; 136:327–329. [PubMed: 420331]
8. Greenfield S, Kaplan SH, Ware JE Jr, Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. J Gen Intern Med. 1988; 3:448–457. [PubMed: 3049968]
9. Hack TF, Degner LF, Dyck DG. Relationship between preferences for decisional control and illness information among women with breast cancer: a quantitative and qualitative analysis. Soc Sci Med. 1994; 39:279–289. [PubMed: 8066506]
10. Kaplan SH, Gandek B, Greenfield S, Rogers W, Ware JE. Patient and visit characteristics related to physicians' participatory decision-making style. Results from the medical outcomes study. Med Care. 1995; 33:1176–1187. [PubMed: 7500658]
11. Makaryus AN, Friedman EA. Patients' understanding of their treatment plans and diagnosis at discharge. Mayo Clin Proc. 2005; 80:991–994. [PubMed: 16092576]
12. Calkins DR, Davis RB, Reiley P, Phillips RS, Pineo KL, Delbanco TL, et al. Patient–physician communication at hospital discharge and patients' understanding of the postdischarge treatment plan. Arch Intern Med. 1997; 157:1026–1030. [PubMed: 9140275]
13. Cumbler E, Wald H, Kutner J. Lack of patient knowledge regarding hospital medications. J Hosp Med. 2010; 5:83–86. [PubMed: 20013875]

14. Institute of Medicine (U.S.). Committee on Quality of Health Care in America. Crossing the Quality Chasm: A new Health System for the 21st Century. National Academy Press; Washington, D.C: 2001.
15. Larson CO, Nelson EC, Gustafson D, Batalden PB. The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. Int J Qual Health Care. 1996; 8:447–456. [PubMed: 9117198]
16. Hibbard JH. Engaging health care consumers to improve the quality of care. Med Care. 2003; 41:I61–I70. [PubMed: 12544817]
17. Tang PC, Lansky D. The missing link: bridging the patient–provider health information gap. Health Aff (Millwood). 2005; 24:1290–1295. [PubMed: 16162575]
18. Skeels, M.; Tan, DS. Identifying opportunities for inpatient-centric technology. Proceedings of the 1st ACM International Health Informatics Symposium, ACM; Arlington, Virginia, USA. 2010;
19. Prey JE, Woollen J, Wilcox L, Sackeim AD, Hripcsak G, Bakken S, et al. Patient engagement in the inpatient setting: a systematic review. J Am Med Inform Assoc. 2014; 21:742–750. [PubMed: 24272163]
20. Shenkin BN, Warner DC. Sounding board. Giving the patient his medical record: a proposal to improve the system. N Engl J Med. 1973; 289:688–692. [PubMed: 4727972]
21. Bronson DL, Rubin AS, Tufo HM. Patient education through record sharing. QRB Qual Rev Bull. 1978; 4:2–4. [PubMed: 104231]
22. Fischbach RL, Sionelo-Bayog A, Needle A, Delbanco TL. The patient and practitioner as co-authors of the medical record. Patient Couns Health Educ. 1980; 2:1–5. [PubMed: 10294999]
23. Slack WV, Slack CW. Patient–computer dialogue. N Engl J Med. 1972; 286:1304–1309. [PubMed: 5024461]
24. Standards for privacy of individually identifiable health information, Final rule. Fed Regist. 2002; 67:53181–53273. [PubMed: 12180470]
25. U.S. Department of Health and Human Services, Health Information Technology. Interim Final Rule. Jan 13. 2010 Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology.
26. Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. J Am Med Inform Assoc. 2006; 13:121–126. [PubMed: 16357345]
27. Halamka JD, Mandl KD, Tang PC. Early experiences with personal health records. J Am Med Inform Assoc. 2008; 15:1–7. [PubMed: 17947615]
28. Delbanco T, Walker J, Darer JD, Elmore JG, Feldman HJ, Leveille SG, et al. Open notes: doctors and patients signing on. Ann Intern Med. 2010; 153:121–125. [PubMed: 20643992]
29. Walker J, Leveille SG, Ngo L, Vodicka E, Darer JD, Dhanireddy S, et al. Inviting patients to read their doctors' notes: patients and doctors look ahead: patient and physician surveys. Ann Intern Med. 2011; 155:811–819. [PubMed: 22184688]
30. Delbanco T, Walker J, Bell SK, Darer JD, Elmore JG, Farag N, et al. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. Ann Intern Med. 2012; 157:461–470. [PubMed: 23027317]
31. Wilcox L, Woollen J, Prey J, Restaino S, Bakken S, Feiner S, et al. Interactive tools for inpatient medication tracking: a multi-phase study with cardiothoracic surgery patients. J Am Med Inform Assoc. 2016; 23:144–158. [PubMed: 26744489]
32. Woollen J, Prey JE, Wilcox L, Sackeim AD, Restaino S, Raza T, et al. Patient experiences using an inpatient personal health record. Appl Clin Inf. 2016 in press.
33. Vawdrey, DK.; Wilcox, LG.; Collins, SA.; Bakken, S.; Feiner, S.; Boyer, A., et al. A tablet computer application for patients to participate in their hospital care. AMIA Annual Symposium Proceedings/AMIA Symposium AMIA Symposium, 2011; 2011; p. 1428-1435.
34. Vawdrey DK, Wilcox LG, Collins S, Feiner S, Mamykina O, Stein DM, et al. Awareness of the care team in electronic health records. Appl Clin Inf. 2011; 2:392–405.
35. Wilcox, L.; Feiner, S.; Restaino, S.; Collins, S.; Vawdrey, D. Designing Inpatient Technology to Meet the Medication Information Needs of Cardiology Patients, IHI; 2012;

36. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ (Clin Res Ed). 2008; 337:a2390.
37. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues Clin Neurosci. 2011; 13:217–224. [PubMed: 21842619]
38. Roland M, Torgerson DJ. Understanding Controlled Trials: What are Pragmatic Trials?. 1998
39. Folstein MF, Folstein SE, McHugh PR. “Mini-mental state”. A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975; 12:189–198. [PubMed: 1202204]
40. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005; 40:1918–1930. [PubMed: 16336556]
41. Fowles JB, Terry P, Xi M, Hibbard J, Bloom CT, Harvey L. Measuring self-management of patients’ and employees’ health: further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. Patient Educ Couns. 2009; 77:116–122. [PubMed: 19356881]
42. Stepleman L, Rutter MC, Hibbard J, Johns L, Wright D, Hughes M. Validation of the patient activation measure in a multiple sclerosis clinic sample and implications for care. Disabil Rehabil. 2010; 32:1558–1567. [PubMed: 20590506]
43. Skolasky RL, Green AF, Scharfstein D, Boult C, Reider L, Wegener ST. Psychometric properties of the patient activation measure among multimorbid older adults. Health Serv Res. 2011; 46:457–478. [PubMed: 21091470]
44. Maindal HT, Sokolowski I, Vedsted P. Translation, adaptation and validation of the American short form Patient Activation Measure (PAM13) in a Danish version. BMC Public Health. 2009; 9:209. [PubMed: 19563630]
45. Green CA, Perrin NA, Polen MR, Leo MC, Hibbard JH, Tusler M. Development of the Patient Activation Measure for mental health. Admin Pol Ment Health. 2010; 37:327–333.
46. Hibbard JH, Greene J, Tusler M. Improving the outcomes of disease management by tailoring care to the patient’s level of activation. Am J Manag Care. 2009; 15:353–360. [PubMed: 19514801]
47. Hibbard JH. Using systematic measurement to target consumer activation strategies. Med Care Res Rev. 2009; 66:9S–27S. [PubMed: 19052169]
48. Mosen DM, Schmittdiel J, Hibbard J, Sobel D, Remmers C, Bellows J. Is patient activation associated with outcomes of care for adults with chronic conditions? J Ambul Care Manage. 2007; 30:21–29. [PubMed: 17170635]
49. Hibbard JH, Tusler M. Assessing activation stage and employing a “next steps” approach to supporting patient self-management. J Ambul Care Manage. 2007; 30:2–8. [PubMed: 17170632]
50. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. J Gen Intern Med. 2012; 27:520–526. [PubMed: 22127797]
51. Greene J, Hibbard JH, Sacks R, Overton V, Parrotta CD. When patient activation levels change, health outcomes and costs change, too. Health Aff. 2015; 34:431–437.
52. Bakken S, Grullon-Figueroa L, Izquierdo R, Lee NJ, Morin P, Palmas W, et al. Development, validation, and use of English and Spanish versions of the telemedicine satisfaction and usefulness questionnaire. J Am Med Inform Assoc. 2006; 13:660–667. [PubMed: 16929036]
53. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004; 36:588–594. [PubMed: 15343421]
54. McKay HG, King D, Eakin EG, Seeley JR, Glasgow RE. The diabetes network internet-based physical activity intervention: a randomized pilot study. Diabetes Care. 2001; 24:1328–1334. [PubMed: 11473065]
55. Shekelle, P.; Morton, S.; Keeler, E. Costs and benefits of health information technology, Evidence Reports/Technology Assessments. Agency for Healthcare Research and Quality; 2006.
56. Bakken S, Ruland CM. Translating clinical informatics interventions into routine clinical care: how can the RE-AIM framework help? J Am Med Inform Assoc. 2009; 16:889–897. [PubMed: 19717799]

57. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999; 89:1322–1327. [PubMed: 10474547]
58. Greene J, Hibbard JH, Sacks R, Overton V, Parrotta CD. When patient activation levels change, health outcomes and costs change too. Health Aff (Project Hope). 2015; 34:431–437.
59. Dalal AK, Dykes PC, Collins S, Lehmann LS, Ohashi K, Rozenblum R, et al. A web-based, patient-centered toolkit to engage patients and caregivers in the acute care setting: a preliminary evaluation. J Am Med Inform Assoc. 2015
60. Dykes PC, Carroll DL, Hurley AC, Benoit A, Chang F, Pozzar R, et al. Building and testing a patient-centric electronic bedside communication center. J Gerontol Nurs. 2013; 39:15–19. [PubMed: 23244060]
61. Dykes, PC.; Stade, D.; Chang, F.; Dalal, A.; Getty, G.; Kandala, R., et al. Participatory design and development of a patient-centered toolkit to engage hospitalized patients and care partners in their plan of care. AMIA Annual Symposium; 2014;
62. King BJ, Mills PD, Fore A, Mitchell C. The Daily Plan (R): including patients for safety's sake. Nurs Manag. 2012; 43:15–18.
63. O'Leary KJ, Lohman ME, Culver E, Killarney A, Smith GR, Liebovitz DM. The effect of tablet computers with a mobile patient portal application on hospitalized patients' knowledge and activation. J Am Med Inform Assoc. 2015:ocv058.
64. Pell JM, Mancuso M, Limon S, Oman K, LC-T. Patient access to electronic health records during hospitalization. JAMA Intern Med. 2015
65. Pell JM, Mancuso M, Limon S, Oman K, Lin CT. Patient access to electronic health records during hospitalization. JAMA Intern Med. 2015; 175:856–858. [PubMed: 25751393]
66. Palma JP, Keller H, Godin M, Wayman K, Cohen RS, Rhine WD, et al. Impact of an EMR-based daily patient update letter on communication and parent engagement in a neonatal intensive care unit. J Particip Med. 2012; 4
67. Palma JP, Keller H, Godin M, Wayman K, Cohen RS, Rhine WD, et al. Impact of an EMR-based daily patient update letter on communication and parent engagement in a neonatal intensive care unit. J Particip Med. 2012; 4
68. Stein, DM.; Wrenn, JO.; Stetson, PD.; Bakken, S. What "to-do" with physician task lists: clinical task model development and electronic health record design implications. AMIA Annual Symposium proceedings/AMIA Symposium AMIA Symposium; 2009; p. 624-628.
69. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res. 2004; 39:1005–1026. [PubMed: 15230939]

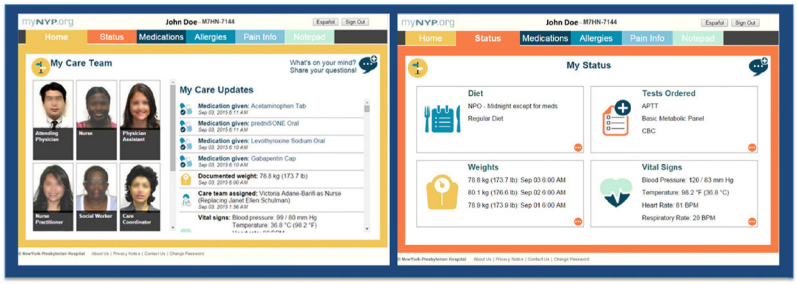

Fig. 1.
Screenshots of the personalized inpatient portal.

Table 1

Functionality of the personalized inpatient portal.

Inpatient PHR function	Description
Secure login and auditing	Login security includes auto timeout and detailed audit logging.
Change password	Enter new password to change the current password.
View tutorial information	Browse tutorials to learn how to use each functions on this.
View care team	Browse current members of the care team by name, role, and photograph.
View my care updates	Browse all care update messages including medications, tests, care team changes and vital signs.
View medications	Browse current medications received and scheduled, including name, dose, route and frequency as well as comprehensive patient-friendly medication information.
Patient questions/concerns	Enter questions and concerns that are viewable by the care team in the electronic health record.
View vital signs, test orders, diet and weight	Longitudinal display of vital signs (blood pressure, heart rate, temperature and weight), test orders, diet orders and weights.
View test and lab results	Longitudinal display of all lab results and notes from test results. *Have test results gone live* (*i.e.: pathology reports*?) *If so, how are they visualized to participants—as a note*?
Medication reconciliation	Browse active, as needed, completed or discontinued hospital medications and active home medications.
Allergy reconciliation	Browse documented allergies.
Pain information	Enter current pain level and browse previous recorded pain levels.
Notepad	Enter personal notes related to the hospital stay.
Spanish translation	Browse all of the pages in Spanish.
Provide clinician feedback	Give clinicians a “like” or a “star” for excellent care.

Table 2

Data collection methods, study variables and proposed statistical methods.

Data collection method	Variable(s) and statistical methods	Collection times
Exclusion criteria		
Mini-mental status exam	Cognitive status	Prior to enrollment
Patient characteristics (differences at baseline and associations with dependent variable)		
Demographic survey and electronic health record data	Socioeconomic status, living situation, marital status, ethnicity, education level, age, sex, admitting diagnosis, health literacy, technology use	At enrollment
Patient survey	Satisfaction and Engagement (13 items, 5-point Likert-type scale) Usefulness (10 item, 5-point Likert-type scale) Method: Linear regression models to assess the effect of treatment arms on summary scores describing levels of satisfaction and engagement	Days 3–5 of hospital stay
Patient Activation Measure (PAM) assessment [69]	Activation level Method: proportional odds logistic regression models to assess the treatment effect on PAM, predictors of lowest level of activation; otherwise, multinomial logistic regression will be used	At enrollment and on days 3–5 of hospital stay
Inpatient portal usage logs	Frequency and duration of system use, type of information accessed or task performed (which features were accessed—medication, allergies, specific tabs) Total time logged per day Method: Linear regression models to investigate the effect of treatment on total time logged per day	Continuously when system is used
Outpatient portal usage logs	Patient use of outpatient portal and access to various features Proportion accessing portal Frequency of login-in of outpatient portal Method: logistic regression to assess the association between treatment and frequency of login-in of outpatient portal.	30 days post-discharge
Administrative electronic health record data	Mortality, hospital readmission within 30 days of discharge Survival analysis, time-to-first event Method: Cox proportional hazard models to examine the association between treatment and time to mortality or hospital readmission (first event).	30 days post-discharge
Clinical electronic health record data	Rate of refusal by patients to accept medications: Number of refusals/number of times asked to accept medications Linear regression to assess the association between treatment arms and rate of refusal. (We may use logit transformation of the outcome depending on distribution).	Retrospectively post-discharge